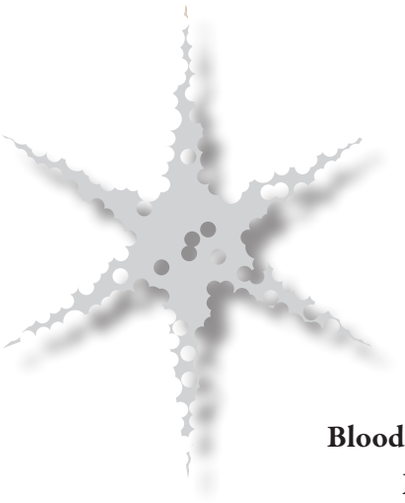
2020 UPDATE

OSHA

Written Communication Plan

New Jersey Funeral
Directors Services, Inc.



OSHA

WRITTEN COMMUNICATION PLAN

Bloodborne Pathogen Exposure Control Plan
Hazard Communication Program
Formaldehyde Exposure Control Plan
Workplace Safety Plan

These documents and accompanying forms have been reviewed and found appropriate to the current employee duties and work practices of this funeral home.

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

OCO Name _____ OCO Signature _____ Year _____

Prior plan documents and accompanying forms have been retired and will be filed at this funeral home for thirty years beyond the last date of appropriateness.

OSHA

WRITTEN COMMUNICATION PLAN

Bloodborne Pathogen Exposure Control Plan
Required May 5, 1992, Updated May 14, 2019

Hazard Communication Program
Required May 23, 1988, Updated February 8, 2013

Formaldehyde Exposure Control Plan
Required February 2, 1988, Updated May 14, 2019

Workplace Safety Plan

This is a generic written program intended to serve as a convenient guide for promoting compliance with OSHA Standards as they apply to funeral directors and funeral homes. It may be expanded, personalized, and tailored to your specific funeral home.

This written plan does not itself alter or determine compliance responsibilities, which are set forth in OSHA Standards themselves and in the Occupational Safety and Health Act. Moreover, because interpretations and enforcement policy may change over time, the funeral home should seek out guidance with regard to current OSHA Compliance requirements, by monitoring ongoing administrative interpretations and decisions by the Occupational Safety and Health Review Commission and by the courts.

Accident Investigation

All accidents that result in injury to workers, regardless of their nature, shall be investigated and reported to the funeral home OSHA Compliance Officer (OCO). It is an integral part of any safety program that documentation take place as soon as possible so that the cause and means of prevention can be identified to prevent reoccurrence.

In the event that an employee injures themselves or there is some other related, serious incident occurring, this plan shall be reviewed to determine if additional practices, procedures, training or safer devices need be implemented to prevent similar types of incidents from occurring in this and other worksites.

At-risk employees acknowledge receipt and acceptance of the funeral home's OSHA Written Communication Plan through the execution of a Communication of Funeral Home Hazards form, and agree to abide by its policies.

PO#20-069S 7/20

DISCLAIMER: This plan or the materials provided with it shall in no way be considered as a complete substitute for any provisions of the Occupational Safety and Health Act (OSHA) of 1970 or for any Standards promulgated under the Act. The actual source Standards discussed are noted in the text and shall be consulted for complete reference to the Standards in their entirety. The use of these materials is in no way to be considered a guarantee of complete regulatory compliance or as an assurance that the funeral home will be free or immune from citations for violations related to the OSHA Standards covered. The overall success or failure of this compliance plan shall depend upon the proper implementation of this plan by the funeral home's management, compliance officer and employees.

Bloodborne Pathogen Exposure Control Plan

Hazard Communication & Formaldehyde

Formaldehyde Exposure Control Plan

Workplace Safety Plan

Bloodborne Pathogen Exposure Control Plan

BP-1 Exposure Control Plan

1.1 - Bloodborne Pathogens Standard, 29 CFR 1910.1030

(1) 29 CFR 1910.1030(c)

Each funeral home having an employee(s) with occupational exposure shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

The Bloodborne Pathogens Standard's definition of Occupational Exposure is "reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties." [29 CFR 1910.1030(b)]

(2) Contents of Plan. *The Exposure Control Plan* of the funeral home contains the following:

a. Exposure Determination. All funeral homes are required to evaluate the work functions of employees with regard to the possible exposure to blood, potentially infectious body fluids or other potentially infectious materials.

b. Methods of Compliance. All funeral homes are required to provide the method of implementation for universal precautions; engineering and work practice controls; personal protective equipment; and housekeeping.

c. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up. All funeral homes are required to provide the method of implementation for these elements of the Standard.

d. Communication of Hazards to Employees. All funeral homes are required to provide communication of hazards by the use of labels and signs and to provide a training program to all employees with occupational exposure.

e. Recordkeeping. All funeral homes are required to provide for this element of the Standard.

f. Exposure Incidents. All funeral homes are required to provide the procedure for evaluation of circumstances surrounding exposure incidents.

1.2 - Policy

It is the policy of the funeral home that "the safety and health of employees shall be given priority over all other operations and activities."

1.3 - Purpose

The purpose of this plan is to establish and define the policies and practices of the funeral home with regard to its obligations under the United States Department of Labor, Occupational Safety and Health Administration (OSHA) regulations known as the Occupational Exposure to Bloodborne Pathogens Standard. The proper citation for this Standard is 29 CFR 1910.1030.

1.4 - Person Responsible: OSHA Compliance Officer (OCO)

The OSHA Compliance Officer is the person responsible for the proper maintenance and implementation of the OSHA Bloodborne Pathogen Exposure Control Plan for this funeral home. *(See inside front cover for the name of the OSHA Compliance Officer.)* The OSHA Compliance Officer shall:

(1) Implement *Bloodborne Pathogen Exposure Control Plan.*

(2) Train employees (and/or implements training programs).

(3) Review risks of exposure:

a. By monitoring all risks within the context of the general business activities engaged in by this funeral home.

b. By evaluating circumstances surrounding any exposure incidents.

c. By regular, periodic review of exposure determination roster.

(4) Ensure effectiveness of work practices. On a regular schedule examines and modifies, as necessary, any work practices regarding safety related issues.

(5) Maintain OSHA-related records.

(6) Implement Hepatitis B Vaccination program.

1.5 - Accessibility of Plan to Employees

The funeral home shall ensure that a copy of the *Bloodborne Pathogen Exposure Control Plan* is accessible to employees in accordance with 29 CFR 1910.1020(e). A copy of the plan is available at the funeral home office.

1.6 - Review of Plan

The Bloodborne Pathogen Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(1) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and percutaneous injuries.

(2) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate, reduce or minimize occupational exposure.

(3) Documentation of review and any applicable updates shall be recorded on the Annual Plan Review Verification located on the inside front cover of the funeral home's OSHA Written Communication Plan.

1.7 - Employee Auditing System

This plan and its supporting materials are available for examination and copying to all employees. All employees are encouraged and requested to make comments on the usefulness of this plan and to contribute any other ideas that shall further the intention of creating a more enjoyable and safer worksite for all of us and our families and the families we serve. The funeral home depends upon our employees to notify the OSHA Compliance Officer, manager or other senior employee of any hazards and maintenance needs that may come to their attention.

BP-2 Exposure Determination

2.1 - 29 CFR 1910.1030(c)(2)

Each funeral home who has an employee(s) with occupational exposure shall prepare an exposure determination.

2.2 - Policy

The policy of the funeral home is to ensure that the risk of employee exposure to bloodborne pathogens is properly evaluated and that information concerning the exposure risk and methods of eliminating or minimizing the risk are transmitted to affected employees.

2.3 - Determination Process

Because this funeral home is a small business, the job classifications referred to in the Bloodborne Pathogens Standard are most properly represented by the names of the individual employees. The exposure determination process relates to the duties assigned to individual employees based upon their abilities, level of education, training and skill.

The exposure determination process used by this funeral home to identify potential bloodborne pathogen exposure risk is the identification of individual employees who are engaged in job functions which create such an exposure risk. All other employees who are not assigned to such job functions shall not be at risk. Employees involved in job functions without an exposure risk shall be notified that they are not authorized to enter work areas where bloodborne pathogen exposure risk exist.

This exposure determination shall be made without regard to the use of personal protective equipment.

2.4 - Evaluation and Selection of Safer Sharps & Devices

The policy of this funeral home shall be that employees that use sharps must, at least annually, identify, evaluate and select engineering and work practice controls, including safer devices.

(1) This evaluation must involve managerial and non-managerial Category I employees responsible for removing, preparing, embalming and washing dead human bodies.

(2) This evaluation will be done on an "active" preparation room basis. When a funeral home has multiple worksites with active prep rooms, the evaluation must involve employees from all worksites.

(3) After a device is evaluated and selected, management must make a decision on implementing that device. *(See Annual Training and Safer Sharps Evaluation Record.)*

(a) If a device is not purchased because of employer or employee concerns, those concerns must be documented. However, if the employer does not purchase a device that had employee support, the employer must also document the employee support, as well as the justification for not purchasing that device.

(b) If a device is purchased without the consent of the employees who evaluated it, the employer must document the employees' concerns, as well as the employers' justification for purchasing that device.

(4) Management will ensure that all affected employees are informed on the process for selecting safer devices.

(5) Management will ensure that employees are trained in the use of safer medical devices before the employees use those devices.

(6) Management will investigate and employees will follow safer work practices that can reduce needlesticks, including: not recapping needles, properly disposing of used needles in puncture-proof sharps containers and eliminating unnecessary use of needles and sharps.

(7) Throughout the year management will involve non-managerial Category I staff, (who will use these devices), in the evaluation and selection process in order to evaluate medical devices and sharps systems that are designed to eliminate or minimize exposure through percutaneous injury.

2.5 - Exposure Risk Job Functions

The list of job functions and/or related tasks performed by employees of this funeral home that involve a risk of exposure to bloodborne pathogens is grouped in categories of exposure I and II. *[See 29 CFR 1910.1030(c)(2).]*

All employees engaged in these job functions which involve an exposure risk shall be trained in accordance with the Bloodborne Pathogens Standard. *[See 29 CFR 1910.1030(g)(2).]*

Category I: Job Functions

(1) Removal of dead human bodies

(2) Preparation of dead human bodies

(3) Embalming of dead human bodies

(4) Washing of dead human bodies

It has been determined that all persons engaged in the removal, preparation and/or embalming of the body of a deceased human being have a Category I exposure to infectious disease by normal exposure to blood, body fluids and tissues of deceased persons.

All employees in this category shall be required to practice Universal Precautions when dealing with blood or body fluids from deceased humans.

Category II: Job Functions

(1) Removal/transportation of dead human bodies

(2) Dressing of dead human bodies

(3) Casketing of dead human bodies

(4) Cosmetizing of dead human bodies

(5) Housekeeping in affected work areas

(6) Medical waste disposal (including contaminated laundry)

It has been determined that persons engaged in transportation, dressing, casketing or cosmetizing of a deceased human body and those persons engaged in housekeeping, laundry or waste disposal functions at this funeral home are engaged in a Category II task which may expose them to blood or body fluids and accordingly shall be required to use Universal Precautions when performing these job functions.

2.6 - Roster

A roster of affected employees with occupational exposure to bloodborne pathogens at this funeral home has been compiled. Occupational exposure is regularly reviewed by the OSHA Compliance Officer. The roster also identifies those employees who do not have occupational exposure to bloodborne pathogens (Category III).

BP-3 Limited Access Areas

3.1 - 29 CFR 1910.1030(d)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure.

3.2 - Policy

At this funeral home only employees who have been trained in the use of Universal Precautions and the other requirements of the Bloodborne Pathogens Standard are authorized to enter work areas where a bloodborne pathogen exposure risk exists.

3.3 - Access Authorization and Notification

From time to time it may be necessary for persons who do not normally enter the preparation room area to have such access. It is the policy of the funeral home to provide notification of the risk of exposure or potential exposure to bloodborne pathogens to any person entering into a funeral home area or performing a job function where such an exposure risk may exist. *(See Communication of Funeral Home Hazards form.)*

This notification policy applies to employees, independent contractors or subcontractors and other persons properly entering into the funeral home environment or interacting with job function related tasks. In addition to this notification, training regarding the risk of bloodborne pathogen exposure and the use of Universal Precautions shall be provided to all affected employees and is available to contractors and other persons seeking access to exposure risk work areas.

Other persons who seek entry to exposure risk work areas as independent contractors, family members of the deceased, government officials or participants in ceremonial activities related to the death of a person whose body is in the possession of this funeral home shall be denied access to exposure risk areas until they have received and acknowledged receipt of notification of:

(1) Exposure risk to bloodborne pathogens *(See Communication of Funeral Home Hazards form.)*

(2) *Bloodborne Pathogen Exposure Control Plan*

(3) Need to exercise universal precautions

(4) Need to wear appropriate personal protective equipment to protect themselves

Application for authorization to enter bloodborne pathogen exposure risk work areas must be made to the funeral home's manager or the OSHA Compliance Officer of the affected work area. The manager or OSHA Compliance Officer in charge of the work area may, at any time, revoke the authorization for a non-employee to be present in an exposure risk area in the event that proper and/or appropriate precautions to protect that person against the exposure risk are not being taken.

BP-4 Universal Precautions

4.1 - 29 CFR 1910.1030(d)(1)

4.2 - Definitions

"Bloodborne pathogens" are microorganisms that can cause disease in humans. They may be present without the knowledge of the carrier. *(See expanded definition incorporated in the Disease Fact Sheets.)*

"Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens."

The use of Universal Precautions is a required concept of care based upon the assumption that all blood and body fluids and materials that have come in contact with blood or body fluids, are potentially infectious. Personal protective clothing and equipment shall be used to create a physical barrier against blood, body fluids and other potentially infectious materials. Safe work practices shall be followed to eliminate or minimize contact with blood, body fluids and other potentially infectious materials.

4.3 - Policy

The funeral home requires the use of Universal Precautions by all employees when an exposure risk is present. The implementation of Universal Precautions shall be based upon the policies and work practices of the funeral home, the training provided to employees to protect themselves from potential exposure to bloodborne pathogens and the good judgment and application of high quality safety and risk control standards by the employee.

BP-5 Engineering Controls

5.1 - 29 CFR 1910.1030(d)(2)

Engineering controls shall be used to eliminate or minimize employee exposure.

5.2 - Policy

The funeral home requires engineering controls be used to eliminate or minimize employee exposure. "Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness."
[See 29 CFR 1910.1030(d)(2) (ii).]

5.3 - Disposal Containers for Sharps

Containers for the disposal of sharps shall be provided that are "closable, puncture resistant, leakproof on sides and bottom and labeled" as required. These containers shall be "easily accessible and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found." *(See Section 10 - Disposal of Medical Waste.)*

5.4 - Handwashing Facilities

Handwashing facilities which are readily accessible to employees shall be provided.

5.5 - Quick Drench Shower and Eye Wash Station

This funeral home provides an emergency quick drench shower and eye wash station which are to be used to immediately flush exposures from the body or mucous membranes.

5.6 - Protective Equipment in Company Vehicles

In all company removal vehicles there shall be provided "Personal Protective Equipment Kits" for employees. The contents of the kits shall be replaced as used upon return to the funeral home. It shall be the responsibility of the person using the personal protective equipment to replace it. Each kit shall contain the following:

(1) Antiseptic towelettes. (When antiseptic towelettes are used, hands shall be washed with soap and running water as soon as feasible.)

(2) Red plastic bags (2) or plastic bags (2) properly labeled with the universal BIOHAZARD symbol (to be used for the temporary storage of soiled personal protective equipment following removals)

(3) Disposable latex/vinyl gloves (2 pair)

(4) Barrier face masks (2)

(5) Full-length fluid repellent coveralls (2)

(6) Shoe covers (2 pair)

(7) Surgical hoods or head covers (2)

(8) Disposable body bags (2)

(9) Eye goggles and/or glasses with solid side shields and/or chin-length faceshield

5.7 - Labels

Orange BIOHAZARD warning labels shall be affixed to containers of regulated waste, supplies or contaminated equipment.

BP-6 Work Practice Controls

6.1 - 29 CFR 1910.1030(d)(2)

Work practice controls shall be used to eliminate or minimize employee exposure.

6.2 - Policy

Work practice policies developed by the funeral home for its employees are an important part of both this *Bloodborne Pathogen Exposure Control Plan* and the *Bloodborne Pathogen Standard Employee Training Program*. The work practice policies developed for use by employees are designed to be a part of and incorporated into this *Bloodborne Pathogen Exposure Control Plan*.

6.3 - General Worksite Practices

Work practice controls shall be used to eliminate or minimize employee exposure. Work practice controls shall be examined and modified as necessary on a regular schedule to ensure their effectiveness. The underlying basis of a sound work practice control system is the concept of universal precautions. Universal Precautions shall be observed to prevent contact with blood or other potentially infectious materials. Because identification of body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

Additionally, the appropriate use of personal protective equipment is fundamental to the performance of duties by those persons having a risk of occupational exposure. *(See Section 7 - Personal Protective Equipment.)*

The following general work rules have been created for summary purposes; they shall not be considered as the only work practices that could be used, nor are they to be viewed as mutually exclusive from the specific work practices described later.

General Work Rules: All of the following work practice requirements are in effect at this funeral home.

(1) Engineering and Work Practice Controls

Engineering and work practice controls shall be used to eliminate or minimize employee exposure.

(2) Personal Protective Equipment

Where occupational exposure remains after institution of engineering and work practice controls, personal protective equipment shall also be used.

(3) Handwashing

Handwashing facilities are provided and are readily accessible to employees within the funeral home.

a. When exposure risks exist outside of the physical funeral home, e.g. removals, antiseptic towelettes are provided in the removal vehicle. When antiseptic towelettes are used, hands shall be washed with soap and running water as soon as feasible.
b. Employees must wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
c. Employees must wash hands and any other skin with soap and water or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(4) Contaminated Needles and Sharps

a. Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless no alternative is feasible.
b. Shearing or breaking of contaminated needles is prohibited. Reusable sharps that are contaminated with blood or other potentially infectious materials shall be decontaminated immediately after use.
c. Decontaminated sharps are placed, sharp end first, into a styrofoam block. No points are to protrude from the styrofoam. The styrofoam is not to be dirty or contaminated with blood or other potentially infectious materials.

(5) Sharps Container

a. The styrofoam containing the sharps is to be stored in a container specifically intended for the storage of reusable sharps. These containers are made available by the funeral home in preparation areas where reusable sharps are used during work practices.
b. These containers are puncture resistant, labeled or color-coded and leakproof on the sides and bottom.
c. At no time shall an employee reach by hand into a container for reusable sharps to retrieve one unless there is no exposed cutting edge or point exposed from its styrofoam covering or it is clearly the only item present in the container and such a removal would not pose a risk of injury to the employee.

(6) No Eating, Drinking, Smoking, Etc.

Eating, drinking, smoking, applying personal cosmetics or lip balm and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure to bloodborne pathogens. Food and drink shall not be kept in refrigerators or cabinets or on shelves, countertops or bench tops where blood or other potentially infectious materials are present.

(7) Minimize Splashing

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, splattering and generation of droplets of these substances.

(8) Contaminated Equipment

a. Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary and feasible.
b. A readily observable label identifying the BIOHAZARDOUS exposure risk of equipment which has been contaminated shall be placed in plain view on the equipment.
c. In the event contaminated equipment is to be serviced, the service representative must be notified of the exposure risk prior to handling the equipment so that proper precautions may be taken.

(9) Skin Conditions

Any employee with a physical condition (chapped or abraded skin or an open wound) that is likely to increase the potential for occupational exposure shall report same to their immediate supervisor, in order that a consultation can occur between the funeral home and employee as to the most appropriate course of action under the circumstances.

(10) Preparation and Embalming

During all preparation and embalming, the following work practices shall be observed:

a. Ensure proper positioning of aspirator discharge (e.g., under water surface)
b. Keep drainage sinks covered with a piece of plexiglass or plastic wrap
c. Return needles, syringes and sharps to secure organized storage
d. Clean up immediately all overt contamination

6.4 - Work Practice: Removal of Dead Human Bodies

Employee occupational activity: Obtaining custody of the dead human body for removal to the funeral home where preparation or embalming is to take place or the place of disposition. These work practices shall apply to all persons who come in contact with the dead human body during the removal process. In the event that contract labor or volunteer labor is used to assist in this process in addition to the funeral home employees, care shall be taken to alert those persons to the need to observe the safe work practices adopted by the funeral home.

Work Practice Policies: Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the removal process.

(1) Disposable latex/vinyl gloves must be worn by all persons at all times when hands come in contact with the dead human body.

(2) Employees shall exercise great care to avoid contact with body fluids. In particular, the eyes, nose and mouth of the employee shall be protected from such contact when a risk of contact exists based upon the condition of the body to be removed or the circumstances of the removal.

(3) A barrier face mask must be worn when lifting the body if the face of the deceased is not covered by a protective barrier cloth, the body of the deceased has open wounds or blood and/or body fluids present a risk of splashing or aerosolization.

(4) Employees shall take steps to avoid unnecessary splashing of blood or body fluids or aerosolization of those fluids. The use of a closed pouch or body bag prior to placement of the body on a stretcher shall help in reducing this type of exposure risk. Safety straps shall be used to secure the body to the stretcher when moving it to the removal vehicle.

(5) All gloves and protective equipment used during the removal shall be placed in either a disposable container or, if reusable, placed in a container suitable for transporting without any unprotected contact until decontamination has occurred. All such containers shall be properly labeled as containing BIOHAZARDOUS materials.

(6) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed. When exposure risks exist outside of the physical funeral home, e.g. removals, antiseptic towelettes are provided in the removal vehicle. When antiseptic towelettes are used, hands shall be washed with soap and running water as soon as feasible.

6.5 - Work Practice: Transportation of Dead Human Bodies

General employee occupational activity: Transporting the dead human body at any time prior to its final disposition. These work practices apply to all persons who come in contact with the dead human body during the transportation process. In the event that contract labor or volunteer labor is used to assist in this process in addition to the funeral home employees, care shall be taken to alert those persons to the need to observe the safe work practices adopted by the funeral home.

Work Practice Policies: Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the transportation process.

(1) The employee shall at all times take steps to prevent the leakage of blood or body fluids from the body of the deceased being transported.

(2) The stretcher upon which the body is placed shall be secured to the removal vehicle to reduce risk of exposure to bloodborne pathogens in the event of shifting or movement of the stretcher in the transportation process.

(3) All traffic rules shall be obeyed by the driver of the transport vehicle.

(4) In the event that contact with the dead human body is required at any time during the transportation process, the safe work practices established for removals shall be observed and implemented.

(5) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed. When exposure risks exist outside of the physical funeral home, e.g. removals, antiseptic towelettes are provided in the removal vehicle. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

6.6 - Work Practice: Preparation and Embalming

General employee occupational activity: Preparation or embalming of the dead human body, including ritual washing.

Work Practice Policies: Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the preparation, embalming and washing process.

(1) Transfer of the deceased from the removal vehicle to the funeral home within which preparation, embalming or ritual washing is to occur requires the use of the safe work practices for removals.

(2) Employees engaging in the preparation, embalming or washing of the deceased shall utilize appropriate personal protective equipment to meet the risk of exposure to bloodborne pathogens. At a minimum, this equipment shall include double latex/vinyl gloves; barrier face mask; goggles

or faceshield; chemical and body fluid proof smock which covers arms, torso and upper legs; disposable protective shoe covers; and a head cover.

(3) Efforts shall be made to reduce or eliminate air expulsion or aerosolization from the body when positioning the deceased for preparation, embalming or washing.

(4) Liquid and semi-liquid materials to be disposed of as the result of the preparation, embalming or washing of a dead human body shall be disposed of immediately upon collection in such a manner as to limit personal exposure. These materials shall be placed into appropriate drains or containers and any residue decontaminated and cleaned away immediately upon completion of the preparation, embalming or washing.

(5) All gloves and protective equipment used during the preparation, embalming or washing shall be placed in either a disposable container or, if reusable, placed in a container suitable for storage without any unprotected contact until decontamination has occurred. All such containers shall be properly labeled as containing BIOHAZARDOUS materials.

(6) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed.

(7) Access to areas of this funeral home in which a risk of exposure to bloodborne pathogens exists shall be limited to employees who have a job description that requires such access. All persons entering areas of potential exposure to bloodborne pathogens must follow the safe work practices adopted by the funeral home. Employees or other persons who have not been trained regarding the safe work practice policies of the funeral home and who have not been provided with personal protective equipment appropriate to meet the risk of potential exposure to bloodborne pathogens or hazardous chemicals and trained in the use of that equipment are to be prohibited from access to potential exposure areas.

6.7 - Work Practice: Dressing, Casketing and Cosmetizing

General employee occupational activity: Dressing, casketing and cosmetizing the deceased.

Work Practice Policies: Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the dressing, casketing and cosmetizing processes.

(1) All persons assisting in the movement of an unembalmed body shall wear latex/vinyl gloves and a barrier face mask in the event the nose and mouth of the deceased are not covered by a protective cloth.

(2) All persons assisting in the movement of an embalmed body shall wear latex/vinyl gloves. Additional personal protective equipment may be called for when engaging in this process. The risk of exposure to bloodborne pathogens shall be assessed by the licensed funeral director or embalmer in charge of the embalming and that person shall direct the use of additional personal protective equipment by other persons assisting in the movement of the body.

(3) Persons engaged in applying cosmetics to the deceased shall consider the use of latex/vinyl gloves while performing this process. In the event there is potential contact with blood or body fluid that may result from engaging in the application of cosmetics, latex/vinyl gloves must be worn and the use of additional personal protective equipment may be appropriate.

(4) All gloves and protective equipment used during the dressing, casketing or cosmetizing shall be placed in either a disposable container or, if reusable, placed in a container suitable for storage without any unprotected contact until decontamination has occurred. All such containers shall be properly labeled as containing BIOHAZARDOUS materials.

(5) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed.

(6) Access to areas of this funeral home in which a risk of exposure to bloodborne pathogens exists shall be limited to employees who have a job description that requires such access. All persons entering areas of potential exposure to bloodborne pathogens must follow the safe work practices adopted by the funeral home. Employees or other persons who have not been trained regarding the safe work practice policies of the funeral home, who have not been provided with personal protective equipment appropriate to meet the risk of potential exposure to bloodborne pathogens or hazardous chemicals and have not been trained in the use of that equipment are to be prohibited from exposure access.

BP-7 Personal Protective Equipment

7.1 - 29 CFR 1910.1030(d)(3)

Provision of the Standard. When there is occupational exposure, the funeral home shall provide, at no cost to the employee, appropriate personal protective equipment.

7.2 - General Personal Protective Equipment

In addition to specific work practice policies for this funeral home, items of personal protective equipment shall be made available to employees. Employees are to receive training in the location and proper use of this equipment prior to commencing work functions which subject the employee to exposure or potential exposure to bloodborne pathogens as covered by the *Bloodborne Pathogens Standard Employee Training Program* and which may require the use of such equipment.

Fundamental to making proper decisions about the appropriate level of personal protective equipment is the underlying approach of Universal Precautions described in Section 4. The material that follows is of a "general" nature regarding personal protective equipment.

(1) Policy

When there is occupational exposure to bloodborne pathogens, appropriate personal protective equipment is provided, at no cost to the at risk employees and other authorized personnel by this funeral home. The equipment provided has been selected because it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth or other mucous membranes under normal conditions of use for the duration of time which the protective equipment shall be used.

(2) Use

All employees and/or any other persons authorized to enter work areas of potential bloodborne pathogen exposure risk must use personal protective equipment to reduce or eliminate that exposure risk. The only exception to this policy shall be if, in the professional judgment of the employee, the use of proper personal protective equipment would pose an increased hazard to the safety of the worker or co-worker. When an employee makes this judgment, the circumstances shall be investigated, documented through the use of an *Employee Injury and Exposure Report* and follow-up to determine whether changes can be instituted to prevent such occurrences in the future.

(3) Selection and Assignment of Personal Protective Equipment

It is the policy of the funeral home to review the specific exposure risks faced by employees with those employees and to discuss the personal protective needs based upon the risk potential. This funeral home shall ensure that the "appropriate personal protective equipment, in the appropriate sizes, is readily accessible at the funeral home or is issued to employees."

In the event that an employee has a particular physical need for a particular type of equipment so as to be properly protected, every effort shall be made to meet that need or the employee shall not be allowed to continue with the tasks requiring that particular protective equipment. "Hypoallergenic gloves, glove liners, powderless gloves or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided."

During discussions of personal protective equipment, the funeral home expects that employees shall inform their manager of problems with personal protective equipment assigned to them, its functionality with regard to the work functions assigned and the availability or suitability of alternative equipment to meet the exposure risk.

(4) Accessibility

The personal protective equipment assigned and available for employee use shall be stored in a location or locations suitable for direct access. Personal equipment shall be selected to meet any special needs of individual employees. Non-employees seeking access to exposure risk areas are not to be authorized to enter those areas without notification of the exposure risk and the need to use appropriate personal protective equipment. General use personal protective equipment shall be available to such non-employees. However, it shall be the responsibility of the non-employee seeking access to an exposure risk area to provide any special equipment designed to meet specific needs of that person.

(5) Cleaning, Laundering and Disposal

Employees are expected to clean, disinfect, launder or dispose of personal protective equipment assigned for their use. These functions must be performed using the standard work practice policies adopted by this funeral home for such tasks *(See Sections: 8 - Housekeeping, 9 - Laundry and 10 - Disposal of Medical Waste)* and at no cost to the employee.

(6) Repair and Replacement

This funeral home shall repair and replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee. However, in the event that damage to equipment is not the result of normal use or wear, repair or replacement costs may be charged to the person to whom the equipment was assigned.

(7) General Personal Protective Equipment Rules

a. If a garment is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.
b. All personal protective equipment shall be removed prior to leaving the work area.
c. When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.
d. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials,

mucous membranes and non-intact skin; when performing vascular access procedures; and when handling or touching contaminated items or surfaces.

e. Disposable (single use) gloves shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured or the ability to function as a barrier is compromised. Disposable gloves shall not be washed or decontaminated for re-use.
f. Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, exhibit other signs of deterioration or their ability to function as a barrier is compromised.
g. Barrier masks in combination with eye protection devices, such as goggles or glasses with solid side shields and/or chin-length faceshields, shall be worn whenever splashes, spray, splatter, droplets of blood or other potentially infectious materials may be generated and eye, nose, mouth contamination can be reasonably anticipated.
h. Appropriate protective clothing such as but not limited to gowns, aprons, lab coats, clinic jackets or similar outer garments shall be worn in occupational exposure situations. The type and character of these items shall depend upon the task and degree of exposure anticipated.
i. Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., during preparation or embalming).

7.3 -Task Specific Personal Protective Equipment

(1) Policy

IN ALL CASES and AT ALL TIMES employees are to implement work practices that minimize splashing, spraying, leaking or contamination of any surface with blood or body fluids.

IN ALL CASES and AT ALL TIMES when engaged in the handling of human remains whether embalmed or not latex/vinyl gloves shall be used as a minimum standard for the use of personal protective equipment. This includes, but is not limited to, embalming and preparation, decontamination, positioning the body, dressing, casketing, cosmetizing, laundry and medical waste handling, etc. As with all personal protective equipment, the gloves shall be removed as soon as feasible, properly disposed of and hands shall immediately be washed using soap and running water.

(2) During Preparation, Embalming and Decontamination

Full personal protective equipment shall be used in all cases as follows:

a. Gloves. Latex/vinyl gloves should be worn at all times and in all cases.
b. Face Mask. A disposable barrier face mask that covers the nose and mouth shall be worn.
c. Face Protection. In conjunction with a face mask, goggles that prevent chemical splash back must be worn or, alternatively, a chin-length faceshield.
d. Gown. A fluid and chemical resistant disposable or washable gown with long sleeves shall be worn at all times.
e. Shoe Covers.
f. Head Cover.

(3) During the Removal and Transportation of Remains

At a minimum, the following personal protective equipment shall be used:

a. Gloves. Latex/vinyl gloves should be worn at all times and in all cases.
b. Face Mask. If the face of the deceased remains uncovered, then a barrier mask shall be used while the remains are being handled.
c. Other. The use of other personal protective equipment shall depend on the presence or likely presence of blood and body fluids and the condition of the remains. For instance, badly decomposed remains must be handled with the full complement of personal protective equipment mandated for embalming procedures.
d. Personal protective equipment soiled during a removal shall immediately be removed and placed in labeled or red, temporary use plastic bags in the removal vehicle, to be properly disposed of upon return to the funeral home and immediately placed in the Regulated Medical Waste disposal container provided for same in the preparation room.
e. Personal protective and related equipment that is used and that is part of the vehicle's supply shall be replaced by the person having used it upon returning to the funeral home.

(4) During Dressing, Casketing, Hairdressing and Cosmetizing

While performing these tasks to embalmed and decontaminated human remains, the following guidelines shall be observed:

a. Gloves. Latex/vinyl gloves shall be worn at all times and in all cases.
b. Other. The use of other personal protective equipment shall depend on the presence or likely presence of blood and body fluids and the condition of the remains. For instance, if a case involved a skin tissue harvest, the need for significantly more personal protective equipment would be warranted.

(5) During Ritual Religious Care

While performing this care which includes but is not limited to "Washing of the remains," the following guidelines shall be observed:

a. Gloves. Latex/vinyl gloves should be worn at all times and in all cases.

b. Face Mask. A disposable barrier face mask that covers the nose and mouth shall be worn.
c. Face Protection. In conjunction with a face mask, goggles that prevent chemical splash back must be worn or, alternatively, a chin-length faceshield.
d. Gown. A fluid and chemical resistant disposable or washable gown with long sleeves shall be worn at all times.
e. Other. The use of other personal protective equipment shall be evaluated and depend on the condition of the remains, the arrangement of the washing facilities and the likelihood of exposure to blood and body fluids.

(6) During Cleaning and Maintenance

While cleaning and performing maintenance of the preparation room and areas immediately adjacent to it, such as changing and dressing rooms, the following guidelines shall be observed:

a. Gloves. Heavy duty utility gloves that are not cracked or otherwise compromised may be used. At the conclusion of cleaning operations involving the preparation room and adjacent areas, the gloves shall be cleaned and decontaminated. Upon reuse, the gloves shall be examined for wear and tear and replaced as is necessary.
b. Gown. A fluid and chemical resistant disposable or washable gown with long sleeves shall be worn at all times.
c. Foot Gear. If the cleaning operation involves the likelihood of the employee's feet becoming wet (from mopping, as an example), waterproof shoe covers (or boots) that can be decontaminated upon completion of the task shall be used.
d. Face Mask. A disposable barrier face mask that covers the nose and mouth shall be worn.
e. Face Protection. In conjunction with a face mask, goggles or glasses with solid side shields that prevent splash back must be worn or, alternatively, a chin-length faceshield *[See 29 CFR 1910.1030(d)(3)(x)].*

(7) During Medical Waste and Laundry Operations

While performing medical waste and laundry operations the following guidelines shall be observed:

a. Gloves. Latex/vinyl gloves shall be worn at all times when handling, transporting and sorting contaminated laundry.
b. Gown. A fluid and chemical resistant disposable or washable gown with long sleeves shall be worn at all times.
c. Other personal protective equipment may be desired or selected as the situation dictates.

BP-8 Housekeeping

8.1 - 29 CFR 1910.1030(d)(4)

Funeral homes shall ensure that the worksite is maintained in a clean and sanitary condition.

8.2 - General Employee Occupational Activity

The general activity is the maintenance and cleaning of this funeral home and the specific tasks of cleaning the preparation room and areas adjacent to the preparation room in which dead human bodies have been held, prepared, embalmed, washed, dressed or casketed. In the event that contract labor or volunteer labor is used in addition to funeral home employees to assist in this process care shall be taken to alert those persons to the need to observe the safe work practices adopted by the funeral home.

It is important that employees involved in cleaning and maintaining facilities be aware of any equipment and clothing that has come into contact with a dead human body in which a reasonable expectation exists of a risk of exposure to blood, body fluids or other potentially infectious materials.

8.3 - Policy

It is the policy of the funeral home that work areas in which a bloodborne pathogen exposure risk exists, e.g. the preparation room and adjacent areas and removal vehicles, are to be maintained in a clean and sanitary condition. Each employee engaged in a work activity that involves the potential for bloodborne pathogen exposure risk is responsible for the proper cleaning and decontamination of all equipment and working surfaces upon completion of the task being performed by that employee. At the completion of each work shift, employees who have encountered a potential bloodborne pathogen exposure risk during their work time are expected to inspect the work area to assure that it is clean and sanitary. It is the duty of the affected employee to assure that the funeral home has been properly cleaned and decontaminated.

8.4 - Housekeeping Practices

(1) All equipment and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

Contaminated work surfaces shall be rinsed with water and ammonia if there is a risk of exposure to formaldehyde. (Special attention shall be addressed to the procedures for cleaning up hazardous chemical spills.) Care shall be taken to use the ammonia solution first so as to neutralize the formaldehyde. Once formaldehyde has been neutralized the ammonia solution shall be rinsed away with water only before the use of any bleach. The combination of bleach and ammonia could create a dangerous gas and must be avoided.

Work surfaces contaminated by blood or other potentially infectious materials shall be decontaminated with a 1:10 solution of bleach and water after completion of the procedure(s) being performed by the employee, immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(2) Protective coverings of equipment shall be removed and decontaminated or replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they have become contaminated during the shift.

(3) All bins, pails, cans and similar receptacles intended for reuse that have a reasonable likelihood of becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regular basis according to the housekeeping work schedule established by this funeral home and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(4) Broken glassware shall not be picked up directly with the hands. It shall be cleaned up using mechanical means such as a brush and dust pan, tongs or forceps.

(5) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless no alternative is feasible. Shearing or breaking of contaminated needles is prohibited. Reusable sharps that are contaminated with blood or other potentially infectious materials shall be decontaminated immediately after use and placed, sharp end first, into a styrofoam block. No points are to protrude from the styrofoam. The styrofoam is not to be dirty or contaminated with blood or other potentially infectious materials. The styrofoam containing sharps is to be stored in a container specifically intended for the storage of reusable sharps. These containers are made available by the funeral home in preparation areas where reusable sharps are used during work practices. These containers are puncture resistant, labeled or color-coded and leakproof on the sides and bottom. At no time shall an employee reach by hand into a container for reusable sharps to retrieve one unless it is clearly the only item present in the container and such a removal would not pose a risk of injury to the employee.

(6) Vehicles used for the removal of human remains shall always be cleaned and decontaminated when there is any overt contamination with blood or body fluids upon return to the funeral home. Removal vehicles shall also be periodically cleaned according to schedule.

(7) When engaged in housekeeping activities, the use of personal protective equipment as prescribed in Section 7 - Personal Protective Equipment of this plan for housekeeping and maintenance activities shall be observed.

8.5 - Housekeeping Work Practice Policies

Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the housekeeping process.

(1) The use of barrier masks in combination with eye protection devices, such as goggles or glasses with solid side shields or chin-length faceshields and rubber gloves over latex/vinyl gloves by employees is required while engaging in any housekeeping function that creates a risk of exposure to bloodborne pathogens. Additional personal protective equipment may be needed to protect against hazardous chemical exposure. Also, protective shoe coverings used in housekeeping activities in bloodborne pathogen exposure areas shall not be worn outside of those areas.

(2) The use of a disinfectant, such as a 1:10 solution of bleach and water, on all equipment and exposed surfaces is required.

(3) All gloves and other personal protective equipment used during housekeeping activities shall be placed in either a disposable container or, if reusable, placed in a container suitable for transporting without any unprotected contact until decontamination has occurred. All such containers shall be properly labeled as containing BIOHAZARDOUS materials.

(4) Reusable rubber gloves and shoe covers must be decontaminated immediately after use and properly stored for future use.

(5) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed.

(6) Broken glassware that may be contaminated with exposure to blood, body fluids or hazardous chemicals shall not be picked up directly with the hands. Such glassware shall be cleaned up using mechanical means such as a brush and dust pan, tongs or forceps.

(7) Access to areas of a funeral home in which a risk of exposure to bloodborne pathogens exists shall be limited to employees who have a job description that requires such access. All persons entering areas of potential exposure to bloodborne pathogens must follow the safe work practices adopted by the funeral home. Employees or other persons who have not been trained regarding the safe work practice policies of the funeral home, have not been provided with personal protective equipment appropriate to meet the risk of potential exposure to bloodborne pathogens or hazardous chemicals and trained in the use of that

equipment are to be prohibited from access to potential exposure areas.

BP-9 Laundry

9.1 - 29 CFR 1910.1030(d)(4)(iv)

9.2 - Laundry Practices

Laundry may consist of reusable personal protective equipment, hospital shrouds/sheets, personal effects of deceased persons, as well as other matter. All such laundry shall be treated as a BIOHAZARD and shall be stored prior to laundering in an appropriate receptacle solely for this purpose which shall be marked with the universal BIOHAZARD symbol and legend.

(1) It shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) All employees who have contact with contaminated laundry must wear protective gloves and other appropriate personal protective equipment. *(See Section 7 for details.)*

(3) To meet the request of any family wishing the return of contaminated clothing or personal effects of a deceased person, such clothing and effects shall first be laundered.

(4) All personal protective equipment used by employees shall be cleaned on a regular basis at no cost to employees.

(5) Laundry so thoroughly contaminated that it is saturated and/or dripping with blood or body fluids shall be disposed of as regulated medical waste and shall not be laundered.

(6) Contaminated laundry shall be placed and transported in bags or containers labeled with the universal BIOHAZARD symbol and legend thus:

BIOHAZARD

(7) Contaminated laundry shall not be pretreated or rinsed in the preparation room, but shall be immediately stored or bagged for laundering and shall be moved in same to the place of laundering where it shall then be handled.

(8) "Contaminated laundry shall be handled as little as possible with a minimum of agitation."

(9) "Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior."

(10) When laundry is transported off site to a commercial laundry, it shall be so transported in bags labeled with the universal BIOHAZARD symbol and legend.

BP-10 Disposal of Medical Waste

10.1 - 29 CFR 1910.1030(d)(4)(iii)

10.2 - General Employee Occupational Activity

The collection and preparation for disposal of sharps or other materials or clothing that have come in contact with blood, body fluids or other potentially infectious materials.

10.3 - Work Practice Policies

Employees shall take great care to protect themselves from contact with blood, body fluids and other potentially infectious materials. All human blood and body fluids are to be treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens. In particular, the following steps shall be followed for implementation as work practices as applicable to occupational risks occurring during the waste disposal process.

(1) Two types of regulated medical waste containers shall be provided: one for sharps and one for all other types of medical waste. In both instances, the containers shall be:

a. Closable
b. Rigid
c. Leakproof
d. Upright
e. And labeled as follows:

BIOHAZARD

These labels shall be fluorescent orange or orange-red and predominantly so, with lettering or symbols in a contrasting color and they shall be affixed to the container(s) by any method that prevents their loss or removal.

Red bags may be used as a substitute for labeling.

(2) Used sharps to be discarded must be disposed of immediately into a container specifically designed for such a purpose which is provided by the funeral home in the Preparation Room. This container must remain upright throughout use, be replaced routinely and not allowed to overfill.

(3) When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately prior to removal or replacement so as to prevent spillage or protrusion of contents during handling, storage, transport or shipping. If leakage is possible, the container shall be placed in a secondary container which is closable; constructed to contain all contents and prevent leakage during handling, storage, transport or shipping; and which is labeled and/or color coded as containing BIOHAZARDOUS materials.

(4) Latex/nylon gloves must be used by employees collecting materials for disposal as regulated medical waste. Additional personal protective equipment may be needed to protect the employee from exposure to bloodborne pathogens depending upon the type of material being collected or discarded. The use of a barrier mask while collecting and preparing materials for disposal is recommended. *(See Section 7 for more details.)*

(5) All materials prepared for disposal shall be placed into containers properly identified as containing BIOHAZARDOUS materials, which are closable, constructed to contain all contents and prevent leakage during handling, storage, transport or shipping.

(6) Broken glassware that may be contaminated with exposure to blood, body fluids or hazardous chemicals shall not be picked up directly with the hands. Such glassware shall be cleaned up using mechanical means, such as a brush and dust pan, tongs or forceps.

(7) The storage of materials in containers to be removed from the funeral home shall be in a location that is secure and removed from public access areas.

(8) All gloves and other personal protective equipment used during waste disposal activities shall be placed in either a disposable container or, if reusable, placed in a container suitable for storage without any unprotected contact until decontamination has occurred. All such containers shall be properly labeled as containing BIOHAZARDOUS materials.

(9) Hands and exposed skin surfaces shall be washed immediately and thoroughly if contaminated by blood or body fluids. Hands shall be washed immediately after gloves are removed.

(10) The waste shall be stored, transported and shipped in accordance with all of the terms and conditions of the "applicable regulations of the United States, States and Territories and political subdivisions of States and Territories" *[29 CFR 1910.1030(d)(4)(iii)(C)]*. For example, the New Jersey Comprehensive Regulated Medical Waste Management Act.

BP-11 Hepatitis B Vaccination

11.1 - 29 CFR 1910.1030(f)

This funeral home shall make available the Hepatitis B vaccine and vaccination series to all employees who have occupational exposure.

11.2 - Policy

All employees of the funeral home who have been identified as having a risk of occupational exposure to bloodborne pathogens shall be offered the opportunity to receive a Hepatitis B vaccination at no charge. The funeral home shall provide any employee with information and training about the Hepatitis B virus and the Hepatitis B vaccination, during regular business hours. We encourage our "exposure risk" employees to take advantage of this offering at any time.

11.3 - Vaccination Practices

This vaccination offer shall be given and the vaccination available within ten (10) days of the employee beginning the job function with the exposure risk. Employees who have previously been vaccinated are not required to be vaccinated again. The vaccination program shall follow the current guidelines of the United States Public Health Service as provided by an appropriately accredited physician.

(1) The vaccine shall be administered under the supervision of a licensed healthcare professional and shall be available to at-risk employees during regular business hours. This healthcare professional shall be provided with a copy of the applicable OSHA Bloodborne Pathogens Standard prior to administering any vaccine to employees.

(2) No employee shall be permitted to receive the vaccine until he has received free training provided by this funeral home and in accordance with terms and conditions stated in this section. This training shall provide "information on the Hepatitis B vaccine including information on its efficacy, safety, method of administration, the benefits of being vaccinated and that the vaccine and vaccination shall be offered free of charge."

(3) When and if the U.S. Public Health Service determines that those persons previously having received the vaccine shall receive a booster, training, information and administration of such boosters shall also be provided free of charge and during regular business hours.

(4) Any employee at risk of occupational exposure as defined is entitled to the information and training described in this section and the Hepatitis B vaccine within ten (10) working days of initial assignment to a position where there is exposure, "unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune or the vaccine is contraindicated for medical reasons."

(5) Employees are not required to be prescreened prior to receiving a Hepatitis B vaccination.

(6) If any employee initially declines Hepatitis B vaccination but at a later date while still covered under the Standard decides to accept the vaccination, this funeral home shall make available the Hepatitis B vaccination at that time.

(7) A *Communication of Funeral Home Hazards* form must be used to document the funeral home's offer of the vaccination and the employee's response.

(8) Employees who decline the Hepatitis B vaccination must sign the OSHA-mandated form *(See Communication of Funeral Home Hazards form),* which contains the following statement:

"I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B Virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with the Hepatitis B vaccine, I can receive the vaccination series at no charge to me."

(9) A copy of the *Communication of Funeral Home Hazards* form shall be kept in the employee's OSHA file.

BP-12 Post-Exposure Evaluation and Follow-Up Program

12.1 - 29 CFR 1910.1030(f)

This funeral home shall make available the post-exposure evaluation and follow-up to all employees who have had an exposure incident.

12.2 - Policy

At this funeral home, the post-exposure evaluation and follow-up is available to all employees who have had a bloodborne pathogen exposure incident.

12.3 - Three Basic Types of Exposure

There are three basic types of occupational exposure that are likely to occur:

(1) A percutaneous exposure; that is, a puncturing or cutting of the skin with a needle or other sharp instrument.

(2) A cutaneous exposure; that is, blood or body fluid contact with chapped, abraded or otherwise non-intact skin.

(3) A mucous membrane exposure; that is, blood or body fluid contact with the eye, the mouth or through the nose.

12.4 - First Aid

Any employee who suffers an occupational exposure shall first administer to themselves or have administered basic first aid as follows:

(1) Cleanse the wound with running water.

(2) Use the emergency eye wash station for splashes to the eye.

(3) For splashes into the mouth, rinse out mouth several times with running water.

(4) For exposure in the nasal membrane (nose), flood to the extent possible with cool running water.

12.5 - Report Exposure

Any exposed employee shall immediately report the occupational exposure to his or her manager in order to obtain professional care and review as provided for in this section.

It is the option of the employee to determine medical assistance as needed. If medical assistance is required the employee shall report directly to the nearest hospital or walk in emergency room or clinic for treatment. In the event that no management staff are available for consultation, the employee shall call the OSHA Compliance Officer regardless of hour to report exposure incident and/or injury.

All bloodborne pathogen exposure incidents must be reported to the funeral home by use of an *Employee Injury and Exposure Report* form from the funeral home, copies of which are available at the funeral home office.

12.6 - The Medical Evaluation

All medical evaluations and procedures including the post-exposure evaluation and follow-up are made available to employees at no cost to the employee at a reasonable time and place by a licensed physician in accordance with U.S. Public Health Service current recommendations. All laboratory tests are to be conducted by an accredited laboratory at no cost to the employee.

When a bloodborne pathogen exposure incident is reported to the funeral home using the *Employee Injury and Exposure Report* form, a confidential medical evaluation and follow-up shall immediately be available to the employee at no cost. This post-exposure evaluation and follow-up shall include:

(1) Name of physician

(2) Documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred.

(3) Identification and documentation of the source individual.

a. When the source individual is already known to be infected with HBV, HCV or HIV, testing for the source individual's known HBV, HCV or HIV status need not be repeated.

b. When the source individual is a deceased person and it is unknown if the source individual's blood is infected with HBV, HCV or HIV the following OSHA Standard, 29 CFR 1910.1030(f)(3)(ii)(A) states: "The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV and HIV infectivity. If consent is not obtained, the funeral home shall establish that legally required consent cannot be obtained."
Note: At this time there remains a variety of unresolved medical and legal issues in this area, such as, if a viable blood sample can be obtained from a deceased person for testing of HBV, HCV or HIV infectivity.

Until these questions have been resolved use the following suggestions and keep a written record of any contact with the deceased person's physician and/or family.

(i) The funeral home shall confer with the deceased person's physician to determine if a medical history of infection with HBV, HCV or HIV existed.

(ii) In the event that the physician refuses giving the medical history on the grounds of confidentiality, request consent for release of medical information from the appropriate family member who has this release authorization.

(iii) If the family refuses consent for the release of medical history, contact the management for advice.

(4) Results from the blood testing of source individuals shall be made available to the affected employee. The employee shall be advised regarding the legal requirements of confidentiality regarding the source individual.

(5) After a bloodborne pathogen exposure incident and if the employee consents to a baseline blood collection, such collection shall be made as soon as feasible after the employee's consent is obtained. If the employee does agree to baseline blood collection but does not consent at the time to HIV serologic testing, the sample is to be preserved for at least ninety (90) days. If, within 90 days of the collection, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(6) Post-exposure prophylaxis (when medically indicated) as recommended by the U.S. Public Health Service, counseling and evaluation of reported illnesses shall also be available to the employee.

12.7 - Information for the Evaluating Healthcare Professional

To provide the medical evaluation of an employee after an exposure incident, the healthcare professional shall receive from this funeral home the following information:

(1) A copy of the *Employee Injury and Exposure Report*.

(2) A copy of the Bloodborne Pathogens Standard, 29 CFR 1910.1030.

(3) A description of the employee's duties as they relate to the exposure incident.

(4) Information regarding known infectivity of the remains involved in the exposure incident.

(5) Copies of employee's medical file as maintained by this funeral home (including vaccination status).

12.8 - Releasing Findings of the Completed Medical Evaluation to the Exposed Employee

Within 15 days of the completion of the post-exposure evaluation by the healthcare professional, the funeral home shall obtain and provide to the exposed employee a copy of the healthcare professional's written opinion, which shall be limited to the following information:

(1) Whether the Hepatitis B vaccination is indicated and if the employee has received it

(2) Whether the employee has been informed of the results of the evaluation

(3) Whether the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment

(4) All other findings or diagnoses shall remain confidential and shall not be included in the written report

BP-13 Hazard Communication–Labels

13.1 - 29 CFR 1910.1030(g)(1)(i)

Warning labels shall be affixed to containers of regulated waste and any other potentially infectious material and to contaminated equipment.

13.2 - Policy

Any containers of any type used to hold infectious or potentially infectious material or regulated medical waste and any contaminated equipment shall be labeled with the universal BIOHAZARD symbol at all times.

The universal BIOHAZARD symbol shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color and shall contain the legend "BIOHAZARD" thus:

13.3 - Hazard Communication Practices

(1) BIOHAZARD symbols shall be affixed to containers in a way that prevents their loss or accidental removal.

(2) Red bags or red containers may be substituted for labels.

(3) The containers in this funeral home that are currently so labeled include, but are not limited to:
   a. General medical waste container
   b. "Sharps" container
   c. Laundry bags/containers
   d. Temporary bags holding unwashed personal effects of deceased persons when contaminated with infectious or potentially infectious materials

BP-14 Employee Training Program

14.1 - 29 CFR 1910.1030(g)(2)

This funeral home shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee during working hours.

14.2 - Policy

The funeral home is committed to effective employee communication and training about the hazards associated with bloodborne pathogens. This funeral home's written *Bloodborne Pathogen Standard Employee Training Program* shall provide the employees with information and training about the Bloodborne Pathogens Standard and the related topics covered in that Standard. The *Bloodborne Pathogen Standard Employee Training Program* is designed to be a part of and incorporated into this *Bloodborne Pathogen Exposure Control Plan*.

14.3 - Training Practices

All employees with occupational exposure or potential exposure to bloodborne pathogens in the funeral home during the conduct of their job functions must participate in a training program during work hours at no cost to the employee. Training shall be provided:

(1) Prior to an employee beginning a job function which involves a risk of exposure to bloodborne pathogens and

(2) At least annually thereafter

Additional training shall be provided to affected employees when changes in job functions or procedures occur which affect the employee's occupational exposure.

The employee training program designed to meet the requirements of the Bloodborne Pathogens Standard shall be presented in vocabulary and content sufficient to meet the educational level, literacy and language of the employees. The persons conducting the training shall be knowledgeable in the subject matter covered by the training program as it relates to the worksite environment of the employee.

Documentation of employee training shall be recorded on the *Annual Training and Safer Sharps Evaluation Record* and retained at the funeral home in the employee OSHA file.

14.4 - Training Program

The training program shall contain, but not be limited to, the following items.

(1) An accessible copy of the regulatory text of the Bloodborne Pathogens Standard and an explanation of its contents.

(2) A general explanation of the epidemiology and symptoms of bloodborne diseases.

(3) An explanation of the modes of transmission of bloodborne pathogens.

(4) A copy of this *Exposure Control Plan* and an explanation of it.

(5) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.

(6) An explanation of the use and limitations of methods that shall prevent or reduce exposure to bloodborne pathogens, such as appropriate engineering controls, work practices and personal protective equipment.

(7) Information on types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.

(8) An explanation of the basis for selection of personal protective equipment.

(9) Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration and its benefits and that the vaccine and vaccination shall be offered free of charge to the employee.

(10) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.

(11) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that shall be made available.

(12) Information on the post-exposure evaluation and follow-up that the funeral home shall provide for the employee following an exposure incident.

(13) An explanation of the signs and labels and/or color coding of BIOHAZARDOUS materials.

(14) An opportunity for interactive questions and answers with the person conducting the training session.

BP-15 Recordkeeping

15.1 - 29 CFR 1910.1030(h)

15.2 - Policy

For every employee who has an occupational exposure, the funeral home shall establish and maintain accurate records and shall provide full access to any employee or employee's agent (when the approval is in writing in the case of medical records), to those records pertaining to that employee, as well as access to any training materials, monitoring results and similar material for examination and copying.

15.3 - Sharps Injury Log

This funeral home shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(1) The type and brand of device involved in the incident

(2) The work area where the exposure incident occurred and

(3) An explanation of how the incident occurred. *(See Sharps Injury Log form.)*

15.4 - Employee Medical Files

Employee medical files shall be maintained for each employee with an occupational exposure to bloodborne pathogens. The funeral home shall ensure the confidentiality of these records and shall not disclose or report their contents without the employee's express written consent to any person within or outside the funeral home except as required by this section or as may be required by law. The employee medical files shall be kept by the funeral home for a minimum of 30 years beyond the last day of employment of the employee by the funeral home.

This file shall contain:

(1) Employee name

(2) Hepatitis B vaccination status (including all of the dates of vaccinations and any medical records relative to the employee's ability to receive a vaccination)

(3) A copy of all results of examinations, medical testing and follow-up procedures

(4) A copy of any healthcare professional's written opinion related to the Hepatitis B vaccination of the employee or any post-exposure evaluation or follow-up

(5) A copy of all information provided to the health care professional by this funeral home

(6) Copies of *Employee Injury and Exposure Report*s regarding the employee

(7) All medical reports, including post-exposure evaluations and treatment

Employee medical records are confidential, but they shall be made available to persons with written authorization for access signed by the employee. All employee records shall be made available to the affected employee upon request. All records shall be available to a properly credentialed representative of OSHA upon request.

15.5 - Employee Training Records

All records related to employee training in accordance with the Bloodborne Pathogens Standard shall be kept in the employee personnel file for at least three years from the training date.

The training records of the funeral home shall include the following:

(1) Dates of training sessions

(2) Contents of such sessions or an accurate summary

(3) The names and qualifications of persons conducting the training

(4) The names and job titles of all persons attending the training sessions

These records, as well as all training material shall be available to any employee upon request for examination and copying or to any employee's agent.

Hazard Communication & Formaldehyde

HAZARD COMMUNICATION PROGRAM

HF-1 Key Elements

1.1 - Hazard Communication Standard, 29 CFR 1910.1200

All funeral homes are required to provide information to their employees about the hazardous chemicals to which they are exposed by means of a Hazard Communication Program, labels and other forms of warning, safety data sheet (SDS) and employee information and training.

1.2 - Formaldehyde Standard, 29 CFR 1910.1048(m)

The funeral home shall develop, implement and maintain in the worksite a written Hazard Communication Program for formaldehyde exposure in the worksite, which at a minimum describes how the requirements specified for labels, other forms of warning, SDS, employee information and training should be met.

1.3 - Policy

The policy of the funeral home is to ensure that the hazards of all chemicals used or stored by this funeral home are evaluated and information concerning the hazards of such chemicals is transmitted to employees who may be exposed to those chemicals.

1.4 - Purpose

The purpose of this program is to establish and define the policies and practices of the funeral home with regard to its obligations under the United States Department of Labor, Occupational Safety and Health Administration (OSHA) regulations known as the Hazard Communication Standard *[29 CFR 1910.1200]* and the Formaldehyde Standard *[29 CFR 1910.1048(m)]*.

1.5 - Person Responsible: OSHA Compliance Officer

The OSHA Compliance Officer is the person responsible for the proper maintenance and implementation of the OSHA Hazard Communication Program for this funeral home. *(See inside front cover for the name of the OSHA Compliance Officer.)* The OSHA Compliance Officer shall:

(1) Implement the *Hazard Communication Program.*

(2) Train employees (and/or implement training programs).

(3) Monitor all chemicals used in the funeral home to evaluate possible hazards:
   a. By developing a list of all hazardous chemicals used in the funeral home.
   b. By reviewing completeness of safety data sheet (SDS) file, transmitting any new SDS information to all exposure risk employees and ensuring that hazardous chemicals without an SDS shall not be used until an SDS is obtained.
   c. By verifying that containers of hazardous chemicals are properly labeled with appropriate warnings.
   d. By reviewing any new hazardous chemicals.

(4) Review potential exposure risk to ensure necessary employee training is provided:
   a. By regular, periodic review of job functions.
   b. By results of monitoring chemicals used.

(5) Maintain OSHA-related records.

1.6 - Accessibility of Plan to Employees

The funeral home shall ensure that a copy of the *Hazard Communication Program* is accessible to employees in accordance with 29 CFR 1910.1020(e). A copy of the program is available in the funeral home office.

1.7 - Review of Program

The *Hazard Communication Program* shall be reviewed and updated at least annually and whenever necessary to reflect changes in tasks, procedures and employee positions that affect occupational exposure.

Documentation of review and any applicable updates shall be recorded on the Annual Plan Review Verification inside the front cover of the funeral home's OSHA Written Communication Plan.

1.8 - Employee Auditing System

This program and its supporting materials are available for examination and copying to all employees. All employees are encouraged and requested to make comments on the usefulness of this program and to contribute any other ideas that will further the intention of creating a more enjoyable and safer worksite for all of us and our families and the families we serve. The funeral home depends upon our employees to notify the funeral home's OSHA Compliance Officer, manager or other senior employee of any hazards and need for maintenance that may come to their attention.

HF-2 List of Hazardous Chemicals

2.1 - 29 CFR 1910.1200(e)(1)(i)

Develop and maintain a list of the hazardous chemicals known to be present using an identity that is referenced on the appropriate SDS (the list may be compiled for the funeral home as a whole or for individual work areas).

2.2 - Policy

The OSHA Compliance Officer shall develop a list of all hazardous chemicals used in the funeral home. This list shall be checked regularly for accuracy and updated when new chemicals are brought into the funeral home. This list shall be used to contact the supplier or manufacturer to obtain the current appropriate SDS for the product. In the event chemicals or substances which contain hazardous chemicals have been in the funeral home for more than one year, this list shall also be used to contact the supplier or manufacturer for updated labels for the product.

Information on all hazardous chemicals within this funeral home can be found in the SDS file.

HF-3 Labels and Other Warnings

3.1 - 29 CFR 1910.1200(f)

3.2 - Policy

No container of hazardous chemicals shall be released for use until the following label information is verified by the OSHA Compliance Officer:

(1) Containers are clearly labeled and identify the hazardous chemicals contained therein

(2) Appropriate hazard warnings are on containers

(3) The manufacturer's name and address are listed on the container's label

(4) Materials capable of releasing formaldehyde at levels above 0.5 ppm shall be labeled "MAY CAUSE CANCER"

The OSHA Compliance Officer shall be responsible for ensuring all secondary containers (i.e., smaller containers filled from a main source or larger container for more convenient use) of hazardous chemicals have the required label identifying the hazardous chemical and appropriate hazard warning. Although this labeling requirement does not apply to portable containers into which hazardous chemicals are transferred from labeled containers and which are intended only for the immediate use of the employee who performs the transfer, any continued use of such a container for storage of the chemical or substance or by other employees shall require a label to be affixed to that secondary container which includes the identity of the hazardous chemical and appropriate hazard warnings.

HF-4 Safety Data Sheets (SDS)

4.1 - 29 CFR 1910.1200(g)

4.2 - Policy

(1) Location of SDS File

Copies of the SDS for hazardous chemicals used or stored in the funeral home shall be available to all employees arranged in alphabetical order by product name. Copies of the SDSs shall be kept in the business office or in the preparation room of every funeral home.

(2) New Information Communicated to Employees

The OSHA Compliance Officer shall review incoming data sheets for new and significant health and safety information. And the OSHA Compliance Officer shall ensure that any new information is transmitted to employees who may be exposed to those chemicals.

(3) Review and Update

It is the responsibility of the OSHA Compliance Officer to review for completeness all SDSs. A new SDS shall be requested from the manufacturer if an SDS is missing or obviously incomplete. Employees are to contact the OSHA Compliance Officer if SDSs are not available or new hazardous chemicals in use do not have a SDS.

(4) If No SDS

Chemicals for which a proper SDS has not been obtained by this funeral home shall not be used until the SDS is obtained and the chemical exposure risk for employees evaluated by the OSHA Compliance Officer.

FORMALDEHYDE EXPOSURE CONTROL PLAN

HF-5 Exposure Control Plan

5.1 - The Formaldehyde Standard, 29 CFR 1910.1048

(1) Permissible Exposure Limits

In accordance with the OSHA Formaldehyde Standard 29 CFR 1910.1048, a funeral home is responsible to ensure that no employee is exposed to airborne concentrations of formaldehyde which exceed the permissible exposure limit (PEL) of time weighted average (TWA) or the short term exposure limit (STEL).

a. TWA—"time weighted average"—means a concentration of 0.75 part formaldehyde per million parts air (0.75 ppm) over an eight-hour time weighted average (TWA).

b. STEL—"short term exposure limit"—means a concentration of 2 parts formaldehyde per million parts of air (2 ppm) over a 15-minute period.

(2) Action Level

"Action level" means a concentration of 0.5 part formaldehyde per million parts air (0.5 ppm) calculated as an eight-hour time weighted average (TWA) concentration.

(3) Exposure Monitoring

To meet the permissible exposure limit responsibility, funeral homes with the potential for such an exposure, based upon the use of formaldehyde based chemicals in the funeral home, must conduct a monitoring of the formaldehyde exposure levels in the funeral home environment.

5.2 - Policy

It is the policy of the funeral home that "the safety and health of employees shall be given priority over all other operations and activities."

5.3 - Purpose

The purpose of this plan is to establish and define the policies and practices of the funeral home with regard to its obligations under the United States Department of Labor, Occupational Safety and Health Administration (OSHA) regulations known as the Formaldehyde Standard. The proper citation for this Standard is 29 CFR 1910.1048.

5.4 - Person Responsible: OSHA Compliance Officer

The OSHA Compliance Officer is the person responsible for the proper maintenance and implementation of the OSHA Formaldehyde Exposure Control Plan for this funeral home. *(See inside front cover page for the name of the OSHA Compliance Officer.)*

The OSHA Compliance Officer shall:

(1) Implement *Formaldehyde Exposure Control Plan*.

(2) Train employees (and/or implement training programs).

(3) Review risks of exposure:

a. By monitoring all risks within the context of the general business activities engaged in by this funeral home.

b. By evaluating circumstances surrounding any exposure incidents.

c. By regular, periodic review of exposure determination roster. *(See Bloodborne Pathogen and Formaldehyde Exposure Determination Risk Roster.)*

(4) Ensure effectiveness of work practices. On a regular schedule, examine and modify as necessary any work practices regarding safety related issues.

(5) Maintain OSHA-related records.

(6) Implement *Formaldehyde Monitoring Program*.

(7) Implement *Respiratory Protection Program* for at-risk employees.

5.5 - Employee Auditing System

This plan and its supporting materials are available for examination and copying to all employees. All employees are encouraged and requested to make comments on the usefulness of this plan and to contribute any other ideas that shall further the intention of creating a more enjoyable and safer worksite for all of us, our families and the families we serve. The funeral home depends upon our employees to notify the OSHA Compliance Officer, manager or other senior employee of any hazards and code violations that may come to their attention or notify the management directly.

HF-6 Exposure Monitoring

6.1 - 29 CFR 1910.1048(d)

Each funeral home which has a worksite covered by this Standard shall monitor employees to determine their exposure to formaldehyde.

6.2 - Policy

The policy of the funeral home is to ensure that the risk of employee exposure to formaldehyde is properly evaluated by monitoring and information concerning the exposure risk and methods of eliminating or minimizing the risk are transmitted to affected employees.

6.3 - General

(1) Monitoring: Representative Sample Strategy

The funeral home has selected the representative sample strategy to monitor exposure risk reflected by the conditions in the at-risk area. A representative employee shall be monitored whose exposure risk shall equal or exceed the exposure risk of all other persons on behalf of whom the monitoring is being conducted.

(2) Determination Process

All persons who have job functions which require them to be in or around areas of potential formaldehyde exposure shall be considered to be at risk regarding such an exposure.

The exposure determination process used by this funeral home to identify potential formaldehyde exposure risk is the identification of individual employees who are engaged in job functions which require their access to such an exposure risk area. All other employees who are not assigned to such job functions shall not be at risk. Employees involved in job functions without an exposure risk shall be notified that they are not authorized to enter work areas where formaldehyde exposure risks exist.

(3) Formaldehyde Exposure Risk Roster

A roster of employees with job functions that require access to the preparation room, a formaldehyde exposure risk area, has been compiled by this funeral home. At-risk employees are identified as those with job functions that require their presence during embalmings in the preparation room and those that have access to the preparation room.

All employees with job functions that require access to the preparation room shall be trained in accordance with the Hazard Communication Standard *[See 29 CFR 1910.1200(h)]* and the Formaldehyde Standard (which includes training in how to recognize the hazards of formaldehyde) *[See 29 CFR 1910.1048(n).]*

(4) Accuracy of Monitoring

Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

(5) Important Exception: When No Monitoring Required

Where the funeral home documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the worksite cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, this funeral home shall not be required to measure employee exposure to formaldehyde.

6.4 - Initial Monitoring

(1) Identified Exposure Risk Employees

A roster of employees with formaldehyde exposure risk at this funeral home has been compiled. *(See Bloodborne Pathogen and Formaldehyde Exposure Determination Risk Roster.)* Occupational exposure is regularly reviewed by the OSHA Compliance Officer.

(2) Representative Sample Strategy

The funeral home has selected the representative sample strategy to monitor for the job functions and exposure risk (as reflected by the conditions at the time of the monitoring) by monitoring using representative employees whose exposure risk shall equal or exceed the exposure risk of all other persons on behalf of whom the monitoring is being conducted.

(3) When to Repeat Initial Monitoring

The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel or control measures which may result in new or additional exposure to formaldehyde.

(4) If Employee Reports Exposure Symptoms

If the funeral home receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, this worksite shall promptly monitor the affected employee's exposure.

6.5 - Periodic Monitoring

This funeral home shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

(1) When At or Above Action Level

If the last monitoring results reveal employee exposure at or above the action level, this funeral home shall repeat monitoring the representative employee(s) at least every six months.

(2) When At or Above STEL

If the last monitoring results reveal employee exposure at or above the STEL, this funeral home shall repeat monitoring of the representative employee(s) at least once a year under worst conditions.

6.6 - Employee Notification of Monitoring

All employees of this funeral home who have a formaldehyde exposure risk within the work area to be monitored are to be notified of the time and place when such monitoring is to be conducted. The reason for this notification is to allow the exposed employee an opportunity to observe the monitoring of the work area, the monitoring technique, conditions monitored and the work practices and engineering controls used during the monitoring process.

6.7 - Termination of Monitoring

This funeral home may discontinue periodic monitoring for employees if results from two consecutive sampling periods, taken at least seven days, apart show employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the funeral home's knowledge of the job and work operation.

HF-7 Monitoring Methods

7.1 - 29 CFR 1910.1048(f)

7.2 - Policy

It is the policy of the funeral home to ensure that no employee is exposed to airborne concentrations of formaldehyde which exceed the "permissible exposure limit" (PEL) of the TWA or STEL.

(1) TWA—"time weighted average"—means a concentration of 0.75 parts formaldehyde per million parts air (0.75 ppm) over an eight-hour time weighted average (TWA).

(2) STEL—"short term exposure limit"—means a concentration of 2 parts formaldehyde per million parts of air (2 ppm) over a 15-minute period.

7.3 - Purpose

The following material is designed to provide a step-by-step description of the process of monitoring for formaldehyde levels. It shall be noted that this description is designed to meet general work conditions found in this funeral home. In the event that special conditions or a work practice differs from those discussed, care shall be taken to appropriately modify the procedures to be implemented so as to properly reflect those conditions.

7.4 - General

(1) Access Authorization During Embalming and Monitoring

a. At this funeral home during monitoring and embalming, only employees who have been trained regarding the requirements of the Hazard Communication Standard and the Formaldehyde Standard (which includes training in how to recognize the hazards of formaldehyde) are authorized to enter the preparation room where a formaldehyde exposure risk exists.

b. Only employees with job functions that require their presence are authorized access during monitoring and embalming in the preparation room. A roster lists employees with this authorization. (*See Bloodborne Pathogen and Formaldehyde Exposure Determination Risk Roster.)*

(2) Location: Limit Exposure Risk Areas

In conducting the formaldehyde monitoring for the funeral home, the monitoring shall be conducted in the area(s) where formaldehyde exposure is likely to occur. In general,

the area to be monitored can be limited to the preparation room so long as that remains the only location within the funeral home facility in which employees or contractors are using formaldehyde-based chemicals or substances in the course of their work that may create an occupational exposure risk.

In the event that another location is used within the funeral home in which such an exposure risk is likely to occur, monitoring shall also be conducted in this area. In this situation management shall consider conducting a feasibility study regarding the combining of all tasks associated with formaldehyde exposure risks into one area or location within the funeral home.

(3) Signs

By June 2016 signs and notices regarding the limitation of access to formaldehyde exposure risk areas to "Authorized Personnel Only" shall be posted in the entrances and access ways to the preparation room regardless of the level of the monitoring results. If either the TWA or the STEL are exceeded, signs shall be posted at the preparation room entrances and accessways bearing the following information:

DANGER

FORMALDEHYDE

MAY CAUSE CANCER

CAUSES SKIN, EYE AND RESPIRATORY IRRITATION

AUTHORIZED PERSONNEL ONLY

(4) Monitoring and Training at Least Once a Year

Monitoring and employee training regarding risks of exposure to formaldehyde in the worksite shall be conducted by this funeral home at least once a year.

7.5 - Representative Sample Monitoring

(1) Selection of Representative Employees for Sample

This funeral home shall select employees to be monitored whose work practices, conditions and exposure risk are the greatest among all affected employees, since the results of the exposure monitoring shall affect all persons represented by the monitoring. In the event that the monitoring results exceed OSHA limits and require action on the part of the funeral home to reduce the level of exposure risk, all employees represented by the monitoring shall be equally affected with regard to the need to modify their work practices or the work environment, including the use of additional personal protective equipment or engineering controls.

(2) Work Volume Considerations

This funeral home when selecting a representative employee for monitoring shall consider work volume and practices that accurately reflect the normal or routine upper level of exposure.

The following are examples of case-year volume considered when monitoring for the Time Weighted Average (TWA) for an eight-hour period:

a. When fewer than 125 embalmings per year, consider monitoring when only one case is being embalmed.
b. When between 125 and 200 embalmings per year, consider monitoring on a day when two cases are embalmed by the representative employee so as to provide a monitoring result that reflects the upper normal exposure range for any one employee.
c. When an excess of 200 embalmings are performed in a year determine the number of cases routinely performed by any one employee which reflects the normal or routine upper level of work activity for an employee.

7.6 - Monitoring Conditions and Results

(1) Monitoring Report

a. Formaldehyde Monitoring Notice and Results: A written record of the conditions that existed at the time the formaldehyde exposure monitoring was conducted is maintained by this funeral home. *(See Formaldehyde Monitoring Notice and Results.)*
b. Essential to proper understanding of monitoring results and notification of affected persons or entities of monitoring results are the following items recorded in the *Formaldehyde Monitoring Notice and Results*:
   (i) Name of employee being monitored (representative sample) and the names of the exposure risk employees for whom the representative sample monitoring is being conducted.
   (ii) Level of exposure being monitored which includes number of embalmings and other work activities being performed by representative employee during monitoring.
   (iii) Personal protective equipment worn.
   (iv) Engineering controls and practices used.
c. Availability of Monitoring Report: This record is available for examination by all affected employees of the funeral home, contractors, sub-contractors, tenants or lessees of the funeral home which are authorized access to potential formaldehyde exposure areas and who have a potential exposure risk resulting from their activities at the funeral home being monitored.

(2) If Results Do Not Exceed Required Limits

In the event that the results of the formaldehyde exposure monitoring conducted at this funeral home do not exceed the Action Level, TWA or STEL, then no further action is required in the next 12 months other than the proper notification of affected persons regarding the monitoring results.

(3) Safety Review: If Results are Close to Exceeding Limits

Care is taken to relate the level of exposure risk involved in the monitoring that is conducted by this funeral home and the results of that monitoring to the ongoing levels of exposure risk to employees. In the event that monitoring results are below the OSHA TWA or STEL limits by marginally low amounts, the conduct of an additional embalming or other exposure risk activity by an employee over and above the conditions at the time of the original monitoring shall be considered by the OSHA Compliance Officer with the following considerations:

a. Added monitoring for the expanded work activities involving formaldehyde exposure risk shall be conducted;
b. Additional work practice rules shall be implemented for the performance of the added tasks; or
c. Additional personal protective equipment and engineering controls shall be utilized until such added monitoring can be properly conducted.

(4) If Results Meet or Exceed PELs

In the event results of the formaldehyde exposure monitoring *meet or exceed* any of the following permissible exposure limits (PELs), then this funeral home shall take the following appropriate action indicated:

a. The Action Level: "0.5 ppm or greater TWA exposure to formaldehyde."
Immediate steps shall be taken to reduce the exposure to formaldehyde. Medical surveillance of exposed employees shall be implemented. Periodic re-monitoring shall be conducted at least every six months or until the exposure results fall below the Action Level.
b. TWA: "0.75 ppm or greater exposure to formaldehyde over an eight-hour period."
A written plan for reduction of exposure to formaldehyde shall be prepared and distributed immediately to all affected persons. In general, this exposure reduction program shall involve the short- or intermediate-term use of respiratory protection to reduce and/or limit exposure and the development of better ventilation of the exposure area through the modification or redesign of the existing system or the installation of a new system. Particular attention shall be paid to the location of ventilator exhaust points and the availability of fresh air intake into the affected area.
Signs and notices indicating the presence of formaldehyde in the exposure area shall be posted. *(See Section 7.4(3) - Signs.)* Periodic remonitoring shall be conducted at least every six months or until the exposure results fall below the Action Level. Medical surveillance of exposed employees shall be implemented.
c. STEL: "2.0 ppm or greater exposure to formaldehyde for a fifteen minute period."
All of the steps indicated for exposures in excess of the TWA will be implemented in the event the STEL limit is exceeded.

(5) Re-Monitoring Approach: Results Meet or Exceed PELs

In the event that permissible exposure limits (PELs) are exceeded, the need for the above actions to continue may be obviated by the re-monitoring of the exposure area twice more within a period of seven days of each remonitoring. If the TWA and STEL monitoring are repeated under similar exposure risk conditions and result in exposure levels that are below the permissible exposure limits (PELs) for the TWA and STEL, this funeral home may return to its regular operating practices and exposure risk reduction procedures.

(6) Notice to Employees of Monitoring Results

a. Within 15 days of receiving the results of exposure monitoring conducted under the Formaldehyde Standard, this funeral home shall notify the affected employees of these results. Notification shall be in writing, either by distributing copies of the results to the employees or by posting the results.
b. If the employee exposure is over either PEL, this funeral home shall develop and implement a written plan to reduce employee exposure to or below both PELs and give written notice to employees. The written notice shall contain a description of the corrective action being taken by the funeral home to decrease exposure.

7.7 - Using Monitoring Devices

(1) Read the instructions that come with the monitoring devices with care. The device selected shall be identified as having met the OSHA guidelines related to such monitoring devices.

(2) The monitoring device for the TWA shall be worn by the employee being monitored for the entire eight hour period of an average work shift and with reference to the exposure risk parameters described in Section 7.5 Representative Sample Monitoring. Conditions at time of monitoring shall be recorded on the *Formaldehyde Monitoring Notice and Results*.

(3) The monitoring devices for both the TWA and the STEL shall be clipped to the outside front of the monitoring employee's clothing on the upper part of the body and near to the face. The employee conducting the testing shall not

touch the monitoring devices prior to removing gloves and rinsing hands (to prevent invalidating the results).

(4) In the event the monitoring device is splashed with formaldehyde during the monitoring period, the monitoring shall be voided and a new monitoring scheduled.

(5) When conducting the Short Term Exposure Limit (STEL) monitoring, the monitoring device shall be worn at the same time the TWA monitoring is being conducted by the same employee conducting the TWA monitoring and during a time when a high level exposure activity is being performed. The use of this approach shall provide this funeral home with a short-term, high-exposure level monitoring result that measures the potential exposure for the fifteen minute period for the representative employee.

(6) The STEL monitoring device shall be worn either during the initial drainage phase of the embalming or during the injection of cavity fluid. This funeral home may also choose to conduct two individual STEL monitoring levels using one monitoring device for the initial drainage and another device for the cavity fluid injection phase of the embalming. The advantage of this high-level exposure monitoring is that this funeral home and its employees are able to obtain information about the potentially peak exposure levels that exist during normal work practices in the work environment.

(7) When the monitoring time is ended, the monitoring device shall be removed by a person other than the employee conducting the monitoring so as to avoid contamination of the device by chemical contact, placed in the pouch provided and sealed in a box for mailing to the sensor testing company for processing.

7.8 - When to Re-Monitor

(1) When an Employee Reports Symptoms of Exposure

When this funeral home receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the exposure of that employee to formaldehyde shall be monitored.

(2) Annual Monitoring

Funeral homes shall monitor at least once a year under worst formaldehyde exposure conditions.

(3) When Work Practices Change

a. In the event the case volume of activity at this funeral home increases, re-monitoring shall be conducted.
b. This funeral home shall consider remonitoring in the event that the case volume decreases substantially to provide a better understanding of the actual exposure levels faced by employees during their work.

(4) When New Chemicals or Techniques are Introduced

In the event that new chemicals or techniques are introduced into the funeral home, re-monitoring shall be conducted. Re-monitoring shall measure whether the changes have affected the formaldehyde exposure levels.

(5) When Risk of Exposure Increases for Any Reason

If a risk of exposure exists that is greater than that which has been monitored, additional monitoring is required to properly identify the formaldehyde exposure risk for those persons experiencing the greater level of exposure.

HF-8 Respiratory Protection Program

8.1 - 29 CFR 1910.1048(g)

Where respiratory protection is required, the funeral home shall provide respiratory protection at no cost to the employee and ensure respirators are properly used. The respirators shall comply with the requirements of this Standard and shall reduce the concentration of formaldehyde inhaled by the employee to at or below both the TWA and the STEL.

8.2 - Policy

At this funeral home in the event that PEL limits have been exceeded, all Formaldehyde Exposure Risk Roster employees who have access to the preparation room during embalmings shall obtain at no cost to the employee a physician medical evaluation, be provided with an appropriate respirator, trained regarding the use of respiratory protection and properly fitted with the respirator until such time that PEL's return to normal.

If an employee requests to use a respirator when PEL limits have not been exceeded, permission will be granted to use a respirator provided that such use will not create a hazard, after the completion of a physician's medical evaluation and the provision of respiratory protection information and training.

8.3 - Purpose

The Respiratory Protection Program has been established in accordance with 29 CFR 1910.134 and 29 CFR 1910.1048 to protect the health of exposure risk employees.

8.4 - Respirator Selection

(1) Approved by MSHA and NIOSH

Respirators shall be selected from those approved by the Mine Safety and Health Administration (MSHA) and by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11 on the basis of hazards to which the worker is exposed.

(2) Type of Respirator Required

a. Negative pressure (elastomeric) full facepiece respirator with cartridges or canisters specifically approved for protection against formaldehyde.
b. Negative pressure (elastomeric) half-mask respirator with cartridges specifically approved for protection against formaldehyde can be substituted for the full

facepiece respirator providing that effective gas-proof goggles are provided and used in combination with the half-mask respirator.

c. If any employee experiences difficulty wearing a negative pressure (elastomeric) respirator, a powered air-purifying respirator adequate to protect against formaldehyde shall be provided.

8.5 - Respirator Usage

(1) When Respirators are Required

Respirators shall be used in the following formaldehyde exposure risk circumstances:

a. During the interval necessary to install or implement feasible engineering and work practice controls;
b. In work operations, such as maintenance, repair activities or (equipment) cleaning for which the funeral home establishes that engineering and work practice controls are not feasible;
c. In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure to or below the PELs; and
d. In emergencies.

(2) Respirator Canister Usage

Negative Pressure (Elastomeric) Respirator Canisters used in atmospheres up to 7.5 ppm (10 x PEL): Canisters shall be replaced every four hours unless they contain a NIOSH-approved end-of-service-life indicator to show when breakthrough occurs.

(3) Fit Testing and Employee Training

The employees at risk of exposure to formaldehyde shall be properly fit tested for and trained in the use of the respirator. Fit testing shall take place after a physician's medical evaluation for respirator use is conducted and the employee is cleared for such use of a respirator by the physician. Training shall be conducted in accordance with the *Respirator Fit Test Program* established by this funeral home.

(4) Respirator Care and Inspection

The person responsible for the care and inspection of the respirators provided by this funeral home is the OSHA Compliance Officer. The OSHA Compliance Officer shall ensure the following tasks:

a. Respirators shall be regularly cleaned and disinfected. Those used by more than one worker shall be thoroughly cleaned and disinfected after each use.
b. Respirators shall be stored in a convenient, clean and sanitary location.
c. Respirators used routinely shall be inspected during cleaning.
d. Worn or deteriorated parts shall be replaced.
e. The respirators available at this funeral home shall be inspected at least once a month.
f. Random inspections shall be conducted by the OSHA Compliance Officer to ensure respirators are properly selected, used, cleaned and maintained.
g. A record shall be kept of inspection dates and findings for respirators maintained for emergency use.

(5) Emergency Procedure

In the event of a large spill in which the apparent ability to properly contain and ventilate the area is uncertain, the employees must evacuate the premises and notify the fire department of the spill. In this case, the respirator use is intended merely for the purposes of the evacuation, when possible. However, the amount of chemical storage in the funeral home's facility and the use of small quantity containers limits the potential exposure risk such that a large spill of more than a bottle is highly unlikely. *(See Section 14.3 - Emergency and First Aid Procedures.)*

(6) Surveillance of Work Area Conditions and Exposure

Employees using respiratory protection shall be monitored through the required use of an exposure incident report as well as by the direct observation of the employee's supervisor.

An exposure incident report is required to be completed in the event of a non-routine exposure incident. The OSHA Compliance Officer shall interview employees after any exposure incident to determine whether the proper procedures were implemented and added or changed practices shall be established to better meet the needs of protecting the employee and to evaluate the need for continued monitoring or medical surveillance.

8.6 - Evaluation of Program

There shall be regular inspection and evaluation to determine the continued effectiveness of the program by the OSHA Compliance Officer.

HF-9 Respirator Fit Test Program

9.1 - 29 CFR 1910.1048(g)(3)(ii)

9.2 - Policy

This funeral home shall ensure that qualitative face fit tests are performed in accordance with the procedures outlined in Appendix A to 29 CFR 1910.134 *(See Respirator Standard)* at the time of initial fitting and thereafter for all employees required by the Formaldehyde Standard to wear negative pressure (elastomeric) respirators or for medically cleared employees who request such use. Fit testing shall take place after the physician's medical evaluation for respirator use is conducted.

9.3 - Purpose

To ensure that the employees who have been determined to have a formaldehyde exposure risk select respirators exhibiting the best facepiece fit. No respirator shall be chosen that would potentially permit the employee to inhale formaldehyde at concentrations in excess of either the TWA or the STEL.

9.4 - Fit Test Provisions

(1) Group of Respirators to Select From

Fit tested employees shall be allowed to pick the most comfortable respirator from a selection including respirators of various sizes from different manufacturers. The selection shall include at least three sizes of elastomeric facepieces of the type of respirator that is to be tested, i.e., three sizes of half mask or three sizes of full facepiece and units from at least two manufacturers.

(2) Fitting Instructions and Demonstration

a. Prior to selecting a respirator, the employee shall be shown how to put the respirator on, how it shall be positioned on the face, how to set strap tension and how to determine a comfortable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. The employee shall have an opportunity to discuss the fit test with the person conducting the fit testing.
b. The employee shall be informed at this time that the selection of respirator shall be of a type that provides the most comfortable fit and that once the respirator is properly fitted and used properly, it shall provide adequate protection.
c. The employee shall hold each of the respirators available for selection up to the face and eliminate those which obviously do not give a comfortable fit.

(3) Five-Minute Practice

The facepiece selected as most comfortable shall then be worn for at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the Comfort Assessment that follows. If the employee is not familiar with using a particular respirator, the mask shall be donned several times and the straps adjusted each time so that the employee may become adept at setting proper tension on the straps.

(4) Comfort Assessment

Assessment of comfort shall include reviewing the following points with the employee and allowing adequate time to determine the comfort of the respirator:

a. Position of the mask on the nose.
b. Room for eye protection.
c. Room to talk.
d. Position of mask on face and cheeks.

(5) Fit Criteria

The following criteria shall be used to determine the adequacy of the respirator fit:

a. Chin properly placed.
b. Adequate strap tension, not overly tight.
c. Fit across nose bridge.
d. Respirator of proper size to span distance from nose to chin.
e. Tendency of respirator to slip.
f. Self observation in mirror to evaluate fit and respirator position.

(6) Obstructions to Testing

The test shall not be conducted if there is any hair growth between the skin and the face piece sealing surface, such as stubble beard growth, beard or long sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

(7) Physician Referral

Employees exhibiting difficulty in breathing during the tests shall be referred to a physician trained in respiratory disease or pulmonary medicine to determine whether the employee can wear a respirator while performing his or her duties.

(8) Fit Test Exercises

Prior to the commencement of the fit test, the employee shall be given a description of the fit test exercises to be performed during the test. The respirator to be tested shall be worn for a period of at least five minutes before the start of the test.

The employee shall perform the exercises described below, in order, while wearing the respirator:

a. Normal breathing. In a normal standing position, without talking, the employee shall breathe normally.
b. Deep breathing. In a normal standing position, the employee shall breathe slowly and deeply, taking caution so as not to hyperventilate.
c. Turning head side to side. Standing in place, the employee shall slowly turn his or her head from side to side between extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.
d. Moving head up and down. Standing in place, the employee shall slowly move his or her head up and down. The employee shall be instructed to inhale in the up position (i.e. when looking toward the ceiling).
e. Talking. The employee shall talk slowly and loudly enough so as to be heard clearly by the test conductor.
f. Grimace. The employee shall grimace by smiling or frowning.

g. Bending over. The employee shall bend at the waist as if he or she were to touch his or her toes. Jogging in place may be substituted for this exercise.
h. Normal breathing. In a normal standing position, without talking, the employee shall breathe normally.

(9) Respirator Fit Test

Each of the Fit Test Exercises shall be performed for one minute except for the grimace which shall be performed for 15 seconds. The employee shall be questioned by the tester regarding the comfort of the respirator at the completion of the test. If the respirator has become uncomfortable, another model shall be tried.

When a respirator is selected after completion of the fit test exercises, the employee shall seat the mask on the face by moving the head from one side to the other and up and down slowly while talking. Then the employee shall conduct both the positive and negative pressure fit checks.

Positive Pressure Fit Check

a. Remove exhalation valve cover. (For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.)
b. Close off the exhalation valve and exhale gently onto the face piece.
c. The face fit is considered satisfactory if a slight positive pressure can be built up inside the face piece without any evidence of outward leakage of air at the seal.

Negative Pressure Fit Check

a. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the face piece collapses slightly and hold the breath for 10 seconds.
b. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

9.5 - Qualitative Fit Tests (QLFT)

(1) OSHA-Approved Tests

Because exposure to formaldehyde can affect the employee's ability to detect common odorants, the fit test selection shall be made appropriate to the employee being tested from the OSHA approved tests.

(2) Test Instructions in Appendix A

The parameters and instructions to be followed for QLFT by this funeral home are in Appendix A to 29 CFR 1910.134. *(See Respirator Standard.)*

(3) Person Responsible

This funeral home has selected the OSHA Compliance Officer to assume the following responsibilities:

a. Implementing the respirator qualitative fit test program.
b. Ensuring that persons administering QLFT are able to prepare test solutions, calibrate equipment, perform the test properly, recognize invalid tests and assure the equipment is in proper working order.
c. Ensuring the QLFT equipment is kept clean and well maintained so as to operate at the parameters for which it was designed.

9.6 - Selection Change

The employee is generally expected to use the respirator during non-routine procedures such as spill clean up. In the event the employee chooses to wear the respirator more frequently or during the performance of routine tasks, a replacement respirator shall be provided if the respirator originally selected becomes uncomfortable.

9.7 - Recordkeeping

For each employee fit tested for respirator use, a record of the test procedure shall be maintained and the fit test certified to by the tester. This certification shall include the name of the employee; the type, manufacturer and size of respirator, the name of the person conducting the test and the date of the test.

HF-10 Engineering Controls and Work Practices

10.1 - 29 CFR 1910.1048(f)

Engineering controls and work practice controls shall be used to eliminate or reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

10.2 - Policies

(1) To Ensure Effectiveness

At this funeral home engineering controls and work practices shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(2) Chemical Spill Training

The policy of the funeral home is to ensure safe work practices which have been established as a part of the funeral home's Training Program to instruct employees in the proper reaction to chemical spills and the clean up of those spills.

(3) Authorized Access and Notification

The funeral home also has established work practice policies designed to limit the number of employees who are exposed to hazardous chemicals. Only authorized persons are allowed to enter exposure risk areas (the preparation room).

a. Access During Monitoring and Embalming. Only employees with job functions that require their presence are authorized access during monitoring and embalming in the preparation room. A roster lists

employees with this authorization.
(*See Bloodborne Pathogen and Formaldehyde Exposure Determination Risk Roster.)*

b. Access at Times Other Than Monitoring and Embalming. From time to time it may be necessary for persons who do not normally enter the preparation room area to have access (access is not authorized during an embalming).

c. Notification and Training. It is the policy of this funeral home to provide notification of the risk of exposure or potential exposure to formaldehyde to any person entering into a funeral home area or performing a job function where such an exposure risk may exist. *(See Communication of Funeral Home Hazards form.)*

   (i) This notification policy applies to employees, independent contractors, subcontractors and other persons properly entering into the funeral home environment or interacting with job function related tasks.

   (ii) In addition to notification, training regarding the risk of formaldehyde exposure shall be provided to all affected employees and is available to contractors and other persons seeking access to exposure risk work areas.

   (iii) Other persons who seek entry to exposure risk work areas such as independent contractors, family members of the deceased, government officials or participants in ceremonial activities related to the death of a person whose body is in the possession of this funeral home, shall be denied access to exposure risk areas until they have received and acknowledged receipt of notification of:

   - Exposure risk to formaldehyde *(See Communication of Funeral Home Hazards form.)*
   - *Formaldehyde Exposure Control Plan*
   - *Hazard Communication Program*
   - Need to wear appropriate personal protective equipment to protect themselves

d. Application for Access. Application for authorization to enter formaldehyde exposure risk work areas must be made to the funeral home's manager or OSHA Compliance Officer of the affected work area. The manager or OSHA Compliance Officer in charge of the work area may, at any time, revoke the authorization for a non-employee to be present in an exposure risk area in the event that proper and/or appropriate precautions to protect that person against the exposure risk are not being taken.

(4) Non-Employees Evacuation

IN THE EVENT OF A LARGE NON-ROUTINE SPILL OF WHATEVER TYPE, ALL PERSONS WHO ARE NOT EMPLOYEES OF THIS FUNERAL HOME SPECIFICALLY TRAINED IN THE PROPER WAY TO CONTAIN AND CLEAN UP THE SPILL MUST EVACUATE THE AFFECTED AREA.

(5) Respiratory Protection

Respiratory protection MUST be worn by employees in accordance with the funeral home's work practices for spills *(See sections 10.5 and 10.6 on spill response)* and the funeral home's *Respiratory Protection Program*.

(6) Report of Exposure Incidents

Employees shall report exposure incidents on an *Employee Injury and Exposure Report*. The funeral home requires this report to be completed in the event of a non-routine exposure incident. The OSHA Compliance Officer shall interview employees after any exposure incident to determine whether the proper procedures were implemented, whether added or changed practices shall be established to better meet the needs of protecting the employee and to evaluate the need for continued monitoring or medical surveillance.

10.3 - Safe Chemical Practices

All of the following safe work practices are in effect at this funeral home:

(1) Know your chemical by always checking the label before using a material. If you are unfamiliar with the chemical, review the Safety Data Sheet (SDS) for more complete product safety information.

(2) Be sure to follow label warnings and directions.

(3) Use your personal protective equipment.

(4) Check for lack of ventilation and other physical hazards before using a hazardous chemical.

(5) Know correct emergency and first aid procedures.

(6) No eating, drinking or smoking in areas where hazardous materials are used or stored. Remember to use good personal hygiene to protect against accidental ingestion.

(7) Never mix chemicals unless specifically instructed to do so on the label or the SDS.

(8) Clean up spills promptly. At the time of the spill the exhaust fan shall be turned up to the maximum.

(9) Dispose of hazardous waste properly.

(10) Avoid reusing containers.

10.4 - General Risk Reduction Practices

(1) Use of proper ventilation.

(2) Careful work practices, avoiding splashes and spills.

(3) Keep the lid on the embalming machine.

(4) Secure lids on all bottles after use.

(5) Treat autopsy viscera in a covered pail or closed viscera bag.

(6) Cover drainage sinks.

(7) Use tubing from initial point of body drainage to terminal point of drainage.

(8) Continually aspirate cavity while injecting autopsied cases.

(9) Keep waste and medical waste receptacles covered.

(10) Contain fumes of cavity packs by covering them with light plastic and taping.

(11) Add a small amount of ammonia to clean up buckets to neutralize any formaldehyde that the mop picks up.

(12) Use only non-absorbent blocks to position the deceased to avoid blocks picking up formaldehyde and giving off fumes.

(13) Fix all leaks in embalming machines or do not use them. Notify the work supervisor and/or co-workers if a machine is not in proper repair.

10.5 - Small Routine Spill Response

Employees shall take great care to protect themselves from contact with hazardous chemicals when a spill occurs. Any type of hazardous chemical or substance spill must be cleaned up promptly. At the time of the spill the exhaust fan shall be turned up to the maximum.

A small routine spill such as a small amount of arterial or cavity fluid (one to two ounces) may be cleaned up with an absorbent material. The cloth or sponge used shall be rinsed with cold running water or two to three gallons of cold water in a pail to dilute the hazardous chemical or substance. Rubber utility gloves must be worn when cleaning up any spill.

10.6 - Larger Non-Routine Spill Response

The response to a larger non-routine hazardous chemical spill requires extra precautions and a higher degree of care.

The following policies with regard to emergency exposure to hazardous chemicals which are non-routine are to be incorporated into the *Employee Training Program*.

(1) Type One—All or a major part of a bottle of fluid. Turn the exhaust fan to maximum and vacate the area immediately to don protective equipment. Properly fitted and tested full-face respirator or half-face respirator (with gas proof goggles) and filter cartridges (designed for formaldehyde exposure) must be used to protect the employee from exposure during the cleanup of this type of spill. The spill shall be covered with an absorbent material. If the spill contains formaldehyde, the area may be sprayed with a small amount of household ammonia to neutralize it. The container in which the ammonia is kept must be properly labeled. After the liquid has been absorbed, place the absorbent material in an open container and remove it to a well ventilated area or outdoors for evaporation to take place. At no time shall persons who are unprotected from the risk of exposure to the chemical be allowed to come in contact with the spilled material until it is completely neutralized and evaporated. Place the absorbent material in a plastic bag for proper disposal. Rubber utility gloves must be worn when cleaning up any spill.

(2) Type Two—A major spill of formaldehyde-based hazardous chemicals of more than a single bottle of fluid, i.e., the breaking or spilling of the reservoir on the embalming machine. Turn the exhaust fan to maximum and vacate the area immediately. Close the door to the area and secure it from entry by other persons. Allow the area affected by the spill to vent for at least thirty minutes before entering the area, using protective equipment as described in the cleanup of a Type One spill above.

(3) Type Three—A spill of a very large quantity of formaldehyde-based hazardous chemicals that cannot be readily vented or cleaned up by the employee or which poses the threat of fire or explosion requires the immediate evacuation of the work area and notification of the fire department.

(4) Powder Spills—Avoid breathing the fumes or dust. Extinguish all ignition sources. Check the SDS on the material spilled for the following information: the types of protective equipment necessary and the use of water in the clean-up process. Carefully sweep up as much powder as possible while using at least a barrier face mask or a dust filter mask, place the material in a disposable covered container. If the spill contains formaldehyde, the area may be sprayed with a small amount of household ammonia to neutralize it. Use a wet mop to clean any remaining residue. Rinse the mop thoroughly under running water. Ventilate the area for drying.

HF-11 Protective Equipment and Clothing

11.1 - 29 CFR 1910.1048 (h)

Funeral homes shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the funeral home shall provide these protective devices at no cost to the employee and ensure that the employee wears them.

11.2 - Policy

When there is occupational exposure to formaldehyde, appropriate protective equipment and clothing is provided at no cost to the at-risk employees and other authorized personnel, by this funeral home. The equipment and clothing provided has been selected because it does not permit formaldehyde to pass

through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth or other mucous membranes under normal conditions of use for the duration of time which the protective equipment and clothing shall be used.

11.3 - Purpose

The health and safety of employees is greatly enhanced in the funeral home environment by the proper use of protective equipment and clothing to reduce or eliminate the risk of exposure to formaldehyde. The requirements of the Formaldehyde Standard are addressed through the establishment of work practice policies and procedures at this funeral home. The practices discussed in this section have been designed to meet the specific requirements of the Standard.

11.4 - Selection

It is the policy of the funeral home to review the specific exposure risks faced by employees with those employees and to discuss the protective needs based upon the risk potential. This funeral home shall ensure that the appropriate protective equipment, in the appropriate sizes, is readily accessible at the funeral home or is issued to employees.

(1) Appropriate to task

All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and faceshields, as appropriate to the operation.

Chemical protective gowns, gloves, goggles, faceshields and respirators are available for the use of employees at this funeral home.

(2) Eye Protection

Where a faceshield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

(3) For Emergency

Follow the work practices established in Section 10.6 - Larger Non-Routine Spill Response.

In the event of a large spill in which the apparent ability to properly contain and ventilate the area is uncertain, the employees must evacuate the premises and notify the fire department of the spill. In this case, the respirator use is intended merely for the purpose of the evacuation, when possible. However, the amount of chemical storage in the funeral home's facility and the use of small quantity containers limits the potential exposure risk in that a large spill of more than a bottle is highly unlikely. *(See Section 14.3 - Emergency and First Aid Procedures.)*

11.5 - Maintenance

(1) Training

a. All employees assigned protective equipment and clothing shall be the employees trained to recognize the hazards of formaldehyde.
b. This funeral home shall inform any person who launders, cleans or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

(2) After Each Use

a. Employees assigned protective equipment and clothing are expected to clean, disinfect, launder or dispose of it after use.
b. The policy of the funeral home is that contaminated clothing or equipment shall be properly rinsed with water and ammonia. Equipment which is to be reused may also have to be decontaminated with regard to bloodborne pathogen contact. *(See Bloodborne Pathogen Exposure Control Plan, Section 8 - Housekeeping and Section 9 - Laundry.)*
c. After the rinsing off of formaldehyde contaminated clothing with ammonia and water, the clothing shall no longer be considered contaminated and may then be appropriately disposed of.

(3) Storage Areas

This funeral home shall establish a storage area for ventilating formaldehyde-contaminated clothing and equipment so that employee exposure is minimized. This area may be the preparation room itself as long as access is restricted during the time period in which such contaminated clothing or equipment is ventilating.

Containers for contaminated clothing and equipment and storage areas shall have labels and signs containing the following information by June 2016:

DANGER

FORMALDEHYDE-CONTAMINATED [CLOTHING] EQUIPMENT

MAY CAUSE CANCER

CAUSES SKIN, EYE AND RESPIRATORY IRRITATION

DO NOT BREATHE VAPOR

DO NOT GET ON SKIN

(4) Prohibit Removal to Employee's Home

This funeral home shall ensure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

(5) Repair or Replace

This funeral home shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

HF-12 Hygiene Protection

12.1 - 29 CFR 1910.1048 (i)

12.2 - Change Area

This funeral home shall provide a change area, as described in 29 CFR 1910.141, for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

A changing area shall be established so that employees may change from their "street" or "business suit" attire into a working suit. Upon completing the work in the preparation room, the room shall be cleaned and decontaminated and all protective clothing is to be properly rinsed and placed in a storage area or proper disposal container. The employee, having completed these cleanup and housekeeping tasks is then free to return to the changing area to put on his or her original clothing.

12.3 - Quick Drench Shower and Eyewash Station

An emergency quick drench shower and eyewash station are located in the preparation room of this funeral home. The quick drench shower and eyewash station are to be used immediately to flush any solutions containing formaldehyde from an employee's skin or eyes.

HF-13 Housekeeping

13.1 - 29 CFR 1910.1048(j)

13.2 - Policy

This funeral home shall conduct a program to detect leaks and spills, including regular visual inspections.

13.3 - Preventative Maintenance of Equipment

At regular intervals, equipment shall be inspected for leaks.

13.4 - Provisions for Spills

At this funeral home there shall be made provisions to contain a spill, to decontaminate the work area and to dispose of the waste. Employees shall be instructed to follow the work practices established in Section 10.6 - Larger Non-Routine Spill Response.

13.5 - Proper Methods for Clean-up and Decontamination

This funeral home shall ensure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for clean-up and decontamination.

13.6 - Formaldehyde Waste Disposal

Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde.

HF-14 Emergencies

14.1 - 29 CFR 1910.1048(k)

14.2 - Policy

In the preparation room where there is the possibility of an emergency involving formaldehyde, this funeral home shall ensure appropriate procedures are adopted to minimize injury and loss of life.

In the event of a large spill in which the apparent ability to properly contain and ventilate the area is uncertain, the employees must evacuate the premises and notify the fire department of the spill. In this case, respirator use is intended merely for the purposes of the evacuation from the exposure area when possible. However, the amount of chemical storage in the funeral home's facility and the use of small quantity containers limits the potential exposure risk in that a large spill of more than a bottle is highly unlikely.
(See Section 10.6 - Larger Non-Routine Spill Response.)

14.3 - Emergency and First Aid Procedures

The following recommended emergency and first aid procedures *(Source: 29 CFR 1010.1048 Appendix A)* have been adopted by the funeral home:

(1) Skin Contact

Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with soap or mild detergent and large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, cover the area with sterile dry dressing and bandages.

Get medical attention if you experience appreciable eye or respiratory irritation.

(2) Eye Contact

Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). In the case of burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you shall be referred promptly to an opthamologist for evaluation.

(3) Ingestion (Swallowing)

If the victim is conscious dilute, inactivate or absorb the ingested formaldehyde by giving milk, activated charcoal or water. Any organic material shall inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

(4) Inhalation (Breathing)

Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim. Medical personnel shall be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first aid or medical personnel shall administer oxygen, if available and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the worker shall be hospitalized for observation and treatment.

HF-15 Medical Surveillance Program

15.1 - 29 CFR 1910.1048 (l)

29 CFR 1910.1048 (l) requires the funeral home to institute medical surveillance programs for all employees exposed to formaldehyde concentrations at or exceeding the action level or the STEL. If an employee develops signs or reports symptoms of overexposure to formaldehyde (regardless of exposure levels in the funeral home) or is exposed in an emergency, a medical surveillance program must also be instituted. This medical surveillance program includes the administration of the Medical Disease Questionnaire authorized by Appendix D to the Standard and physical examinations by a physician.

Note: In the event that an employee reports significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation or dermal sensitization attributed to the funeral home formaldehyde exposure, the provisions for "medical removal" contained in 29 CFR 1910.1048 (l)(8) and (9) shall also apply.

15.2 - Key Elements

The following items identify the key elements to the funeral home *Formaldehyde Medical Surveillance Program*:

(1) Employees Covered

a. This funeral home shall institute medical surveillance programs for all employees exposed to formaldehyde concentrations at or exceeding the action level or exceeding the STEL.

b. This funeral home shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, this funeral home may rely on the evidence that signs and symptoms associated with formaldehyde exposure shall occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in material in concentrations less than 0.1 percent.

(2) Examination by Physician

a. All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay and at a reasonable time and place.

b. This funeral home shall notify employees of the name of the physician who is to conduct physical examinations in accordance with the *Formaldehyde Medical Surveillance Program*.

(3) Medical Disease Questionnaire

This funeral home shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter.

This funeral home shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde:

a. Administration of a medical disease questionnaire *[See 29 CFR 1910.1048 Appendix D],* which is designed to elicit information on work history; smoking history; any evidence of eye, nose or throat irritation; chronic airway problems or hyperactive airway disease; allergic skin conditions or dermatitis; and upper or lower respiratory problems.

b. A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

(4) Medical Examinations

Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

a. A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath or irritation of the eyes.

b. Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second [FEV(1)] and forced expiratory flow (FEF).

c. Any other test which the examining physician deems necessary to complete the written opinion.
d. Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

(5) Examinations for Employees Exposed in an Emergency

This funeral home shall make medical examinations available, as soon as possible, to all employees who have been exposed to formaldehyde in an emergency.

a. The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity and any evidence of eye, nose or throat irritation.
b. Other examinations shall consist of those elements considered appropriate by the examining physician.

(6) Information Provided to the Physician

The funeral home shall provide the following information to the examining physician:

a. A copy of the Formaldehyde Standard *(29 CFR 1910.1048)* and Appendix A, B, C and D.
b. A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde.
c. The representative exposure level for the employee's job assignment. *(See the most recent Formaldehyde Monitoring Notice and Results.)*
d. Information concerning any personal protective equipment and respiratory protection used or to be used by the employee.
e. Information from previous medical examinations of the affected employee within the control of this funeral home.
f. In the event of a non-routine examination because of an emergency, the funeral home shall provide to the physician, as soon as possible, a description of how the emergency occurred and the exposure the victim may have received.

(7) Physician's Written Opinion

a. For each examination required under the Formaldehyde Standard, this funeral home shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:
   (i) The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;
   (ii) Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;
   (iii) A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency and whether there is a need for further examination or treatment.
b. This funeral home shall retain the results of the medical examination and tests conducted by the physician.
c. The funeral home shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

(8) Medical Removal

a. Medical removal provisions apply when an employee reports significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation or dermal sensitization attributed to the funeral home formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal condition contains less than 0.05% formaldehyde.
b. An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by this funeral home. If the physician determines that a medical examination is not necessary based on the physician's evaluation of the medical disease questionnaire there shall be a two-week evaluation and remediation period to permit the funeral home to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.
c. If the signs or symptoms have not subsided or have not been remedied by the end of the two-week period or earlier, the employee shall be examined by a physician selected by this funeral home. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1% formaldehyde.

d. Medical examinations shall be conducted in compliance with the requirements of 29 CFR 1910.1048 paragraph (l)(5)(i) and (ii) *[incorporated in this Plan's Medical Surveillance Program, See Key Elements, (5) a. and b.]* Additional guidelines for conducting medical exams are contained in 29 CFR 1910.1048 Appendix C.

e. If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation or dermal sensitization result from the funeral home formaldehyde exposure and recommends restrictions or removal, this funeral home shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, this funeral home shall remove the affected employee from the current formaldehyde exposure and, if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

f. When an employee is removed according to the *Medical Surveillance Program*, this funeral home shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to six months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The funeral home shall maintain the employee's current earnings, seniority and other benefits. If there is no such work available, this funeral home shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to funeral home formaldehyde exposure, until the employee is determined to be able to return to the original job status or for six months, whichever comes first.

g. This funeral home shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status or if the removal is to be permanent.

h. The obligation of this funeral home to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or funeral home-funded compensation program or from employment with another worksite made possible by virtue of the employee's removal.

i. In making determinations of the formaldehyde content of materials under the Medical Removal provisions, the funeral home may rely on objective data.

(9) Multiple Physician Review

a. After this funeral home selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

b. The funeral home shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation for the purpose of medical removal or restriction.

c. This funeral home may condition its participation in and payment for the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a second medical opinion or receipt of the initial physician's written opinion, whichever is later:

(i) The employee informing the funeral home of the intention to seek a second medical opinion; and

(ii) The employee initiating steps to make an appointment with a second physician.

d. If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the funeral home and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the funeral home and the employee, through their respective physicians, shall designate a third physician who shall be a specialist in the field at issue:

(i) To review the findings, determinations or recommendations of the prior physicians; and

(ii) To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians, as the third physician deems necessary, to resolve the disagreement of the prior physicians.

e. In the alternative, the funeral home and the employee or authorized employee representative may jointly designate such third physician.

f. This funeral home shall act consistent with the findings, determinations and recommendations of the third physician, unless the funeral home and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

15.3 - Implementing the *Medical Surveillance Program*

When the conditions are met that require the initiation of the *Formaldehyde Medical Surveillance Program*, the following steps shall be taken by the OSHA Compliance Officer:

(1) Gather Medical Records

Gather the employees medical records maintained by the funeral home and make copies for the funeral home's physician to review.

(2) Prepare Materials for Physician

Prepare all of the materials identified in Section 15.2 (6) Information Provided to the Physician for presentation to the funeral home's physician by the employee.

(3) Obtain Copies of Results

Obtain a copy of the physician's written report regarding the examination of the employee(s) affected and copies of the completed *Medical Disease Questionnaire* and any results of tests required by the Formaldehyde Standard.

(4) Physician's Recommendations

Put into effect the physician's recommendations regarding exposure limitations to formaldehyde and the use of personal protective equipment (including respiratory protection).

(5) Implement Medical Removal If Results Indicate It

Implement the provisions of the Formaldehyde Medical Removal as required by the Standard if the results of the medical examination so indicate.

(6) Keep Records

Maintain copies of all records related to the employee's medical examinations and related materials in the employee medical file. This information must be retained for at least 30 years from the last day of the employee's work at the funeral home. In particular, the following items shall be included in the employee medical file:

a. The name of the employee;
b. The physician's written opinion;
c. A list of any employee health complaints that may be related to exposure to formaldehyde; and
d. A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the Standard or mandated by the examining physician.

EMPLOYEE INFORMATION AND TRAINING

HF-16 Work Practices and Protective Equipment

16.1 - Work Practices

Work practice policies developed by the funeral home for its employees are an important part of both the worksite's *Hazard Communication Program* and *Formaldehyde Exposure Control Plan*. The work practices *(See Section 10 - Engineering Controls and Work Practices)* developed for use by employees are designed to be a part of and incorporated into this *Training Program*.

16.2 - Protective Equipment

Appropriate protective equipment is provided, at no cost to the at-risk employees and other authorized personnel, by this funeral home. Employees shall receive training in the location and proper use of this equipment prior to commencing work functions which subject the employee to exposure or potential exposure to hazardous chemicals as covered by the Hazard Communication Standard, Formaldehyde Standard and which may require the use of such equipment. *(See Sections: 8 - Respiratory Protection Program; 9 - Respirator Fit Test Program; and 11 - Protective Equipment and Clothing.)*

HF-17 Training in the Hazard Communication Standard

17.1 - 29 CFR 1910.1200(h)

17.2 - Policy

It is the policy of the funeral home that only employees who have been trained regarding the requirements of the Hazard Communication Standard are authorized to enter work areas where a hazardous chemical exposure risk exists.

17.3 - OSHA Required Training

The OSHA Compliance Officer shall be responsible for ensuring that employees who are exposed to hazardous chemicals in the course of their employment shall be informed and trained on the following:

(1) An understanding of the purpose and intent of the Hazard Communication Standard, including employee rights under the Standard.

(2) Specific work practices or job functions which involve exposure or potential exposure to hazardous chemicals.

(3) Location and availability of the written *Hazard Communication Program* list(s) of hazardous chemicals and SDSs.

(4) Ways to lessen or prevent exposure to hazardous chemicals in the funeral home through usage control, work practices, personal protective equipment and emergency procedures.

(5) Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the funeral home, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released).

(6) Specific procedures the funeral home has implemented to protect employees from exposure to hazardous chemicals, such as appropriate monitoring practices, emergency procedures and funeral home policies.

(7) The physical and health hazards of the chemicals in the work area.

(8) How to read labels and SDSs to obtain appropriate hazard information.

(9) The details of this funeral home's *Hazard Communication Program*.

(10) The recordkeeping and reporting policies and requirements of the funeral home regarding accidents, injuries and exposure incidents related to hazardous chemicals.

17.4 - Introduction of Any New Hazardous Chemicals

When new hazardous chemicals are introduced, the OSHA Compliance Officer shall review the new hazardous chemicals and ensure the necessary employee training is performed.

17.5 - Review of Job Functions

The OSHA Compliance Officer is to determine whether any potential exposure to hazardous chemicals used or stored in the funeral home exists. Those employees who are exposed to hazardous chemicals in the course of their employment shall be so informed and trained in accordance with the Hazard Communication Standard.

Employees who have not been exposed to hazardous chemicals previously, but who have changed job functions in the funeral home such that an exposure to hazardous chemicals shall exist shall be informed and trained in accordance with the Hazard Communication Standard prior to the commencement of the job function(s) which involve the potential exposure.

HF-18 Training in the Formaldehyde Standard

18.1 - 29 CFR 1910.1048(n)

18.2 - Policy

This funeral home shall ensure that all employees who are assigned to worksites where there is exposure to formaldehyde participate in a training program.

18.3 - Frequency

This funeral home shall provide such information and training to employees at the time of initial assignment and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

Documentation of employee training shall be recorded on the *Annual Training and Safer Sharps Evaluation Record* and retained at the funeral home in the employee OSHA file.

18.4 - Training Program

The training program shall be conducted in a manner in which the employee is able to understand and shall include:

(1) A discussion of the contents of this regulation and the contents of the SDS;

(2) The purpose for and a description of the *Medical Surveillance Program* required by this Standard, including:

a. A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde;

b. Instructions to immediately report to the funeral home the development of any adverse signs or symptoms that the employee suspects are attributable to formaldehyde exposure;

(3) A description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

(4) The purpose for, proper use of and limitations of personal protective clothing and equipment;

(5) Instructions for the handling of spills, emergencies and clean-up procedures;

(6) An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

(7) A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

18.5 - Access to Training Materials

(1) The funeral home shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(2) The funeral home shall provide, upon request, all training materials relating to the *Employee Training Program* to the Assistant Secretary of the United States Department of Labor and the OSHA Director.

RECORDKEEPING

HF-19 Recordkeeping Requirements

19.1 - 29 CFR 1910.1048 (o)

19.2 - Policy

For every employee who has an occupational exposure, the funeral home shall establish and maintain accurate records and shall provide full access to any employee or employee's agent (when the approval is in writing in the case of medical records) to those records pertaining to that employee as well as access to any training materials, monitoring results and similar material for examination and copying.

19.3 - Exposure Measurements

This funeral home shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

(1) Date of measurement;

(2) Operation being monitored;

(3) Methods of sampling and analysis and evidence of their accuracy and precision;

(4) Number, durations, time and results of samples taken;

(5) Types of protective devices worn; and

(6) Names, job classifications and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

19.4 - Exposure Determinations

Where this funeral home has determined that no monitoring is required under this Standard, the funeral home shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

19.5 - Medical Surveillance

This funeral home shall establish and maintain an accurate record for each employee subject to medical surveillance under the Formaldehyde Standard. This record shall include:

(1) The name of the employee;

(2) Physician's written opinion;

(3) List of any employee health complaints that may be related to exposure to formaldehyde; and

(4) Copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the Standard or mandated by the examining physician.

19.6 - Respirator Fit Testing

The funeral home shall establish and maintain accurate records for employees subject to medical evaluation and negative pressure (elastomeric) respirator fit testing required by the Formaldehyde and other applicable Standards. This record shall include:

(1) Copy of *Physician's Medical Evaluation for Respirator Use and Fit Test* form.

(2) Copy of the protocol selected for respirator fit testing.

(3) Copy of the results of any fit testing performed.

(4) Size and manufacturer of the types of respirators available for selection.

(5) Date of the most recent fit testing, name of each tested employee, name of the person conducting the test and the respirator type, manufacturer and size selected.

19.7 - Record Retention

The funeral home shall retain records for at least the following periods:

(1) Exposure records and determinations shall be kept for at least 30 years.

(2) Medical records shall be kept for the duration of employment plus 30 years.

(3) Respirator fit testing records shall be kept until replaced by a more recent record.

(4) Training records shall be kept for three years from the date on which the training occurred.

19.8 - Availability of Records

(1) Upon request, the funeral home shall make all records maintained as a requirement of this Standard available for examination and copying to the Assistant Secretary of the United States Department of Labor and the OSHA Director.

(2) This funeral home shall make employee exposure records, including estimates made from representative monitoring, available upon request for examination and copying to the subject employee or former employee representatives in accordance with 29 CFR 1910.1020 (a) to (e) and (g) to (i).

(3) Employee medical records shall be provided upon request for examination and copying to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020 (a) to (e) and (g) to (i).

Workplace Safety Plan

WS-1 Key Elements

1.1 - Occupational Safety and Health Standards, 29 CFR 1910

Occupational Safety and Health Standards refers to a group of standards covering a wide variety of funeral home conditions and equipment for general industry.

1.2 - Policy

It is the policy of the funeral home that "the safety and health of employees will be given priority over all other operations and activities."

1.3 - Purpose

The purpose of this plan is to establish and define funeral home safety policies and practices, so that all employees fully understand the priority and importance of safety and health protection in this worksite.

1.4 - Areas Covered

The *Workplace Safety Plan* encompasses this funeral home's entire facility including:

(1) Public and employee access areas to building

(2) Outside and around buildings

(3) Floors, walls and ceilings

(4) Exits, stairs and walkways

(5) Ramps, driveways and parking areas

1.5 - The Basic Formula

(1) Identify Potential Hazards

A continual process shall be implemented through the following work practices:

a. Worksite Analysis as a means of evaluating and identifying potential hazards through annual worksite analysis
b. Self-inspection as a means of evaluating and identifying potential hazards through routine inspections
c. Evaluation of any new work practices or physical alterations to the facilities prior to being used or implemented
d. Employees trained to notify the OSHA Compliance Officer of any safety or maintenance problems
e. The OSHA Compliance Officer regularly reviews job functions to determine whether any potential exposure to hazards exists

(2) Eliminate or Abate the Hazard

In the event that a hazard is identified, either by an employee, patron or other person, an immediate inspection and evaluation of the condition shall be made by the OSHA Compliance Officer, manager or designee of this funeral home. Then steps shall be taken to correct any problem.

(3) Inform and Train

Training shall be provided to all employees related to any identified potential hazards to which they are exposed during the course of their employment. This training shall be conducted prior to the employee commencing the duties which create the exposure to the potential hazard and at periodic times thereafter as may be necessary or required by specific OSHA Standards or other regulations.

It is the policy of the funeral home to provide notification of the potential of any exposure to a hazard to any person entering into a funeral home area or performing a job function where such a hazard may exist. *(See Communication of Funeral Home Hazards form.)*

(4) Work Practices and Personal Protective Equipment

Safe work practices shall be used to eliminate, prevent or reduce potential hazards.

When there is occupational exposure to potential hazards, appropriate personal protective equipment is provided, at no cost, to the at-risk employees and other authorized personnel by this funeral home. Employees shall receive training in the location, proper use and maintenance of this equipment prior to commencing work functions which subject the employee to exposure or potential exposure to hazards which may exist and which may require the use of such equipment. Personal protective equipment policies related to the OSHA Bloodborne Pathogens Standard and the Formaldehyde Standard have also been developed by this funeral home and are incorporated into the regulatory compliance programs designed for those Standards. *(See Bloodborne Pathogen Exposure Control Plan* and *Formaldehyde Exposure Control Plan.)*

1.6 - The Action Plan

This funeral home is committed to an effective Workplace Safety Plan by ensuring the following:

(1) The plan is not ironclad and will be altered according to corresponding changes in the funeral home

(2) The plan incorporates all aspects of the funeral home from the highest to lowest priority

(3) The plan provides that changes and improvements are documented and implemented

1.7 - Person Responsible: OSHA Compliance Officer

The OSHA Compliance Officer is the person responsible for the proper maintenance and implementation of the OSHA Workplace Safety Plan for this funeral home. *(See inside front cover for the name of the OSHA Compliance Officer.)* The OSHA Compliance Officer shall:

(1) Implement the *Workplace Safety Plan*.

(2) Train employees (and/or implement training programs).
   a. Provide visible top management involvement in implementing the training program, so that all employees understand that management's commitment is serious.
   b. Arrange for and encourage employee involvement in training, so that they will commit their insight and energy to the *Workplace Safety Plan*.
   c. Assign and communicate responsibility for all aspects of the *Workplace Safety Plan*, so that employees in all parts of the organization know what performance is expected of them.
   d. Provide adequate authority and resources to responsible parties, so that assigned responsibilities can be met.
   e. Hold employees accountable for meeting their responsibilities, so that essential tasks will be performed.
   f. Instruct employees to notify the OSHA Compliance Officer of any potential hazards.

(3) Implement thorough worksite analysis by the following:
   a. Routine self-inspections
   b. Annual worksite analysis
   c. Evaluation of new equipment, physical alterations to the facilities or new work practices
   d. Employee reports of any safety or maintenance problems

(4) Review potential hazards to ensure necessary employee training is provided.
   a. By regular, periodic review of job functions
   b. By review of any Injury and Exposure Reports

(5) Train employees for emergencies by conducting training and emergency drills, as needed, to ensure that proper safe responses to emergencies will be "second nature" for all persons involved, including the leaders (senior employees) who will be expected to manage and coordinate emergency response activities.

(6) Implement the Medical Emergency Plan *(See Section 7 - Medical Emergency Plan)* that includes first aid kit(s) on site as well as nearby physician and emergency medical care to reduce the risk of any injury or illness.

(7) Ensure all accidents are investigated and any fatalities or serious accidents are reported. (This funeral home is required to report within 48 hours of a fatality accident or an accident that resulted in hospitalization of five or more employees. The report may be given or made either orally or in writing to the nearest OSHA Area Office. OSHA's 24-hour hotline is 1-800-321-OSHA for job safety and health emergencies.)

(8) Maintain OSHA-related records.

1.8 - Accessibility of Plan to Employees

The funeral home shall ensure that a copy of the *Workplace Safety Plan* is accessible to employees in accordance with 29 CFR 1910.1020(e). A copy of the plan is available in the funeral home office.

1.9 - Review of Program

The *Workplace Safety Plan* shall be reviewed and updated at least annually and whenever necessary to reflect changes in tasks, procedures and employee positions which affect potential hazards.

Documentation of review and any applicable updates shall be recorded on the *Annual Training and Safer Sharps Evaluation Record*. This record shall be retained with the funeral home's OSHA Written Communication Plan.

1.10 - Employee Auditing System

This plan and its supporting materials are available for examination and copying to all employees. All employees are encouraged and requested to make comments on the usefulness of this plan and to contribute any other ideas that will further the intention of creating a more enjoyable and safer worksite for all of us, our families and the families we serve. The funeral home depends upon our employees to notify the OSHA Compliance Officer, manager or worksite of any hazards and maintenance needs that may come to their attention.

WS-2 Worksite Analysis

2.1 - Policy

This funeral home ensures potential hazards are identified and evaluated by committing to regularly scheduled funeral home analysis. In order that all hazards and potential hazards are identified, the following steps shall be taken:

(1) Routine self-inspections

(2) Annual Worksite Analysis

(3) Analysis of planned and new work practices, materials and equipment

(4) Instruction and encouragement of employees to be alert to and to report conditions that appear hazardous on a daily basis

(5) Investigation of accidents, incidents and injuries so that their causes and means for their prevention can be identified

2.2 - Purpose

Worksite analysis shall be an ongoing process that assists the funeral home in identifying and evaluating what is needed to keep a safe and healthy worksite.

2.3 - Annual Worksite Analysis

This funeral home shall annually conduct a comprehensive worksite analysis of the entire facility, equipment, signs, operational forms, OSHA written plans and OSHA-related records using Worksite Analysis forms. The Worksite Analysis forms contain items specific to this funeral home as found in the General Industry Digest, U.S. Department of Labor, Occupational Safety and Health Administration, 1991, OSHA 2201 (Revised).

The OSHA Compliance Officer shall be responsible for an assessment of this funeral home. The worksite analysis consists of the following activities:

(1) Identifying any existing or potential safety and health hazards

(2) Assessing existing safety and health programs

This funeral home shall require contracted professionals to evaluate, test and maintain for their safe operation certain items on the Worksite Analysis forms. Examples of such items are plumbing, electrical, automotive, heating and air.

2.4 - Routine Self-Inspections

The environment in and around this funeral home shall be maintained in good order and shall be routinely inspected by following the *Primary and General Worksite Analysis* forms. An example of items to be inspected are automotive equipment, embalming machine, quick drench eyewash station and all fire safety equipment.

To ensure a continual evaluation process, routine self-inspections shall be completed and encompassing the following conditions:

(1) Evaluate, prior to being used or implemented, any new equipment, physical alterations to the facilities or new work practices

(2) Visually inspect as a regular routine the facilities and existing equipment

(3) Self-inspections are to note the continued presence, proper location and proper functioning of items listed on Worksite Analysis forms

(4) Any maintenance needs identified are to be reported to the OSHA Compliance Officer upon completion of inspection

(5) Dangerous conditions are to be reported immediately

(6) It is the policy of this funeral home to make repairs promptly

(7) Employees shall be alert for visual observation of problems on a daily basis. However, for recordkeeping purposes, the *Primary and General Worksite Analysis* forms are used to record the actual inspection of each item during a routine self-inspection.

WS-3 Work Practices

3.1 - Policy

The funeral home requires work practice controls be used to eliminate or minimize employee exposure to potential hazards. These controls shall be examined and modified as necessary on a regular schedule to ensure their effectiveness.

In the event a hazard is identified, either by an employee, patron or other person, an immediate inspection and evaluation of the condition shall be made by the OSHA Compliance Officer, manager or designee of this funeral home. Then, steps shall be taken to correct any problem.

3.2 - Employee Responsibilities

(1) Follow this funeral home's rules and policies

(2) *Not to work* if under the influence of alcohol or drugs

(3) *Not to endanger* co-workers

(4) Clean and maintain equipment and work areas

(5) Inspect equipment so that it is in proper working order before, after and during use

(6) Report problems to the OSHA Compliance Officer

(7) Report injuries and exposure incidents to the OSHA Compliance Officer

(8) Follow all OSHA Standards and federal, state and local laws

3.3 - General Safe Work Practices

This funeral home shall ensure that safe work practices for preventing or controlling existing or potential hazards are implemented and maintained by the OSHA Compliance Officer. All of the following safe work practices are in effect at this funeral home:

(1) Proper Lifting

Employees are trained in and use proper lifting techniques when transferring dead human remains, using stretchers, caskets, biers, church trucks and jacks.

(2) Spills

Employees clean up spills promptly. All at-risk employees have been trained in the proper reaction to chemical spills and the clean up of those spills. (*See Hazard Communication, Section 10.5 - Small Routine Spill Response and Section 10.6 - Larger Non-Routine Spill Response.)*

(3) Wet Floors

Immediate steps shall be taken by employees to mop and clean the affected areas and warn patrons and other employees of the danger.

(4) Snow, Ice or Debris

All walkways and driveways shall be kept cleared of ice, snow, debris and other materials. If a surface is slippery, an

abrasive material shall be spread on the surface or persons shall be directed around the slippery area.

(5) Universal Precautions

The use of Universal Precautions is required when an exposure risk to bloodborne pathogens is present. See this funeral home's *Bloodborne Pathogen Exposure Control Plan* when dangerous conditions result from exposure or injury involving bloodborne pathogens.

(6) Housekeeping

In general everything shall be:

a. Neat and orderly
b. Cleaned regularly and effectively
c. Containers covered
d. All items properly stored

(7) Automotive Equipment

Employees using vehicles on behalf of this funeral home are required to:

a. Be properly licensed to operate a motor vehicle. (The appropriateness of the license for the type of vehicle operation to be performed shall be checked by management. This funeral home shall maintain a photo copy of the driver's license of all persons authorized to operate a motor vehicle on behalf of the funeral home.)
b. Obey all traffic laws while operating vehicles for or on behalf of this worksite.
c. Notify the funeral home if there has been a suspension or revocation of their driver's license.
d. Wear seat belts at all times during the operation of a motor vehicle.
e. Visually check the air pressure of tires every time a vehicle is to be used. In the event that the tires look soft (or too hard) adjustment of the pressure shall be made.
f. Check or have an attendant check the major fluids of the vehicle being used every time gas is refilled, i.e. oil, transmission fluid, brake fluid, windshield washer fluid.
g. Report all vehicle maintenance problems to the management immediately upon discovery. Minor maintenance such as fluid replacement may be conducted immediately upon discovery of the need.
h. Conduct regular periodic visual inspections of motor vehicle equipment for safety or maintenance problems.

WS-4 Personal Protective Equipment

4.1 - Policy

When there is occupational exposure to potential hazards, appropriate personal protective equipment is provided, at no cost to the at-risk employees and other authorized personnel, by this funeral home.

Employees shall receive training in the location, proper use and maintenance of this equipment prior to commencing work functions which subject the employee to exposure or potential exposure to hazards that may exist and that may require the use of such equipment.

4.2 - Use

All employees and/or any other persons involved in a potential hazard risk task must use personal protective equipment to reduce or eliminate that risk. The only exception to this policy will be when in the professional judgment of the employee, the use of proper personal protective equipment would pose an increased hazard to the safety of the worker or co-worker. When an employee makes this judgment, the circumstances will be investigated and documented through the use of an *Employee Injury and Exposure Report* and followed up to determine whether changes can be instituted to prevent such occurrences in the future.

4.3 - Selection and Assignment of Personal Protective Equipment

It is the policy of the funeral home to review the specific exposure risks faced by employees with those employees and to discuss the personal protective needs based upon the risk potential. This funeral home will ensure that the "appropriate personal protective equipment, in the appropriate sizes, is readily accessible at the funeral home or is issued to employees."

In the event an employee has a particular physical need for a particular type of equipment so as to be properly protected, every effort will be made to meet that need or the employee will not be allowed to continue with the tasks requiring that particular protective equipment. "Hypoallergenic gloves, glove liners, powderless gloves or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided."

During discussions of personal protective equipment, the funeral home expects employees will inform their supervisor of problems with personal protective equipment assigned to them, its functionality with regard to the work functions assigned and the availability or suitability of alternative equipment to meet the exposure risk.

4.4 - Accessibility

The personal protective equipment assigned and available for employee use will be stored in a location or locations suitable for direct access. Personal equipment will be provided to meet any special needs of individual employees. Non-employees seeking access to exposure risk areas are not to be authorized to enter those areas without notification of the exposure risk and the need to use appropriate personal protective equipment. General use personal protective equipment will be available to such non-employees. However, it shall be the responsibility of the non-employee seeking access to an exposure risk area to provide any special equipment designed to meet specific needs of that person.

4.5 - Cleaning, Laundering and Disposal

Employees are expected to clean, disinfect, launder or dispose of personal protective equipment assigned for their use. These functions must be performed using the standard work practice policies adopted by the funeral home for such tasks *(For blood contamination, see Bloodborne Pathogen Exposure Control Plan, Sections: 8 - Housekeeping, 9 - Laundry and 10 - Disposal of Medical Waste)* and at no cost to the employee. If any clothing or equipment is contaminated with blood or formaldehyde, employees are prohibited from taking those items home.

4.6 - Repair and Replacement

This funeral home will repair and replace personal protective equipment as needed to maintain its effectiveness at no cost to the employee. However, in the event damage to equipment is not the result of normal use or wear, repair or replacement costs may be charged to the person to whom the equipment was assigned.

4.7 - For Formaldehyde and Bloodborne Pathogens

Personal protective equipment policies related to the OSHA Bloodborne Pathogens Standard and Formaldehyde Standard have also been developed by this funeral home and are incorporated into the regulatory compliance programs designed for those Standards. *(See Bloodborne Pathogen Exposure Control Plan and Formaldehyde Exposure Control Plan.)*

4.8 - Lawn and Building Maintenance

Eye, ear, hand and foot protection will be provided and used as instructed.

4.9 - Housekeeping

Routine housekeeping shall require the use of heavy duty gloves at a minimum and the requirement may be expanded to include; goggles, faceshields, face masks, gowns, aprons and shoe covers depending upon the situation encountered, *(See Bloodborne Pathogen Exposure Control Plan, Sections: 7- Personal Protective Equipment and 8 - Housekeeping.)*

WS-5 Emergency Evacuation Plan

5.1 - 29 CFR 1910.38

29 CFR 1910.38 was used as a reference and a guide.

5.2 - Policy

It is the policy of the funeral home that "the safety and health of employees will be given priority over all other operations and activities." In accordance with this policy, the following plan has been developed for implementation by the employees of this funeral home regarding response to emergency situations which may arise.

5.3 - Review Process

After a response to any emergency, the OSHA Compliance Officer and the manager of this funeral home shall review the response as to whether the emergency plan was effective. As the result of this review, changes shall be made in the plan to correct or improve it for the future.

5.4 - When Evacuation Is Necessary

This funeral home shall ensure that employees are alerted to the various types of situations which may arise that require a full or partial evacuation of this funeral home. The preservation of life, health and general safety of all persons within the funeral home is the most important consideration in determining the need to evacuate the facility.

5.5 - Employee Training

This funeral home shall ensure the following:

(1) Designation and training of a sufficient number of employees to assist in a safe and orderly emergency evacuation of all employees.

(2) Review of plan with each employee covered by the plan at the following times:
   a. Initially when plan is developed
   b. Whenever the employee's responsibilities or designated actions under the plan change
   c. Whenever the plan is changed
   d. At least annually with periodic drills or discussions being conducted by management with the employees during the course of each year

(3) Review of the plan with each employee upon initial assignment of those parts of the plan which the employee must know to protect the employee in the event of an emergency.

(4) Records of employee training shall be maintained through this funeral home in the employee's file.

5.6 - Assessing the Situation

Employees shall be trained to make the following decisions:

(1) Assess what type of emergency exists

(2) How severe the threat is to health and safety.

(3) Whether action by the employee or other persons on the scene can appropriately address the needs of the emergency.

(4) Whether this funeral home shall be fully or partially evacuated to protect against health or safety problems for persons in the facility.

(5) Whether emergency aid shall be summoned.

5.7 - Who Is in Charge

In the event of an emergency, the person in charge of implementing the Emergency Evacuation Plan is to be the OSHA Compliance Officer, owner or manager of this funeral home. In the absence of the OSHA Compliance Officer, owner or manager when the emergency occurs or in the event of an emergency occurring in a limited part of this funeral home, the order for the chain of command for the implementation of the

Emergency Evacuation Plan shall be the senior licensed funeral director followed by the next most senior employee who is located at or near the location of the emergency.

5.8 - Escape Procedures

(1) It is the duty of the OSHA Compliance Officer, owner, manager, the senior licensed funeral director or senior employee as discussed above in the section "Who Is In Charge" to assess the emergency, which may call for the implementation of the Evacuation Plan.

(2) The evacuation of this funeral home's facility shall depend upon the type of emergency and the threat posed to all or a part of the facility and/or its occupants.

(3) If the emergency threatens the health and safety of the occupants of the entire facility, then the entire facility shall be evacuated.

(4) If the emergency situation affects only a part of the facility, such as in the event of a chemical spill, water leak, etc., only that portion of the facility in which the threat to health and safety exists shall be evacuated.

(5) All employees shall be informed of the location of every exit available at this funeral home.

(6) Any employee who is operating a machine or piece of equipment which is powered shall, in the event of an emergency or evacuation notification, cease operation of the device and turn it off. In particular, this includes all equipment in operation in the Preparation Room.

(7) During the evacuation process, employees shall make an effort to conduct a quick visual check of the areas of the facility being vacated so as to identify whether other employees or patrons are still in the facility or in need of notification of the evacuation. Such a check shall be conducted briefly, but at no time shall the check be conducted when a danger of immediate harm exists for the employee. The result of such a check shall be to aid in the notification of persons of the danger or emergency and to assist emergency response personnel in searching for or identifying missing persons.

5.9 - Notification of the Evacuation

The employee in charge of the emergency scene is responsible for notifying other employees, patrons or other persons who may be in this funeral home's facility of the emergency condition and implementing the facility evacuation.

Care shall be taken to avoid undue shock or panic when such a notification is given. When possible, the announcement of the need to vacate the facility shall be made in a calm and orderly manner. However, in the event of a dramatic event like a fire that is in danger of being out of control, all effort shall be made to alert everyone in the building to the danger as quickly as possible without creating panic.

5.10 - Evacuation Assembly Areas

If the evacuation is for this funeral home's entire facility, all employees and patrons shall exit to a safe location away from the threat of danger from the emergency. If the emergency event causing the evacuation represents a potential danger outside of the facility as well as inside, i.e., storms, flooding, civil or criminal disturbances, etc., all patrons and employees shall be directed to disburse to their homes or a location designated by governmental authorities. Employees shall notify the person in charge of the evacuation that they are leaving the facility or its vicinity.

If the danger resulting in the evacuation does not extend beyond the facility, all employees, unless injured and seeking emergency aid, shall assemble after exiting the facility at either of the following assembly points:

(1) The main parking area; or

(2) If the emergency prevents assembly in the main parking areas, go to the area behind emergency vehicle(s).

Whenever possible, an injured employee shall notify another employee that they are leaving the area to seek aid.

5.11 - Procedures for Accounting for Employees

(1) It is the responsibility of the two top persons in the chain of command to identify the employees who are working in this funeral home's facility at the time the emergency occurs. In the event of an evacuation the person in charge shall report to the main parking area assembly point. The second in the chain of command shall report to the assembly point behind emergency vehicle(s) and identify the employees as they exit the facility. Inquiry shall be made of the employees about whether all patrons have safely exited the facility. Whenever possible, patrons shall also be questioned as to whether all of their companions have safely exited the facility.

(2) After having identified exiting employees, the person in charge may direct all or specific employees to other locations outside the facility for safety, to seek additional aid or to notify the owner or manager.

(3) The person in charge shall notify emergency personnel responding to the emergency of any persons who have not safely exited the facility and their location if known.

(4) If the evacuation is for a portion of the facility only, the person in charge of the emergency shall determine if all persons have safely exited the area of the facility where the emergency exists. Notification shall be given to responding emergency personnel regarding any persons who have not safely exited the evacuation area. Persons exiting the evacuation area shall assemble in an area of the facility removed from the danger of the emergency. If possible, the assembly area shall be immediately inside the main entrance or as designated by the person in charge. However, if the person in charge is not immediately able to designate a

safe assembly area, the next most Senior Employee shall designate such an area and direct employees and patrons to it.

5.12 - Emergency Aid

The employee in charge of the emergency response is responsible to decide whether emergency assistance shall be called. Aid shall be summoned by telephoning the emergency number posted on or near all telephones. In the event of a facility-wide evacuation, if possible, a second employee shall be detailed by the employee in charge to telephone for assistance. If the telephone system in the facility does not function, an employee shall, if possible, be detailed to telephone from off premises.

In the event of fire, medical emergencies or civil or criminal disturbances, it is this funeral home's standard approach to telephone for assistance.

Immediately after evacuation and telephoning for emergency assistance, notify the OSHA Compliance Officer, manager or owner regarding the evacuation and the problem.

WS-6 Fire Protection Plan

6.1 - 29 CFR 1910.38

29 CFR 1910.38 was used as a reference and a guide.

6.2 - Policy

It is the policy of the funeral home that "the safety and health of employees shall be given priority over all other operations and activities." In accordance with this policy, the following plan has been developed for implementation by the employees of this funeral home regarding response to emergency situations which may arise.

On a monthly basis, the OSHA Compliance Officer shall inspect for continued presence, proper location and proper functioning, if possible, of all safety equipment. At least annually, this funeral home shall have all safety equipment inspected and tested by a qualified service.

6.3 - Review Process

After a response to any emergency, the OSHA Compliance Officer and the manager of the funeral home shall review the response as to whether the emergency plan was effective. As the result of this review, changes shall be made in the plan to correct or improve it for the future.

6.4 - Employee Training

It is the policy of the funeral home that employees shall be trained in the use of emergency fire protection equipment available at this funeral home and in general fire prevention techniques.

Each employee shall be instructed at the time of initial employment and at least annually thereafter regarding:

(1) Various types of fires

(2) Specific known fire risks associated with this funeral home and its facility

(3) Location and use of the specific fire extinguishers and any other safety equipment available at this funeral home's facility

(4) The need to implement the worksite's emergency evacuation plan

(5) When and where to call for emergency aid

6.5 - Fire Hazards and No Smoking Policy

There are several known potential fire hazards that exist in and around this funeral home. They are addressed below along with a no smoking policy that employees shall follow to reduce or eliminate those fire risks.

A no smoking policy is in effect where the use and storage of chemicals may create a potential fire risk:

(1) In the Preparation Room

(2) While working on automotive maintenance

(3) In chemical storage areas

6.6 - Fire Extinguishers and Safety Equipment

Portable fire extinguishers have been located throughout this funeral home for use by employees in the event of fire, These fire extinguishers have been selected to address the types of fire risk that exist in the areas in which they are located.

(1) All safety equipment, including fire extinguishers, shall be inspected and tested at least annually by a qualified service.

(2) Each employee shall be made familiar with the location of fire extinguishers and any other safety equipment.

(3) Fire extinguishers are identified by signs.

6.7 - Equipment Testing and Maintenance

It is the policy of this funeral home that all safety equipment, including fire extinguishers and any other devices or controls related to fire detection or prevention, shall be well maintained on a monthly basis. It is the duty of all employees to report any maintenance or repair problems related to this equipment to the funeral home's manager immediately upon the identification of such a problem. At least annually, all safety equipment shall be tested and maintained by a qualified service.

6.8 - Housekeeping

All fire protection equipment shall be visually inspected by an employee on a monthly basis. All storage areas of the facility shall be inspected for fire and safety hazards by an employee on a monthly basis. It is the duty of all employees to report at once any perceived safety or fire hazards to the OSHA Compliance Officer, manager or owner.

WS-7 Medical Emergency Plan

7.1 - Policy

It is the policy of the funeral home that "the safety and health of employees shall be given priority over all other operations and

activities." In accordance with this policy the following medical assistance shall be made available for emergency situations which may arise:

(1) Designated funeral home physician

(2) The location of the nearest emergency room

(3) Emergency phone numbers posted near each telephone

(4) First aid kit(s)

(5) Quick drench shower and eyewash station

It is the policy of this funeral home that medical assistance for injuries or illness occurring on the premises or while in performance of work duties on behalf of this funeral home are only to be responded to by persons who are qualified and/or properly certified to provide assistance as needed in the situation as it presents itself.

The role of the employees of this funeral home in response to illness or injury problems is to assess the situation and to summon appropriate assistance if indicated. No employee of this funeral home shall attempt to perform or provide first aid to an injured or ill coworker or patron unless qualified to do so.

7.2 - Review Process

After a response to any emergency, the OSHA Compliance Officer and the manager of this funeral home shall review the response as to whether the emergency plan was effective. As the result of this review, changes shall be made in the plan to correct or improve it for the future.

7.3 - Assessment of the Problem

An employee confronted with a problem related to the injury or illness of a person on the premises of this funeral home or during the performance of work on behalf of this funeral home, shall be alert to the circumstances of the injury or illness and assess the situation with regard to the need for an emergency response by medical personnel or a change in the physical conditions surrounding the injured or ill person. The employee shall summon emergency assistance (by telephoning the emergency number posted near telephone) based upon that employee's evaluation of the situation as well as consultation with the sick or injured person or their family representative.

7.4 - First Aid and Emergency Response

Although unqualified employees are not to provide direct medical aid to injured or ill persons, the following actions may be appropriate as a response to the situation:

(1) First aid supplies or equipment shall be available for the use of the injured or ill person at their discretion.

(2) No employee is to use first aid or direct others in the use of first aid unless qualified and/or properly certified to provide assistance. (Any actions of the employee to provide medical assistance shall not be conducted by or on behalf of this worksite and shall be solely the actions of the employee individually and as such shall be the responsibility of that employee personally.)

(3) The primary function of the employee in a medical emergency shall be to assess the scope of the problem so as to identify whether emergency aid shall be summoned. This assessment shall be conducted in conjunction with the sick or injured person whenever possible.

(4) If the sick or injured person is unable to communicate, the employee shall use his or her judgment as to whether to contact emergency aid, but consider that calling for emergency aid is probably the appropriate step to take.

(5) If the sick or injured person is mobile, the employee shall recommend going to the nearest hospital emergency facility and offer to call for emergency aid.

(6) If the sick or injured person is immobile, the employee shall call for emergency aid.

7.5 - Notification of the Problem

The employee in charge of the response to the injury or illness shall notify the OSHA Compliance Officer, manager, senior licensee or senior employee of the problem as soon as possible after addressing the needs of the sick or injured person and obtaining information to complete a report related to the incident. If the supervisor of the employee involved in the problem was not notified, the employee shall do so when the supervisor is available.

7.6 - Reporting the Injury or Incident

Employee and Non Employee Injury and Exposure Reports shall be completed by every employee witnessing a medical problem and the events surrounding it. Efforts shall be made to obtain the names and addresses of all persons present who observed the medical problem.

7.7 - Transport to a Medical Facility

If the sick or injured person went or was transported to a medical facility, the employee responding to the incident shall find out the name of the facility and check on the proper arrival of the person either in person or by telephone as appropriate in the judgment of the employee or the supervisor. The following day the employee or the supervisor shall check on the condition of the person affected.

7.8 - Employee Training

It is the policy of the funeral home that all employees be informed of these policies regarding the response to a medical problem of a co-worker or patron. All employees shall be notified of these policies upon commencement of work with this funeral home and at least annually thereafter.

WS-8 Employee Information and Training

8.1 - Policy

Training shall be provided to all employees of the funeral home who have an occupational exposure to potential hazards. This training is considered to be an essential element of the provision of a safe funeral home.

No employees of this funeral home shall attempt to operate any machinery or equipment for which they have not received instructions or training in its proper operation.

8.2 - Frequency

Training shall be conducted prior to the employee commencing the duties which create the exposure to the potential hazard, whenever changes are made in work practices or work conditions and at periodic times thereafter as may be necessary or required by specific OSHA Standards or other regulations. The training shall be repeated at least annually by this funeral home.

8.3 - Training Method

Training shall be conducted on a level that can be readily understood by the employee. An opportunity for interaction with the trainer (questions and answers) regarding the information provided shall be included with any training.

8.4 - Work Practices

The training provided to employees shall provide information about work practice policies that are designed to reduce or eliminate exposures to potential hazards. The training shall be conducted by persons familiar with the work practice policies related to the employees duties and/or with the proper operation of equipment to be used.

Work practice policies developed by the funeral home for its employees are an important part of the worksite's *Workplace Safety Plan.* The work practices *(See Section 3 -Work Practices)* developed for use by employees are designed to be a part of and incorporated into this Training Program.

8.5 - Protective Equipment

Appropriate protective equipment shall be provided, at no cost to the at-risk employees and other authorized personnel, by this funeral home. Employees shall receive training in the location and proper use of this equipment prior to commencing work functions which subject the employee to exposure or potential exposure to hazardous conditions.
(See Section 4 - Personal Protective Equipment.)

8.6 - Training Program

The OSHA Compliance Officer shall be responsible for ensuring that employees shall be informed and trained on the following:

(1) An understanding of the purpose and intent of the *Workplace Safety Plan*.

(2) A discussion of the contents of the *Workplace Safety Plan.*

(3) Specific work practices or job functions that involve exposure or potential exposure to hazardous conditions.

(4) Location and availability of the written *Workplace Safety Plan*.

(5) How to lessen or prevent exposure to hazardous conditions in the funeral home through usage control, work practices, personal protective equipment and emergency procedures.
   a. Work practices pertinent to each employee.
   b. The purpose for, proper use of and limitations of personal protective clothing and equipment.
   c. Instructions for the handling of spills, emergencies and clean-up procedures.
   d. An explanation of the importance of work practice controls for employee protection and any necessary instruction in the use of these controls.
   e. The emergency procedures for evacuation, fire protection and a medical emergency, including the specific duties or assignments of each employee in the event of an emergency.

(6) The purpose for and a description of worksite analysis which is necessary for identifying potential hazards, including:
   a. A description of the potential hazard areas and the no smoking policy associated with these hazard areas.
   b. The importance of reporting any and all unsafe or unhealthful conditions that exist in the funeral home to the OSHA Compliance Officer.
   c. Instructions to immediately report any potential hazards.

(7) The physical and health hazards of potential risks in the work area.

(8) The use of signs, warnings and notices to inform employees of potential hazards, including the following:
   a. "DANGER":
      (i) Indicates an imminently hazardous situation which, if not avoided, shall result in death or serious injury.
      (ii) Limited to the most extreme situations.
   b. "WARNING":
      (i) Indicates that a hazard presents some probability of death or serious injury.
      (ii) Potentially hazardous, could result in death or serious injury.
   c. "CAUTION":
      (i) Indicates that a hazard may result in moderate or minor injury.
      (ii) Serves as an extra reminder of hazardous equipment or indicates where hazardous materials are stored or used.
      (iii) Warns against potential hazards or cautions against unsafe work practices.

d. "NOTICE" or "EMERGENCY":
   (i) States a funeral home policy related to the safety of personnel or protection of property (i.e., "NOTICE: AUTHORIZED PERSONNEL ONLY").
   (ii) Gives general instructions and suggestions relative to safety (i.e., "Emergency Eyewash").

(9) This funeral home's policy is to provide notification of the potential of any hazard to any person entering into a funeral home area or performing a job function where such a hazard may exist. *(See Communication of Funeral Home Hazards form.)*

(10) The recordkeeping and reporting policies and requirements of this funeral home regarding accidents, injuries and exposure incidents related to potential hazards.

8.7 - New Hazards

When new hazards have been identified or introduced in the funeral home, the OSHA Compliance Officer shall review the new hazard and ensure that the necessary employee training is performed.

8.8 - Review of Job Functions

Employees who have not been exposed to potentially hazardous job assignments previously, but who have changed job functions in the funeral home such that a potential exposure to a hazard shall exist shall be informed and trained by the OSHA Compliance Officer, in accordance with the *Workplace Safety Plan* prior to the commencement of the job function(s) which involve the potential exposure.

8.9 - Access to Training Materials

(1) This funeral home shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

(2) The funeral home shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary of the United States Department of Labor and the OSHA Director.

WS-9 Recordkeeping

9.1 - Policy

For every employee who has a worksite injury or incident, the funeral home shall establish and maintain accurate records and shall provide full access to any employee or employee's agent (when approval is in writing in the case of medical records), those records pertaining to that employee as well as access to any training materials, monitoring results and similar material for examination and copying.

9.2 - Maintaining Records

This funeral home shall establish and maintain the following records:

(1) OSHA Poster

Under provisions of 29 CFR 1903.2 worksites must post the "JOB SAFETY AND HEALTH IT'S THE LAW!" (OSHA 3165) notice or facsimile in a conspicuous place where notices to employees are customarily posted.

(2) Workers' Compensation Carrier

The name of the funeral home workers' compensation carrier shall be made available for employees.

(3) Medical Records

Employee medical files shall be maintained for each employee with an injury and/or exposure incident. The funeral home shall ensure the confidentiality of these records and shall not disclose or report their contents without the employee's express written consent to any person within or outside the funeral home except as required by this section or as may be required by law. The employee medical files shall be kept by the funeral home for a minimum of 30 years beyond the last day of employment of the employee by the funeral home.

This file shall contain:

a. Employee name
b. Hepatitis B vaccination status (including all of the dates of vaccinations and any medical records relative to the employee's ability to receive a vaccination)
c. A copy of all results of examinations, medical testing and follow-up procedures
d. A copy of any healthcare professional's written opinion related to the Hepatitis B vaccination of the employee or any post-exposure evaluation or follow-up
e. A copy of all information provided to the healthcare professional by this worksite
f. Copies of Injury and Exposure Reports regarding the employee
g. All medical reports, including post-exposure evaluations and treatment

Employee medical records are confidential, but they shall be made available to persons with written authorization for access signed by the employee. All employee records shall be made available to the affected employee upon request. All records shall be available to a properly credentialed representative of OSHA upon request.

(4) Written Control Plans

This funeral home shall maintain copies of the following written plans in the Office to be accessible for employees.

(a) *Bloodborne Pathogen Exposure Control Plan*
(b) *Hazard Communication Program*

(c) *Formaldehyde Exposure Control Plan* (which has been made part of the *Hazard Communication Program*)
(d) *Workplace Safety Plan*

(5) Medical Waste Logs

These logs shall be maintained in accordance with the New Jersey Comprehensive Medical Waste Act.

(6) Permits

All permits required for the operation of this funeral home shall be maintained and posted as required by the individual agencies.

(7) Licenses

All licenses required for the lawful operation of this funeral home as well as required of the individual employees by federal, state or local law shall be maintained and updated as appropriate.

(8) Training Records

All records related to employee training in accordance with the Bloodborne Pathogens Standard shall be kept in the employee personnel file for at least three years from the training date.

The training records of this funeral home shall include the following:

a. Dates of training sessions
b. Contents of such sessions or an accurate summary
c. The names and qualifications of persons conducting the training
d. The names and job titles of all persons attending the training sessions

Individual employee records as well as all training material shall be available to the employee or the employee's agent upon request for examination and copying.

9.3 - Availability of Records

(1) Upon request, the funeral home shall make all records maintained as a requirement of this Standard available for examination and copying to the Assistant Secretary of the United States Department of Labor and the OSHA Director.

(2) Employee medical records shall be provided upon request for examination and copying to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020 (a) to (e) and (g) to (i).

WS-10 Fall Protection

10.1 - Policy

The following Fall Protection Plan is prepared for the prevention of injuries associated with falls. Each Fall Protection Plan must be developed and evaluated on a site by site basis. It is recommended that employees discuss the written Fall Protection Plan with their OSHA Compliance Officer (OCO) at the start of employment or whenever questions may arise.

The funeral home is dedicated to the protection of its employees from on-the-job injuries. All employees of the funeral home have the responsibility to work safely on the job. The purpose of this plan is: (a) To supplement our standard safety policy by providing safety standards specifically designed to cover fall protection on the job and; (b) to ensure that each employee is trained and made aware of the safety provisions which are to be implemented by this plan prior to the start of employment.

10.2 - Identifying Fall Protection Areas

This Fall Protection Plan addresses the use of conventional fall protection at a number of areas at the funeral home, specifically body/casket lift areas.

This plan is designed to enable employers and employees to recognize the fall hazards on this job and to establish the procedures necessary to prevent falls to lower levels or through holes and openings in lift/floor surfaces. Each employee will be trained in these procedures and strictly adhere to them unless by doing so the employee would be exposed to a greater hazard. If, in the employee's opinion, this is the case, the employee is to notify the OCO of the concern and have it addressed before proceeding. Safety policy and procedure cannot be administered, implemented, monitored and enforced by any one individual. The total objective of a safe, accident free work environment can only be accomplished by a dedicated, concerted effort by every individual involved with our work, from management down to the last employee. Each employee must understand their value to the funeral home; the costs of accidents are monetary, physical and emotional; the objective of the safety policy and procedures; the safety rules that apply to the safety policy and procedures; and what their individual role is in administering, implementing, monitoring and compliance of the safety policy and procedures. This allows for a more personal approach to compliance through planning, training, understanding and cooperative effort, rather than by strict, enforcement. If for any reason unsafe behaviors persist, strict enforcement will be implemented.

10.3 - Person Responsible: OSHA Compliance Officer

Identifying Fall Protection areas. It is the responsibility of the OCO to implement this Fall Protection Plan. The OCO is responsible for continual observational safety checks of the funeral home and enforcement of the safety policy and procedures. The OCO also is required to correct any unsafe acts or conditions immediately. It is the responsibility of the employee to understand and adhere to the procedures of this plan and to follow the instructions of the OCO. It is also the responsibility of the employee to bring to management's attention any unsafe or hazardous conditions or acts that may cause injury to themselves or other employees. The funeral home and the OCO must approve any changes to this Fall Protection Plan.

10.4 - Body/Casket Lift Use Authorization

Only individuals with the appropriate experience, skills and training will be authorized to use body/casket lifts. All employees who will be working with body/casket lifts under this safety program shall have been trained and instructed in the following areas:

(1) Recognition of the fall hazards in the work area (at the leading edge of the lift shaft)

(2) Avoidance of fall hazards using established work practices, which have been made known to the employees

(3) Recognition of unsafe practices or working conditions that could lead to a fall

(4) The function, use and operation of safety systems, guardrail systems and other protection to be used

10.5 - Physical Protections to be Used as Follows

(1) All lifts are to be located behind locked solid door(s). The door is to be key or combination locked with keys and/or combinations issued only to employees who need access to the lift and are trained in the lift functions and aware of fall protections.

(2) Even when a lockable door is present, a chain or cable is to be attached across the door opening whenever the lift is not in use. If a chain or cable is used, it shall be flagged at not more than 6 foot intervals with a high visibility material.

The chain or cable shall be rigged and supported in such a way that its lowest point (including sag) is no less than 34 inches from the lift/floor surface and its highest point (at attachment) is no more than 39 inches from lift/floor surface.

(3) Where a lift has been installed and it is impossible to be located behind a lockable door a guardrail is to be installed. The top edge height of the guardrail is to be 42 inches plus or minus 3 inches above the lift/floor level.

When guardrails alone are used at lift locations, a chain, gate or removable guardrail shall be placed across the access opening when lift operations are not taking place.

Balusters when used between posts are to be no more than 19 inches apart. Other structures such as midrails and architectural panels may be installed so that there are no openings in the guardrail that are more than 19 inches wide.

Guardrails shall be capable of withstanding, without fail, a force of at least 200-pounds applied within 2 inches of the top edge, in any inward or downward direction, at any point along the top edge.

When the 200-pound test load specified is applied in a downward direction, the top edge of the guardrail shall not deflect to a height less than 39 inches above the lift/floor level.

Guardrails shall be surfaced as to prevent injury to an employee from punctures or lacerations and to prevent snagging of clothing.

(4) All lift areas/shafts are to be illuminated with sufficient lighting whenever employees are working in, on or around the lift. Where possible, automatic lighting should be installed so that a light will illuminate whenever the door is opened.

(5) Warning lines or Controlled Access Zones (CAZ) are to be clearly defined and consist of high visibility material, paint or tape provided at the edge of the floor and on the lift floor itself at all levels including the lowest "drop" level.

A Controlled Access Zone means an area designated and clearly marked in which the edge of the lift and the edge of the floor are clearly marked. Control zones shall comply with the following provisions:

a. When used to control access to areas where leading edge and other operations are taking place the controlled access zone shall be defined by a control line or by any other means that restricts access, such as locked shaft doors, chains, cables, guardrails, etc.
b. The control line shall extend along the entire length of the unprotected floor and lift edge and shall be approximately parallel to the unprotected floor and lift edge.
c. The control line shall be connected on each side to a guardrail or wall.
d. Control lines shall consist of chains, cables or equivalent materials as follows:
    (i) Each line shall be flagged or otherwise clearly marked at not more than 6-foot intervals with high-visibility materials.
    (ii) Each line shall be rigged and supported in such a way that its lowest point (including sag) is not less than 39 inches from the lift/floor surface and its highest point is not more than 45 inches from the lift/floor surface.
    (iii) Each line shall have a minimum breaking strength of 200-pounds.

10.6 - Signs

Signs and notices regarding the limited access of the body/casket lift to the decedent, casket, stretcher or other appropriate freight shall be posted either on/in the lift or in the immediate proximity of the lift so as to be immediately visible by all operators.

The sign to be posted shall clearly state:

ELEVATOR FOR FREIGHT ONLY
NOT FOR PASSENGERS

10.7 - Enforcement

Constant awareness of and respect for fall hazards and compliance with all safety rules are considered conditions of employment. The OCO, as well as individuals in management, reserve the right to issue disciplinary warnings to employees, up to and including termination, for failure to follow the guidelines of this program.

10.8 - Accident Investigations

All accidents that result in injury to workers, regardless of their nature, shall be investigated and reported to the funeral home by the OCO. It is an integral part of any safety program that documentation take place as soon as possible so that the cause and means of prevention can be identified to prevent a reoccurrence.

In the event that an employee falls or there is some other related, serious incident occurring, this plan shall be reviewed to determine if additional practices, procedures or training need to be implemented to prevent similar types of falls or incidents from occurring.

After notifying the OSHA Compliance Officer of any accident involving damage to an elevator/lift and after seeking medical attention if required, the construction official of the town shall be notified.

The damaged elevator/lift shall not then be operated until repaired, examined by the elevator subcode official and approved for re-use.

10.9 - Changes to Plan

The funeral home and the OCO will approve any changes to the plan. This plan shall be reviewed by a qualified person to determine if additional practices, procedures or training need to be implemented by the OCO to improve existing or provide additional fall protection. Workers shall be notified and trained, if necessary, in the new procedures. A copy of this plan and all approved changes shall be maintained at the worksite.

10.10 - Fall Protection System to be Used on this Job

The nature of body/casket lift operation normally exposes the employee to a fall hazard for a short period of time. This Plan details how the funeral home through its funeral home OCO's will minimize these hazards.

When using the Plan to implement the fall protection options available, workers must be protected through limited access to potentially hazardous locations, such as body/casket lifts, shafts and openings. Before any non-conventional fall protection systems are used as part of the work plan, a Controlled Access Zone (CAZ) shall be clearly defined by the OCO as an area where a recognized potential hazard exists. The demarcation of the lift CAZ shall be communicated by the OCO in a recognized manner, either through signs, paint, tapes, cables or chains.

The funeral home shall take the following steps to ensure that the CAZ is clearly marked or controlled by the OCO:

(1) All access to the CAZ must be restricted to authorized employees.

(2) Signs and notices regarding the limited access of the body/casket lift to the decedent, casket, stretcher or other appropriate freight shall be posted either on/in the lift or in the immediate proximity of the lift so as to be immediately visible by all operators.

The sign to be posted shall clearly state:

ELEVATOR FOR FREIGHT ONLY
NOT FOR PASSENGERS

(3) The OCO will ensure that all protective elements of the CAZ be implemented prior to the beginning of work.

Every body/casket lift area will be clearly marked at the edge by a locked door and chain or cable, paint or tape and be sufficiently illuminated.

Workers shall have no other duties to perform during lift operations.

(4) All lifts will be illuminated from the inside of the shaft with sufficient wattage to light all exposed levels.

(5) Lifts that are contained within shafts and have doors at all levels will require that the doors remain locked at all times (other than when placing or removing a body/casket on the lift platform) in order to ensure that workers must stop, pause and open prior to entering the shaft.

Workers will remain on the main level floor and not enter the lift until the light is illuminated and the lift is deemed to be in place.

(6) Where a lift does not have doors at all levels chains or cables will be hung across lift openings.

(7) Workers will never leave the area of the lift with doors opened and/or unlocked or chains, cables, etc. unfastened.

(8) A worker will not ride on lifts meant for the transfer of freight and/or human remains.

Once lift operations begin, workers not involved in the activity shall not stand or walk below or adjacent to the opening or in any area where they could be struck by falling objects.

(9) The OCO shall determine the individual limits of this area, which shall be clearly communicated to the appropriate staff.

(10) A lock box/cage should be placed over the controls on all levels to limit access to authorized personnel.

OSHA

GUIDE TO
FUNERAL HOME TRAINING

Training Guide and Standards

This guide is provided as part of the OSHA Written Communication Plan prepared by New Jersey Funeral Directors Services, Inc. OSHA-required topics for annual training are highlighted in the Standards.

Note: Some of the information and statistics described herein have been acquired from, the Centers for Disease Control and Prevention (CDC) Website www.cdc.gov and the World Health Organization (WHO) Website www.who.int.

OSHA Standards

Bloodborne Pathogens

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1030
Title: Bloodborne pathogens
Appendix: A

1910.1030(a)
Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

1910.1030(b)
Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap, and single-use towels or air-drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for: (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

1910.1030(c)
Exposure Control—

1910.1030(c)(1)
Exposure Control Plan.

1910.1030(c)(1)(i)
Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)
The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)
The exposure determination required by paragraph (c)(2),

1910.1030(c)(1)(ii)(B)
The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this Standard, and

1910.1030(c)(1)(ii)(C)
The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this Standard.

1910.1030(c)(1)(iii)
Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)
The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)
Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)
Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)
An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)
The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)
Exposure Determination.

1910.1030(c)(2)(i)
Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)
A list of all job classifications in which all employees in those job classifications have occupational exposure;

1910.1030(c)(2)(i)(B)
A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)
A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this Standard.

1910.1030(c)(2)(ii)
This exposure determination shall be made without regard to the use of personal protective equipment.

1910.1030(d)
Methods of Compliance—

1910.1030(d)(1)
General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)
Engineering and Work Practice Controls.

1910.1030(d)(2)(i)
Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

1910.1030(d)(2)(ii)
Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)
Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)
When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

1910.1030(d)(2)(v)
Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

1910.1030(d)(2)(vi)
Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

1910.1030(d)(2)(vii)
Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

1910.1030(d)(2)(vii)(A)
Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)
Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

1910.1030(d)(2)(viii)
Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)
Puncture resistant;

1910.1030(d)(2)(viii)(B)
Labeled or color-coded in accordance with this Standard;

1910.1030(d)(2)(viii)(C)
Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)
In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

1910.1030(d)(2)(ix)
Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

1910.1030(d)(2)(x)
Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

1910.1030(d)(2)(xi)
All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)
Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

1910.1030(d)(2)(xiii)
Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1910.1030(d)(2)(xiii)(A)
The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

1910.1030(d)(2)(xiii)(B)
If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this Standard.

1910.1030(d)(2)(xiii)(C)
If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)
Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)
A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)
The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)
Personal Protective Equipment—

1910.1030(d)(3)(i)
Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)
Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)
Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners,

powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)
Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this Standard, at no cost to the employee.

1910.1030(d)(3)(v)
Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)
If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)
All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)
When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

1910.1030(d)(3)(ix)
Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

1910.1030(d)(3)(ix)(A)
Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(B)
Disposable (single use) gloves shall not be washed or decontaminated for re-use.

1910.1030(d)(3)(ix)(C)
Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)
If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1910.1030(d)(3)(ix)(D)(1)
Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)
Make gloves available to all employees who wish to use them for phlebotomy;

1910.1030(d)(3)(ix)(D)(3)
Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)
Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)
When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)
When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)
When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)
Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)
Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)
Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)
Housekeeping—

1910.1030(d)(4)(i)
General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

1910.1030(d)(4)(ii)
All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

1910.1030(d)(4)(ii)(A)
Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)
Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)
All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)
Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)
Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

1910.1030(d)(4)(iii)
Regulated Waste—

1910.1030(d)(4)(iii)(A)
Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)
Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1910.1030(d)(4)(iii)(A)(1)(i)
Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)
Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)
Leakproof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this Standard.

1910.1030(d)(4)(iii)(A)(2)
During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)
Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

1910.1030(d)(4)(iii)(A)(2)(ii)
Maintained upright throughout use; and

1910.1030(d)(4)(iii)(A)(2)(iii)
Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)
When moving containers of contaminated sharps from the area of use, the containers shall be:

1910.1030(d)(4)(iii)(A)(3)(i)
Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

1910.1030(d)(4)(iii)(A)(3)(ii)
Placed in a secondary container if leakage is possible. The second container shall be:

1910.1030(d)(4)(iii)(A)(3)(ii)(A)
Closable;

1910.1030(d)(4)(iii)(A)(3)(ii)(B)
Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

1910.1030(d)(4)(iii)(A)(3)(ii)(C)
Labeled or color-coded according to paragraph (g)(1)(i) of this Standard.

1910.1030(d)(4)(iii)(A)(4)
Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)
Other Regulated Waste Containment —

1910.1030(d)(4)(iii)(B)(1)
Regulated waste shall be placed in containers which are:

1910.1030(d)(4)(iii)(B)(1)(i)
Closable;

1910.1030(d)(4)(iii)(B)(1)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(1)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) this Standard; and

1910.1030(d)(4)(iii)(B)(1)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(B)(2)
If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

1910.1030(d)(4)(iii)(B)(2)(i)
Closable;

1910.1030(d)(4)(iii)(B)(2)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this Standard; and

1910.1030(d)(4)(iii)(B)(2)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(C)
Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

1910.1030(d)(4)(iv)
Laundry.

1910.1030(d)(4)(iv)(A)
Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)
Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)
Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this Standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

1910.1030(d)(4)(iv)(A)(3)
Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)
The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

1910.1030(d)(4)(iv)(C)
When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

1910.1030(e)
HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)
This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the Standard.

1910.1030(e)(2)
Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)
Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)
Special Practices.

1910.1030(e)(2)(ii)(A)
Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

1910.1030(e)(2)(ii)(B)
Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)
Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)
When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this Standard.

1910.1030(e)(2)(ii)(E)
All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)
Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)
Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)
Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)
Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)
Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)
All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)
A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)
A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)
Containment Equipment.

1910.1030(e)(2)(iii)(A)
Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)
Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)
HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)
Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)
An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)
HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)
The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)
The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)
Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)
Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)
An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)
A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)
Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)
Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up—

1910.1030(f)(1)
General.

1910.1030(f)(1)(i)
The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii)
The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)
Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)
Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)
Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)
Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)
The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

1910.1030(f)(2)
Hepatitis B Vaccination.

1910.1030(f)(2)(i)
Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)
The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)
If the employee initially declines hepatitis B vaccination but at a later date while still covered under the Standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)
The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v)
If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)
Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)
Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)
Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)
The source individual's blood shall be tested as soon as feasible and after **consent** is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)
When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)
Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)
Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)
The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)
If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)
Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)
Counseling; and

1910.1030(f)(3)(vi)
Evaluation of reported illnesses.

1910.1030(f)(4)
Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)
The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)
The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)
A copy of this regulation;

1910.1030(f)(4)(ii)(B)
A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)
Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)
Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)
All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)
Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)
The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)
The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)
That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)
That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii)
All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)
Medical Recordkeeping. Medical records required by this Standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)
Communication of Hazards to Employees—

1910.1030(g)(1)
Labels and Signs—

1910.1030(g)(1)(i)
Labels.

1910.1030(g)(1)(i)(A)
Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)
Labels required by this section shall include the following legend:

BIOHAZARD

1910.1030(g)(1)(i)(C)
These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)
Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)
Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)
Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)
Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)
Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

1910.1030(g)(1)(i)(I)
Regulated waste that has been decontaminated need not be labeled or color-coded.

1910.1030(g)(1)(ii)
Signs.

1910.1030(g)(1)(ii)(A)
The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

BIOHAZARD

(NAME OF THE INFECTIOUS AGENT)
(SPECIAL REQUIREMENTS FOR ENTERING THE AREA)
(NAME, TELEPHONE NUMBER OF THE LABORATORY DIRECTOR OR OTHER RESPONSIBLE PERSON.)

1910.1030(g)(1)(ii)(B)
These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)
Information and Training.

1910.1030(g)(2)(i)
The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

1910.1030(g)(2)(ii)
Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)
At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)
At least annually thereafter.

1910.1030(g)(2)(iii)
[Reserved]

1910.1030(g)(2)(iv)
Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)
Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)
Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)
The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)
An accessible copy of the regulatory text of this Standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)
A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)
An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)
An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)
An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

1910.1030(g)(2)(vii)(F)
An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)
Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)
An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)
Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)
Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

1910.1030(g)(2)(vii)(K)
An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)
Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

1910.1030(g)(2)(vii)(M)
An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

1910.1030(g)(2)(vii)(N)
An opportunity for interactive questions and answers with the person conducting the training session.

1910.1030(g)(2)(viii)
The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)
Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)
The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)
The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)
The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

1910.1030(h)
Recordkeeping—

1910.1030(h)(1)
Medical Records.

1910.1030(h)(1)(i)
The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)
This record shall include:

1910.1030(h)(1)(ii)(A)
The name of the employee;

1910.1030(h)(1)(ii)(B)
A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)
A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)
The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

1910.1030(h)(1)(ii)(E)
A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)
Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

1910.1030(h)(1)(iii)(A)
Kept confidential; and

1910.1030(h)(1)(iii)(B)
Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)
The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)
Training Records.

1910.1030(h)(2)(i)
Training records shall include the following information:

1910.1030(h)(2)(i)(A)
The dates of the training sessions;

1910.1030(h)(2)(i)(B)
The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)
The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)
The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)
Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)
Availability.

1910.1030(h)(3)(i)
The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)
Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)
Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

1910.1030(h)(4)
Transfer of Records. The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

OSHA recently discovered mistakes made by the Federal Register editors of the CFR in implementing the 2001 OSHA final rule for Bloodborne Pathogens; these mistakes affected 29 CFR 1910.1030(h) and (i). OSHA

is in the process of correcting these mistakes in the CFR. In the meantime, OSHA is revising this website to reflect the correct regulations as they will soon appear in eCFR and in the July 1, 2012, edition of the hard copy CFR. We will remove this notice from this website when the Federal Register editors make the necessary corrections in the eCFR.

1910.1030(h)(5)
Sharps injury log.

1910.1030(h)(5)(i)
The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)
The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)
The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)
An explanation of how the incident occurred.

1910.1030(h)(5)(ii)
The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR Part 1904.

1910.1030(h)(5)(iii)
The sharps injury log shall be maintained for the period required by 29 CFR 1904.33.

1910.1030(i)
Dates—

1910.1030(i)(1)
Effective Date. The Standard shall become effective on March 6, 1992.

1910.1030(i)(2)
The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)
Paragraphs (g)(2) Information and Training and (h) Recordkeeping of this section shall take effect on or before June 4, 1992.

1910.1030(i)(4)
Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs of this section, shall take effect July 6, 1992.

[56 FR 64004, 64175, Dec. 6, 1991, 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, 5508, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001; 71 FR 16672, 16673, April 3, 2006; 73 FR 75586, Dec. 12, 2008; 76 FR 33608, June 8, 2011; 76 FR 80740, Dec. 27, 2011; 77 FR 19934, April 3, 2012; 84 FR 21597, May 14, 2019]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1030 Appendix A
Title: Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

[56 FR 64004, 64182, Dec. 6, 1991; 57 FR 29206, July 1, 1992]

Hazard Communication

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200
Title: Hazard Communication
Appendix: A, B, C, D, E

Note: The following text for 1910.1200 has been updated to align with the UN Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 3, issued in the Federal Register, March 26, 2012. This rule became effective May 25, 2012.

Also, the Hazard Communication page, on OSHA.gov, includes downloadable versions of the revised 1910.1200 Final Rule and appendices, updated to align with the GHS; a comparison of the Hazard Communication Standard, issued in 1994 (HazCom 1994), with the revised Hazard Communication Final Rule issued in 2012 (HazCom 2012); frequently asked questions on the revisions; and new guidance materials on the revisions. The page also contains the full regulatory text and appendices of HazCom 1994.

1910.1200(a)
Purpose.

1910.1200(a)(1)
The purpose of this section is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the classified hazards is transmitted to employers and employees. The requirements of this section are intended to be consistent with the provisions of the United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 3. The transmittal of information is to be accomplished by means of comprehensive hazard communication programs, which are to include container labeling and other forms of warning, safety data sheets and employee training.

1910.1200(a)(2)
This occupational safety and health Standard is intended to address comprehensively the issue of classifying the potential hazards of chemicals, and communicating information concerning hazards and appropriate protective measures to employees, and to preempt any legislative or regulatory enactments of a state, or political subdivision of a state, pertaining to this subject. Classifying the potential hazards of chemicals and communicating information concerning hazards and appropriate protective measures to employees, may include, for example, but is not limited to, provisions for: developing and maintaining a written hazard communication program for the workplace, including lists of hazardous chemicals present; labeling of containers of chemicals in the workplace, as well as of containers of chemicals being shipped to other workplaces; preparation and distribution of safety data sheets to employees and downstream employers; and development and implementation of employee training programs regarding hazards of chemicals and protective measures. Under section 18 of the Act, no state or political subdivision of a state may adopt or enforce any requirement relating to the issue addressed by this Federal Standard, except pursuant to a Federally-approved state plan.

1910.1200(b)
Scope and application.

1910.1200(b)(1)
This section requires chemical manufacturers or importers to classify the hazards of chemicals which they produce or import, and all employers to provide information to their employees about the hazardous chemicals to which they are exposed, by means of a hazard communication program, labels and other forms of warning, safety data sheets, and information and training. In addition, this section requires distributors to transmit the required information to employers. (Employers who do not produce or import chemicals need only focus on those parts of this rule that deal with establishing a workplace program and communicating information to their workers.)

1910.1200(b)(2)
This section applies to any chemical which is known to be present in the workplace in such a manner that employees may be exposed under normal conditions of use or in a foreseeable emergency.

1910.1200(b)(3)
This section applies to laboratories only as follows:

1910.1200(b)(3)(i)
Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

1910.1200(b)(3)(ii)
Employers shall maintain any safety data sheets that are received with incoming shipments of hazardous chemicals, and ensure that they are readily accessible during each workshift to laboratory employees when they are in their work areas;

1910.1200(b)(3)(iii)
Employers shall ensure that laboratory employees are provided information and training in accordance with paragraph (h) of this section, except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section; and,

1910.1200(b)(3)(iv)
Laboratory employers that ship hazardous chemicals are considered to be either a chemical manufacturer or a distributor under this rule, and thus must ensure that any containers of hazardous chemicals leaving the laboratory are labeled in accordance with paragraph (f) of this section, and that a safety data sheet is provided to distributors and other employers in accordance with paragraphs (g)(6) and (g)(7) of this section.

1910.1200(b)(4)
In work operations where employees only handle chemicals in sealed containers which are not opened under normal conditions of use (such as are found in marine cargo handling, warehousing, or retail sales), this section applies to these operations only as follows:

1910.1200(b)(4)(i)
Employers shall ensure that labels on incoming containers of hazardous chemicals are not removed or defaced;

1910.1200(b)(4)(ii)
Employers shall maintain copies of any safety data sheets that are received with incoming shipments of the sealed containers of hazardous chemicals, shall obtain a safety data sheet as soon as possible for sealed containers of hazardous chemicals received without a safety data sheet if an employee requests the safety data sheet, and shall ensure that the safety data sheets are readily accessible during each work shift to employees when they are in their work area(s); and,

1910.1200(b)(4)(iii)
Employers shall ensure that employees are provided with information and training in accordance with paragraph (h) of this section (except for the location and availability of the written hazard communication program under paragraph (h)(2)(iii) of this section), to the extent necessary to protect them in the event of a spill or leak of a hazardous chemical from a sealed container.

1910.1200(b)(5)
This section does not require labeling of the following chemicals:

1910.1200(b)(5)(i)
Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(5)(ii)
Any chemical substance or mixture as such terms are defined in the Toxic Substances Control Act (15 U.S.C. 2601 *et seq.*), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(5)(iii)
Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (*e.g.* flavors and fragrances), as such terms are defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) or the Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151 *et seq.*), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;

1910.1200(b)(5)(iv)
Any distilled spirits (beverage alcohols), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the Federal Alcohol Administration Act (27 U.S.C. 201 *et seq.*) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;

1910.1200(b)(5)(v)
Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq*.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission; and,

1910.1200(b)(5)(vi)
Agricultural or vegetable seed treated with pesticides and labeled in accordance with the Federal Seed Act (7 U.S.C. 1551 *et seq.*) and the labeling regulations issued under that Act by the Department of Agriculture.

1910.1200(b)(6)
This section does not apply to:

1910.1200(b)(6)(i)
Any hazardous waste as such term is defined by the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C. 6901 *et seq.*), when subject to regulations issued under that Act by the Environmental Protection Agency;

1910.1200(b)(6)(ii)
Any hazardous substance as such term is defined by the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) (42 U.S.C. 9601 *et seq.*) when the hazardous substance is the focus of remedial or removal action being conducted under CERCLA in accordance with Environmental Protection Agency regulations.

1910.1200(b)(6)(iii)
Tobacco or tobacco products;

1910.1200(b)(6)(iv)
Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this Standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);

1910.1200(b)(6)(v)
Articles (as that term is defined in paragraph (c) of this section);

1910.1200(b)(6)(vi)
Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;

1910.1200(b)(6)(vii)
Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), when it is in solid, final form for direct administration to the patient (*e.g.*, tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (*e.g.*, over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (*e.g.*, first aid supplies);

1910.1200(b)(6)(viii)
Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;

1910.1200(b)(6)(ix)
Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 *et seq.*) and Federal Hazardous Substances Act (15 U.S.C. 1261 *et seq.*) respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;

1910.1200(b)(6)(x)
Nuisance particulates where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;

1910.1200(b)(6)(xi)
Ionizing and nonionizing radiation; and,

1910.1200(b)(6)(xii)
Biological hazards.

1910.1200(c)

Definitions. Article means a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

Chemical means any substance, or mixture of substances.

Chemical manufacturer means an employer with a workplace where chemical(s) are produced for use or distribution.

Chemical name means the scientific designation of a chemical in accordance with the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) rules of nomenclature, or a name that will clearly identify the chemical for the purpose of conducting a hazard classification.

Classification means to identify the relevant data regarding the hazards of a chemical; review those data to ascertain the hazards associated with the chemical; and decide whether the chemical will be classified as hazardous according to the definition of hazardous chemical in this section. In addition, classification for health and physical hazards includes the determination of the degree of hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

Commercial account means an arrangement whereby a retail distributor sells hazardous chemicals to an employer, generally in large quantities over time and/or at costs that are below the regular retail price.

Common name means any designation or identification such as code name, code number, trade name, brand name or generic name used to identify a chemical other than by its chemical name.

Container means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

Designated representative means any individual or organization to whom an employee gives written authorization to exercise such employee's rights under this section. A recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.

Director means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Distributor means a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.

Employee means a worker who may be exposed to hazardous chemicals under normal operating conditions or in foreseeable emergencies. Workers such as office workers or bank tellers who encounter hazardous chemicals only in non-routine, isolated instances are not covered.

Employer means a person engaged in a business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.

Exposure or exposed means that an employee is subjected in the course of employment to a chemical that is a physical or health hazard, and includes potential (e.g. accidental or possible) exposure. "Subjected" in terms of health hazards includes any route of entry (e.g. inhalation, ingestion, skin contact or absorption.)

Foreseeable emergency means any potential occurrence such as, but not limited to, equipment failure, rupture of containers, or failure of control equipment which could result in an uncontrolled release of a hazardous chemical into the workplace.

Hazard category means the division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

Hazard class means the nature of the physical or health hazards, e.g., flammable solid, carcinogen, oral acute toxicity.

Hazard not otherwise classified (HNOC) means an adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazard(s) of a chemical, including, where appropriate, the degree of hazard.

Hazardous chemical means any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.

Health hazard means a chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to §1910.1200—Health Hazard Criteria.

Immediate use means that the hazardous chemical will be under the control of and used only by the person who transfers it from a labeled container and only within the work shift in which it is transferred.

Importer means the first business with employees within the Customs Territory of the United States which receives hazardous chemicals produced in other countries for the purpose of supplying them to distributors or employers within the United States.

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous chemical that is affixed to, printed on, or attached to the immediate container of a hazardous chemical, or to the outside packaging.

Label elements means the specified pictogram, hazard statement, signal word and precautionary statement for each hazard class and category.

Mixture means a combination or a solution composed of two or more substances in which they do not react.

Physical hazard means a chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. See Appendix B to §1910.1200—Physical Hazard Criteria.

Pictogram means a composition that may include a symbol plus other graphic elements, such as a border, background pattern, or color, that is intended to convey specific information about the hazards of a chemical. Eight pictograms are designated under this Standard for application to a hazard category.

Precautionary statement means a phrase that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical, or improper storage or handling.

Produce means to manufacture, process, formulate, blend, extract, generate, emit, or repackage.

Product identifier means the name or number used for a hazardous chemical on a label or in the SDS. It provides a unique means by which the user can identify the chemical. The product identifier used shall permit cross-references to be made among the list of hazardous chemicals required in the written hazard communication program, the label and the SDS.

Pyrophoric gas means a chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130 degrees F (54.4 degrees C) or below.

Responsible party means someone who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

Safety data sheet (SDS) means written or printed material concerning a hazardous chemical that is prepared in accordance with paragraph (g) of this section.

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The signal words used in this section are "danger" and "warning." "Danger" is used for the more severe hazards, while "warning" is used for the less severe.

Simple asphyxiant means a substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

Specific chemical identity means the chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Trade secret means any confidential formula, pattern, process, device, information or compilation of information that is used in an employer's business, and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it. Appendix E to §1910.1200—Definition of Trade Secret, sets out the criteria to be used in evaluating trade secrets.

Use means to package, handle, react, emit, extract, generate as a byproduct, or transfer.

Work area means a room or defined space in a workplace where hazardous chemicals are produced or used, and where employees are present.

Workplace means an establishment, job site, or project, at one geographical location containing one or more work areas.

1910.1200(d)
Hazard classification.

1910.1200(d)(1)
Chemical manufacturers and importers shall evaluate chemicals produced in their workplaces or imported by them to classify the chemicals in accordance with this section. For each chemical, the chemical manufacturer or importer shall determine the hazard classes, and, where appropriate, the category of each class that apply to the chemical being classified. Employers are not required to classify chemicals unless they choose not to rely on the classification performed by the chemical manufacturer or importer for the chemical to satisfy this requirement.

1910.1200(d)(2)
Chemical manufacturers, importers or employers classifying chemicals shall identify and consider the full range of available scientific literature and other evidence concerning the potential hazards. There is no requirement to test the chemical to determine how to classify its hazards. Appendix A to § 1910.1200 shall be consulted for classification of health hazards, and Appendix B to § 1910.1200 shall be consulted for the classification of physical hazards.

1910.1200(d)(3)
Mixtures.

1910.1200(d)(3)(i)
Chemical manufacturers, importers, or employers evaluating chemicals shall follow the procedures described in Appendices A and B to Sec. 1910.1200 to classify the hazards of the chemicals, including determinations regarding when mixtures of the classified chemicals are covered by this section.

1910.1200(d)(3)(ii)
When classifying mixtures they produce or import, chemical manufacturers and importers of mixtures may rely on the information provided on the current safety data sheets of the individual ingredients, except where the chemical manufacturer or importer knows, or in the exercise of reasonable diligence should know, that the safety data sheet misstates or omits information required by this section.

1910.1200(e)
Written hazard communication program.

1910.1200(e)(1)
Employers shall develop, implement, and maintain at each workplace, a written hazard communication program which at least describes how the criteria specified in paragraphs (f), (g), and (h) of this section for labels and other forms of warning, safety data sheets, and employee information and training will be met, and which also includes the following:

1910.1200(e)(1)(i)
A list of the hazardous chemicals known to be present using a product identifier that is referenced on the appropriate safety data sheet (the list may be compiled for the workplace as a whole or for individual work areas); and,

1910.1200(e)(1)(ii)
The methods the employer will use to inform employees of the hazards of non-routine tasks (for example, the cleaning of reactor vessels), and the hazards associated with chemicals contained in unlabeled pipes in their work areas.

1910.1200(e)(2)
Multi-employer workplaces. Employers who produce, use, or store hazardous chemicals at a workplace in such a way that the employees of other employer(s) may be exposed (for example, employees of a construction contractor working on-site) shall additionally ensure that the hazard communication programs developed and implemented under this paragraph (e) include the following:

1910.1200(e)(2)(i)
The methods the employer will use to provide the other employer(s) on-site access to safety data sheets for each hazardous chemical the other employer(s)' employees may be exposed to while working;

1910.1200(e)(2)(ii)
The methods the employer will use to inform the other employer(s) of any precautionary measures that need to be taken to protect employees during the workplace's normal operating conditions and in foreseeable emergencies; and,

1910.1200(e)(2)(iii)
The methods the employer will use to inform the other employer(s) of the labeling system used in the workplace.

1910.1200(e)(3)
The employer may rely on an existing hazard communication program to comply with these requirements, provided that it meets the criteria established in this paragraph (e).

1910.1200(e)(4)
The employer shall make the written hazard communication program available, upon request, to employees, their designated representatives, the Assistant Secretary and the Director, in accordance with the requirements of 29 CFR 1910.1020 (e).

1910.1200(e)(5)
Where employees must travel between workplaces during a workshift, i.e., their work is carried out at more than one geographical location, the written hazard communication program may be kept at the primary workplace facility.

1910.1200(f)
Labels and other forms of warning—

1910.1200(f)(1)
Labels on shipped containers. The chemical manufacturer, importer, or distributor shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked. Hazards not otherwise classified do not have to be addressed on the container. Where the chemical manufacturer or importer is required to label, tag or mark the following information shall be provided:

1910.1200(f)(1)(i)
Product identifier;

1910.1200(f)(1)(ii)
Signal word;

1910.1200(f)(1)(iii)
Hazard statement(s);

1910.1200(f)(1)(iv)
Pictogram(s);

1910.1200(f)(1)(v)
Precautionary statement(s); and,

1910.1200(f)(1)(vi)
Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party.

1910.1200(f)(2)
The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(i) through (v) of this section is in accordance with Appendix C to § 1910.1200, for each hazard class and associated hazard category for the hazardous chemical, prominently displayed, and in English (other languages may also be included if appropriate).

1910.1200(f)(3)
The chemical manufacturer, importer, or distributor shall ensure that the information provided under paragraphs (f)(1)(ii) through (iv) of this section is located together on the label, tag, or mark.

1910.1200(f)(4)
Solid materials.

1910.1200(f)(4)(i)
For solid metal (such as a steel beam or a metal casting), solid wood, or plastic items that are not exempted as articles due to their downstream use, or shipments of whole grain, the required label may be transmitted to the customer at the time of the initial shipment, and need not be included with subsequent shipments to the same employer unless the information on the label changes;

1910.1200(f)(4)(ii)
The label may be transmitted with the initial shipment itself, or with the safety data sheet that is to be provided prior to or at the time of the first shipment; and,

1910.1200(f)(4)(iii)
This exception to requiring labels on every container of hazardous chemicals is only for the solid material itself, and does not apply to hazardous chemicals used in conjunction with, or known to be present with, the material and to which employees handling the items in transit may be exposed (for example, cutting fluids or pesticides in grains).

1910.1200(f)(5)
Chemical manufacturers, importers, or distributors shall ensure that each container of hazardous chemicals leaving the workplace is labeled, tagged, or marked in accordance with this section in a manner which does not conflict with the requirements of the Hazardous Materials Transportation Act (49 U.S.C. 1801 et seq.) and regulations issued under that Act by the Department of Transportation.

1910.1200(f)(6)
Workplace labeling. Except as provided in paragraphs (f)(7) and (f)(8) of this section, the employer shall ensure that each container of hazardous chemicals in the workplace is labeled, tagged or marked with either:

1910.1200(f)(6)(i)
The information specified under paragraphs (f)(1)(i) through (v) of this section for labels on shipped containers; or,

1910.1200(f)(6)(ii)
Product identifier and words, pictures, symbols, or combination thereof, which provide at least general information regarding the hazards of the chemicals, and which, in conjunction with the other information immediately available to employees under the hazard communication program, will provide employees with the specific information regarding the physical and health hazards of the hazardous chemical.

1910.1200(f)(7)
The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys the information required by paragraph (f)(6) of this section to be on a label. The employer shall ensure the written materials are readily accessible to the employees in their work area throughout each work shift.

1910.1200(f)(8)
The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer. For purposes of this section, drugs which are dispensed by a pharmacy to a health care provider for direct administration to a patient are exempted from labeling.

1910.1200(f)(9)
The employer shall not remove or deface existing labels on incoming containers of hazardous chemicals, unless the container is immediately marked with the required information.

1910.1200(f)(10)
The employer shall ensure that workplace labels or other forms of warning are legible, in English, and prominently displayed on the container, or readily available in the work area throughout each work shift. Employers having employees who speak other languages may add the information in their language to the material presented, as long as the information is presented in English as well.

1910.1200(f)(11)
Chemical manufacturers, importers, distributors, or employers who become newly aware of any significant information regarding the hazards of a chemical shall revise the labels for the chemical within six months of becoming aware of the new information, and shall ensure that labels on containers of hazardous chemicals shipped after that time contain the new information. If the chemical is not currently produced or imported, the chemical manufacturer, importer, distributor, or employer shall add the information to the label before the chemical is shipped or introduced into the workplace again.

1910.1200(g)
Safety data sheets.

1910.1200(g)(1)
Chemical manufacturers and importers shall obtain or develop a safety data sheet for each hazardous chemical they produce or import. Employers shall have a safety data sheet in the workplace for each hazardous chemical which they use.

1910.1200(g)(2)
The chemical manufacturer or importer preparing the safety data sheet shall ensure that it is in English (although the employer may maintain copies in other languages as well), and includes at least the following section numbers and headings, and associated information under each heading, in the order listed (See Appendix D to § 1910.1200—Safety Data Sheets, for the specific content of each section of the safety data sheet):

1910.1200(g)(2)(i)
Section 1, Identification;

1910.1200(g)(2)(ii)
Section 2, Hazard(s) identification;

1910.1200(g)(2)(iii)
Section 3, Composition/information on ingredients;

1910.1200(g)(2)(iv)
Section 4, First-aid measures;

1910.1200(g)(2)(v)
Section 5, Fire-fighting measures;

1910.1200(g)(2)(vi)
Section 6, Accidental release measures;

1910.1200(g)(2)(vii)
Section 7, Handling and storage;

1910.1200(g)(2)(viii)
Section 8, Exposure controls/personal protection;

1910.1200(g)(2)(ix)
Section 9, Physical and chemical properties;

1910.1200(g)(2)(x)
Section 10, Stability and reactivity;

1910.1200(g)(2)(xi)
Section 11, Toxicological information;

1910.1200(g)(2)(xii)
Section 12, Ecological information;

1910.1200(g)(2)(xiii)
Section 13, Disposal considerations;

1910.1200(g)(2)(xiv)
Section 14, Transport information;

1910.1200(g)(2)(xv)
Section 15, Regulatory information; and

1910.1200(g)(2)(xvi)
Section 16, Other information, including date of preparation or last revision.

Note 1 to paragraph (g)(2): To be consistent with the GHS, an SDS must also include the headings in paragraphs (g)(2)(xii) through (g)(2)(xv) in order.

Note 2 to paragraph (g)(2): OSHA will not be enforcing information requirements in sections 12 through 15, as these areas are not under its jurisdiction.

1910.1200(g)(3)
If no relevant information is found for any sub-heading within a section on the safety data sheet, the chemical manufacturer, importer or employer preparing the safety data sheet shall mark it to indicate that no applicable information was found.

1910.1200(g)(4)
Where complex mixtures have similar hazards and contents (i.e. the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture), the chemical manufacturer, importer or employer may prepare one safety data sheet to apply to all of these similar mixtures.

1910.1200(g)(5)
The chemical manufacturer, importer or employer preparing the safety data sheet shall ensure that the information provided accurately reflects the scientific evidence used in making the hazard classification. If the chemical manufacturer, importer or employer preparing the safety data

sheet becomes newly aware of any significant information regarding the hazards of a chemical, or ways to protect against the hazards, this new information shall be added to the safety data sheet within three months. If the chemical is not currently being produced or imported, the chemical manufacturer or importer shall add the information to the safety data sheet before the chemical is introduced into the workplace again.

1910.1200(g)(6)(i)
Chemical manufacturers or importers shall ensure that distributors and employers are provided an appropriate safety data sheet with their initial shipment, and with the first shipment after a safety data sheet is updated;

1910.1200(g)(6)(ii)
The chemical manufacturer or importer shall either provide safety data sheets with the shipped containers or send them to the distributor or employer prior to or at the time of the shipment;

1910.1200(g)(6)(iii)
If the safety data sheet is not provided with a shipment that has been labeled as a hazardous chemical, the distributor or employer shall obtain one from the chemical manufacturer or importer as soon as possible; and,

1910.1200(g)(6)(iv)
The chemical manufacturer or importer shall also provide distributors or employers with a safety data sheet upon request.

1910.1200(g)(7)(i)
Distributors shall ensure that safety data sheets, and updated information, are provided to other distributors and employers with their initial shipment and with the first shipment after a safety data sheet is updated;

1910.1200(g)(7)(ii)
The distributor shall either provide safety data sheets with the shipped containers, or send them to the other distributor or employer prior to or at the time of the shipment;

1910.1200(g)(7)(iii)
Retail distributors selling hazardous chemicals to employers having a commercial account shall provide a safety data sheet to such employers upon request, and shall post a sign or otherwise inform them that a safety data sheet is available;

1910.1200(g)(7)(iv)
Wholesale distributors selling hazardous chemicals to employers over-the-counter may also provide safety data sheets upon the request of the employer at the time of the over-the-counter purchase, and shall post a sign or otherwise inform such employers that a safety data sheet is available;

1910.1200(g)(7)(v)
If an employer without a commercial account purchases a hazardous chemical from a retail distributor not required to have safety data sheets on file (i.e., the retail distributor does not have commercial accounts and does not use the materials), the retail distributor shall provide the employer, upon request, with the name, address, and telephone number of the chemical manufacturer, importer, or distributor from which a safety data sheet can be obtained;

1910.1200(g)(7)(vi)
Wholesale distributors shall also provide safety data sheets to employers or other distributors upon request; and,

1910.1200(g)(7)(vii)
Chemical manufacturers, importers, and distributors need not provide safety data sheets to retail distributors that have informed them that the retail distributor does not sell the product to commercial accounts or open the sealed container to use it in their own workplaces.

1910.1200(g)(8)
The employer shall maintain in the workplace copies of the required safety data sheets for each hazardous chemical, and shall ensure that they are readily accessible during each work shift to employees when they are in their work area(s). (Electronic access and other alternatives to maintaining paper copies of the safety data sheets are permitted as long as no barriers to immediate employee access in each workplace are created by such options.)

1910.1200(g)(9)
Where employees must travel between workplaces during a workshift, *i.e.*, their work is carried out at more than one geographical location, the material safety data sheets may be kept at the primary workplace facility. In this situation, the employer shall ensure that employees can immediately obtain the required information in an emergency.

1910.1200(g)(10)
Safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of hazardous chemicals in a work area where it may be more appropriate to address the hazards of a process rather than individual hazardous chemicals. However, the employer shall ensure that in all cases the required information is provided for each hazardous chemical, and is readily accessible during each work shift to employees when they are in their work area(s).

1910.1200(g)(11)
Safety data sheets shall also be made readily available, upon request, to designated representatives, the Assistant Secretary, and the Director, in accordance with the requirements of § 1910.1020(e).

1910.1200(h)
Employee information and training.

1910.1200(h)(1)
Employers shall provide employees with effective information and training on hazardous chemicals in their work area at the time of their initial assignment, and whenever a new chemical hazard the employees have not previously been trained about is introduced into their work area. Information and training may be designed to cover categories of hazards (e.g., flammability, carcinogenicity) or specific chemicals. Chemical-specific information must always be available through labels and safety data sheets.

1910.1200(h)(2)
Information. Employees shall be informed of:

1910.1200(h)(2)(i)
The requirements of this section;

1910.1200(h)(2)(ii)
Any operations in their work area where hazardous chemicals are present; and,

1910.1200(h)(2)(iii)
The location and availability of the written hazard communication program, including the required list(s) of hazardous chemicals, and safety data sheets required by this section.

1910.1200(h)(3)
Training. Employee training shall include at least:

1910.1200(h)(3)(i)
Methods and observations that may be used to detect the presence or release of a hazardous chemical in the work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance or odor of hazardous chemicals when being released, etc.);

1910.1200(h)(3)(ii)
The physical, health, simple asphyxiation, combustible dust, and pyrophoric gas hazards, as well as hazards not otherwise classified, of the chemicals in the work area;

1910.1200(h)(3)(iii)
The measures employees can take to protect themselves from these hazards, including specific procedures the employer has implemented to protect employees from exposure to hazardous chemicals, such as appropriate work practices, emergency procedures, and personal protective equipment to be used; and,

1910.1200(h)(3)(iv)
The details of the hazard communication program developed by the employer, including an explanation of the labels received on shipped containers and the workplace labeling system used by their employer; the safety data sheet, including the order of information and how employees can obtain and use the appropriate hazard information.

1910.1200(i)
Trade secrets.

1910.1200(i)(1)
The chemical manufacturer, importer, or employer may withhold the specific chemical identity, including the chemical name, other specific identification of a hazardous chemical, or the exact percentage (concentration) of the substance in a mixture, from the safety data sheet, provided that:

1910.1200(i)(1)(i)
The claim that the information withheld is a trade secret can be supported;

1910.1200(i)(1)(ii)
Information contained in the safety data sheet concerning the properties and effects of the hazardous chemical is disclosed;

1910.1200(i)(1)(iii)
The safety data sheet indicates that the specific chemical identity and/or percentage of composition is being withheld as a trade secret; and,

1910.1200(i)(1)(iv)
The specific chemical identity and percentage is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of this paragraph (i).

1910.1200(i)(2)
Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity and/or specific percentage of composition of a hazardous chemical is necessary for emergency or first-aid treatment, the chemical manufacturer, importer, or employer shall immediately disclose the specific chemical identity or percentage composition of a trade secret chemical to that treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The chemical manufacturer, importer, or employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (i)(3) and (4) of this section, as soon as circumstances permit.

1910.1200(i)(3)
In non-emergency situations, a chemical manufacturer, importer, or employer shall, upon request, disclose a specific chemical identity or percentage composition, otherwise permitted to be withheld under paragraph (i)(1) of this section, to a health professional (i.e. physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives, if:

1910.1200(i)(3)(i)
The request is in writing;

1910.1200(i)(3)(ii)
The request describes with reasonable detail one or more of the following occupational health needs for the information:

1910.1200(i)(3)(ii)(A)
To assess the hazards of the chemicals to which employees will be exposed;

1910.1200(i)(3)(ii)(B)
To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;

1910.1200(i)(3)(ii)(C)
To conduct pre-assignment or periodic medical surveillance of exposed employees;

1910.1200(i)(3)(ii)(D)
To provide medical treatment to exposed employees;

1910.1200(i)(3)(ii)(E)
To select or assess appropriate personal protective equipment for exposed employees;

1910.1200(i)(3)(ii)(F)
To design or assess engineering controls or other protective measures for exposed employees; and,

1910.1200(i)(3)(ii)(G)
To conduct studies to determine the health effects of exposure.

1910.1200(i)(3)(iii)
The request explains in detail why the disclosure of the specific chemical identity or percentage composition is essential and that, in lieu thereof, the disclosure of the following information to the health professional, employee, or designated representative, would not satisfy the purposes described in paragraph (i)(3)(ii) of this section:

1910.1200(i)(3)(iii)(A)
The properties and effects of the chemical;

1910.1200(i)(3)(iii)(B)
Measures for controlling workers' exposure to the chemical;

1910.1200(i)(3)(iii)(C)
Methods of monitoring and analyzing worker exposure to the chemical; and,

1910.1200(i)(3)(iii)(D)
Methods of diagnosing and treating harmful exposures to the chemical;

1910.1200(i)(3)(iv)
The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and,

1910.1200(i)(3)(v)
The health professional, and the employer or contractor of the services of the health professional (i.e. downstream employer, labor organization, or individual employee), employee, or designated representative, agree in a written confidentiality agreement that the health professional, employee, or designated representative, will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (i)(6) of this section, except as authorized by the terms of the agreement or by the chemical manufacturer, importer, or employer.

1910.1200(i)(4)
The confidentiality agreement authorized by paragraph (i)(3)(iv) of this section:

1910.1200(i)(4)(i)
May restrict the use of the information to the health purposes indicated in the written statement of need;

1910.1200(i)(4)(ii)
May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,

1910.1200(i)(4)(iii)
May not include requirements for the posting of a penalty bond.

1910.1200(i)(5)
Nothing in this Standard is meant to preclude the parties from pursuing non-contractual remedies to the extent permitted by law.

1910.1200(i)(6)
If the health professional, employee, or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the chemical manufacturer, importer, or employer who provided the information shall be informed by the health professional, employee, or designated representative prior to, or at the same time as, such disclosure.

1910.1200(i)(7)
If the chemical manufacturer, importer, or employer denies a written request for disclosure of a specific chemical identity or percentage composition, the denial must:

1910.1200(i)(7)(i)
Be provided to the health professional, employee, or designated representative, within thirty days of the request;

1910.1200(i)(7)(ii)
Be in writing;

1910.1200(i)(7)(iii)
Include evidence to support the claim that the specific chemical identity or percent of composition is a trade secret;

1910.1200(i)(7)(iv)
State the specific reasons why the request is being denied; and,

1910.1200(i)(7)(v)
Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the trade secret.

1910.1200(i)(8)
The health professional, employee, or designated representative whose request for information is denied under paragraph (i)(3) of this section may refer the request and the written denial of the request to OSHA for consideration.

1910.1200(i)(9)
When a health professional, employee, or designated representative refers the denial to OSHA under paragraph (i)(8) of this section, OSHA shall consider the evidence to determine if:

1910.1200(i)(9)(i)
The chemical manufacturer, importer, or employer has supported the claim that the specific chemical identity or percentage composition is a trade secret;

1910.1200(i)(9)(ii)
The health professional, employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and,

1910.1200(i)(9)(iii)
The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.

1910.1200(i)(10)(i)
If OSHA determines that the specific chemical identity or percentage composition requested under paragraph (i)(3) of this section is not a "bona fide" trade secret, or that it is a trade secret, but the requesting health professional, employee, or designated representative has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means to protect the confidentiality of the information, the chemical manufacturer, importer, or employer will be subject to citation by OSHA.

1910.1200(i)(10)(ii)
If a chemical manufacturer, importer, or employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health services are provided without an undue risk of harm to the chemical manufacturer, importer, or employer.

1910.1200(i)(11)
If a citation for a failure to release trade secret information is contested by the chemical manufacturer, importer, or employer, the matter will be adjudicated before the Occupational Safety and Health Review Commission in accordance with the Act's enforcement scheme and the applicable Commission rules of procedure. In accordance with the Commission rules, when a chemical manufacturer, importer, or employer continues to withhold the information during the contest, the Administrative Law Judge may review the citation and supporting documentation "in camera" or issue appropriate orders to protect the confidentiality of such matters.

1910.1200(i)(12)
Notwithstanding the existence of a trade secret claim, a chemical manufacturer, importer, or employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the chemical manufacturer, importer, or employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.

1910.1200(i)(13)
Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process information which is a trade secret.

1910.1200(j)
Effective dates.

1910.1200(j)(1)
Employers shall train employees regarding the new label elements and safety data sheets format by December 1, 2013.

1910.1200(j)(2)
Chemical manufacturers, importers, distributors, and employers shall be in compliance with all modified provisions of this section no later than June 1, 2015, except:

1910.1200(j)(2)(i)
After December 1, 2015, the distributor shall not ship containers labeled by the chemical manufacturer or importer unless the label has been modified to comply with paragraph (f)(1) of this section.

1910.1200(j)(2)(ii)
All employers shall, as necessary, update any alternative workplace labeling used under paragraph (f)(6) of this section, update the hazard communication program required by paragraph (h)(1), and provide any additional employee training in accordance with paragraph (h)(3) for newly identified physical or health hazards no later than June 1, 2016.

1910.1200(j)(3)
Chemical manufacturers, importers, distributors, and employers may comply with either § 1910.1200 revised as of October 1, 2011, or the current version of this Standard, or both during the transition period.

[59 FR 6170, Feb. 9,1994; 59 FR 17479, April 13, 1994; 59 FR 65947, 65948, Dec. 22, 1994; 61 FR 5507, 5508, Feb. 13, 1996; 77 FR 17785, 17786, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 78 FR 9313, Feb. 8, 2013]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200 Appendix A
Title: Health Hazard Criteria (Mandatory)

A.0 GENERAL CLASSIFICATION CONSIDERATIONS

A.0.1 Classification
A.0.1.1 The term "hazard classification" is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

(a) identification of relevant data regarding the hazards of a chemical;

(b) subsequent review of those data to ascertain the hazards associated with the chemical;

(c) determination of whether the chemical will be classified as hazardous and the degree of hazard.

A.0.1.2 For many hazard classes, the criteria are semi quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

A.0.2 Available data, test methods and test data quality

A.0.2.1 There is no requirement for testing chemicals.

A.0.2.2 The criteria for determining health hazards are test method neutral, i.e., they do not specify particular test methods, as long as the methods are scientifically validated.

A.0.2.3 The term "scientifically validated" refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible with a given substance, and the standardized test yields "valid" data for defining the hazard class of concern.

A.0.2.4 Existing test data are acceptable for classifying chemicals, although expert judgment also may be needed for classification purposes.

A.0.2.5 The effect of a chemical on biological systems is influenced, by the physico-chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

A.0.2.6 For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) shall be taken into account in the evaluation of human health hazards of a chemical.

A.0.3 Classification based on weight of evidence

A.0.3.1 For some hazard classes, classification results directly when the data satisfy the criteria. For others, classification of a chemical shall be determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of hazard shall be considered together, including the results of valid in vitro tests, relevant animal data, and human experience such as epidemiological and clinical studies and well-documented case reports and observations.

A.0.3.2 The quality and consistency of the data shall be considered. Information on chemicals related to the material being classified shall be considered as appropriate, as well as site of action and mechanism or mode of action study results. Both positive and negative results shall be considered together in a single weight-of-evidence determination.

A.0.3.3 Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, shall normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources shall be evaluated in order to resolve the question of classification. Reliable, good quality human data shall generally have precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to

assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience but require an assessment of the robustness, quality and statistical power of both the human and animal data.

A.0.3.4 Route of exposure, mechanistic information, and metabolism studies are pertinent to determining the relevance of an effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the chemical should not be classified.

A.0.3.5 Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to good scientific principles and with statistically and biologically significant positive results may justify classification.

A.0.4 Considerations for the classification of mixtures

A.0.4.1 For most hazard classes, the recommended process of classification of mixtures is based on the following sequence:

(a) Where test data are available for the complete mixture, the classification of the mixture will always be based on those data;

(b) Where test data are not available for the mixture itself, the bridging principles designated in each health hazard chapter of this appendix shall be considered for classification of the mixture;

(c) If test data are not available for the mixture itself, and the available information is not sufficient to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

A.0.4.2 An exception to the above order or precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity. For these three hazard classes, mixtures shall be classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. See chapters A.5, A.6, and A.7 for further information on case-by-case bases.

A.0.4.3 Use of cut-off values/concentration limits

A.0.4.3.1 When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

A.0.4.3.2 If the classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient shall be classified accordingly.

A.0.4.3.3 In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

A.0.4.4 Synergistic or antagonistic effects

When performing an assessment in accordance with these requirements, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

A.0.5 Bridging principles for the classification of mixtures where test data are not available for the complete mixture

A.0.5.1 Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

A.0.5.1.1 Dilution

For mixtures classified in accordance with A.1 through A.10 of this Appendix, if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

(a) the new diluted mixture shall be classified as equivalent to the original tested mixture; or

(b) for classification of acute toxicity in accordance with A.1 of this Appendix, paragraph A.1.3.6 (the additivity formula) shall be applied.

A.0.5.1.2 Batching

For mixtures classified in accordance with A.1 through A.10 of this Appendix, the toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the same chemical manufacturer, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary.

A.0.5.1.3 Concentration of mixtures

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, if a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture shall be classified in Category 1.

A.0.5.1.4 Interpolation within one toxicity category

For mixtures classified in accordance with A.1, A.2, A.3, A.8, A.9, or A.10 of this Appendix, for three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has

concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B.

A.0.5.1.5 Substantially similar mixtures

For mixtures classified in accordance with A.1 through A.10 of this Appendix, given the following set of conditions:

(a) Where there are two mixtures: (i) A + B;

(ii) C + B;

(b) the concentration of ingredient B is essentially the same in both mixtures;

(c) the concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);

(d) and data on toxicity for A and C are available and substantially equivalent; i.e., they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

A.0.5.1.6 Aerosols

For mixtures classified in accordance with A.1, A.2, A.3, A.4, A.8, or A.9 of this Appendix, an aerosol form of a mixture shall be classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

A.1 ACUTE TOXICITY

A.1.1 Definition

Acute toxicity refers to those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

A.1.2 Classification criteria for substances

A.1.2.1 Substances can be allocated to one of four toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to the numeric cut-off criteria as shown in Table A.1.1. Acute toxicity values are expressed as (approximate) LD50 (oral, dermal) or LC50 (inhalation) values or as acute toxicity estimates (ATE). See the footnotes following Table A.1.1 for further explanation on the application of these values.

Table A.1.1: Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

Exposure Route	Category 1	Category 2	Category 3	Category 4
Oral (mg/kg bodyweight) *see: Note (a) Note (b)*	≤ 5	>5 and ≤ 50	>50 and ≤ 300	>300 and ≤ 2000
Dermal (mg/kg body weight) *see: Note (a) Note (b)*	≤ 50	>50 and ≤ 200	>200 and ≤ 1000	>1000 and ≤ 2000
Inhalation: Gases (ppmV) *see: Note (a) Note (b) Note (c)*	≤ 100	>100 and ≤ 500	>500 and ≤ 2500	>2500 and ≤ 20000
Inhalation: Vapors (mg/l) *see: Note (a) Note (b) Note (c) Note (d)*	≤ 0.5	>0.5 and ≤ 2.0	>2.0 and ≤ 10.0	>10.0 and ≤ 20.0
Inhalation: Dusts and Mists (mg/l) *see: Note (a) Note (b) Note (c)*	≤ 0.05	>0.05 and ≤ 0.5	>0.5 and ≤ 1.0	>1.0 and ≤ 5.0

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

Notes to Table A.1.1:

(a) The acute toxicity estimate (ATE) for the classification of a substance is derived using the LD_{50}/LC_{50} where available;

(b) The acute toxicity estimate (ATE) for the classification of a substance or ingredient in a mixture is derived using:

(i) the LD_{50}/LC_{50} where available. Otherwise,

(ii) the appropriate conversion value from Table 1.2 that relates to the results of a range test, or

(iii) the appropriate conversion value from Table 1.2 that relates to a classification category;

(c) Inhalation cut-off values in the table are based on 4 hour testing exposures. Conversion of existing inhalation toxicity data which has been generated according to 1 hour exposure is achieved by dividing by a factor of 2 for gases and vapors and 4 for dusts and mists;

(d) For some substances the test atmosphere will be a vapor which consists of a combination of liquid and gaseous phases. For other substances the test atmosphere may consist of a vapor which is nearly all the gaseous phase. In these latter cases, classification is based on ppmV as follows: Category 1 (100 ppmV), Category 2 (500 ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

The terms "dust," "mist "and "vapor" are defined as follows:

(i) Dust: solid particles of a substance or mixture suspended in a gas (usually air);

(ii) Mist: liquid droplets of a substance or mixture suspended in a gas (usually air);

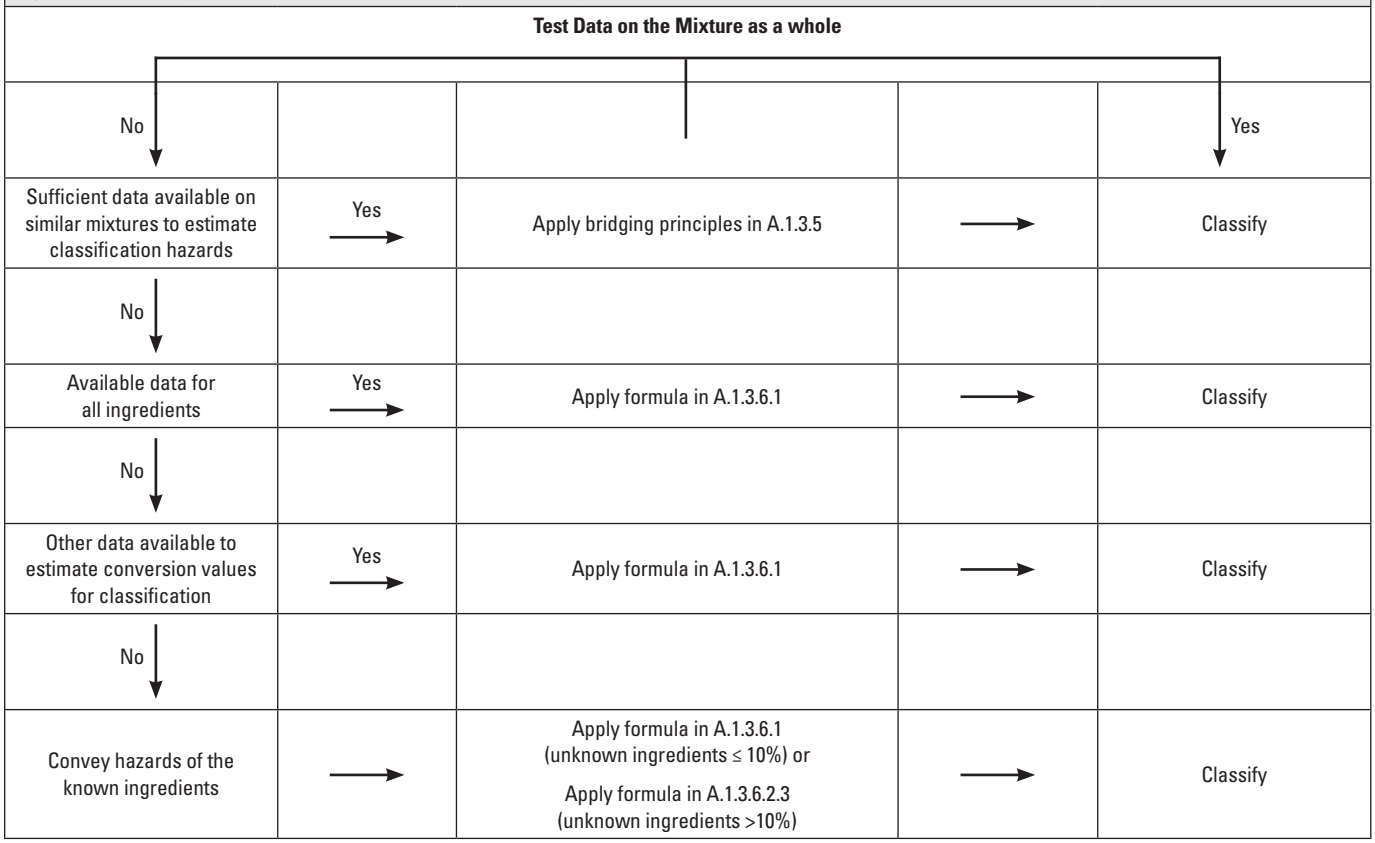
(iii) Vapor: the gaseous form of a substance or mixture released from its liquid or solid state.

A.1.2.3 The preferred test species for evaluation of acute toxicity by the oral and inhalation routes is the rat, while the rat or rabbit are preferred for evaluation of acute dermal toxicity. Test data already generated for the classification of chemicals under existing systems should be accepted when reclassifying these chemicals under the harmonized system. When experimental data for acute toxicity are available in several animal species, scientific judgment should be used in selecting the most appropriate LD50 value from among scientifically validated tests.

A.1.3 Classification criteria for mixtures

A.1.3.1 The approach to classification of mixtures for acute toxicity is tiered, and is dependent upon the amount of information available for the mixture itself and for its ingredients. The flow chart of Figure A.1.1 indicates the process that must be followed:

Figure A.1.1: Tiered approach to classification of mixtures for acute toxicity



A.1.3.2 Classification of mixtures for acute toxicity may be carried out for each route of exposure, but is only required for one route of exposure as long as this route is followed (estimated or tested) for all ingredients and there is no relevant evidence to suggest acute toxicity by multiple routes. When there is relevant evidence of acute toxicity by multiple routes of exposure, classification is to be conducted for all appropriate routes of exposure. All available information shall be considered. The pictogram and signal word used shall reflect the most severe hazard category; and all relevant hazard statements shall be used.

A.1.3.3 For purposes of classifying the hazards of mixtures in the tiered approach:

(a) The "relevant ingredients" of a mixture are those which are present in concentrations ≥ 1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases). If there is reason to suspect that an ingredient present at a concentration < 1% will affect classification of the mixture for acute toxicity, that ingredient shall also be considered relevant. Consideration of ingredients present at a concentration < 1% is particularly important when classifying untested mixtures which contain ingredients that are classified in Category 1 and Category 2;

(b) Where a classified mixture is used as an ingredient of another mixture, the actual or derived acute toxicity estimate (ATE) for that mixture is used when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

(c) If the converted acute toxicity point estimates for all ingredients of a mixture are within the same category, then the mixture should be classified in that category.

(d) When only range data (or acute toxicity hazard category information) are available for ingredients in a mixture, they may be converted to point estimates in accordance with Table A.1.2 when calculating the classification of the new mixture using the formulas in A.1.3.6.1 and A.1.3.6.2.4.

A.1.3.4 Classification of mixtures where acute toxicity test data are available for the complete mixture

Where the mixture itself has been tested to determine its acute toxicity, it is classified according to the same criteria as those used for substances, presented in Table A.1.1. If test data for the mixture are not available, the procedures presented below must be followed.

A.1.3.5 Classification of mixtures where acute toxicity test data are not available for the complete mixture: bridging principles

A.1.3.5.1 Where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.1.3.6 Classification of mixtures based on ingredients of the mixture (additivity formula)

A.1.3.6.1 Data available for all ingredients

The acute toxicity estimate (ATE) of ingredients is considered as follows:

(a) Include ingredients with a known acute toxicity, which fall into any of the acute toxicity categories, or have an oral or dermal LD50 greater than 2000 but less than or equal to 5000 mg/kg body weight (or the equivalent dose for inhalation);

(b) Ignore ingredients that are presumed not acutely toxic (e.g., water, sugar);

(c) Ignore ingredients if the data available are from a limit dose test (at the upper threshold for Category 4 for the appropriate route of exposure as provided in Table A.1.1) and do not show acute toxicity.

Ingredients that fall within the scope of this paragraph are considered to be ingredients with a known acute toxicity estimate (ATE). See note (b) to Table A.1.1 and paragraph A.1.3.3 for appropriate application of available data to the equation below, and paragraph A.1.3.6.2.4.

The ATE of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal or inhalation toxicity:

The formula for oral, dermal or inhalation toxicity

$$\frac{100}{ATEmix} = \sum_{n} \frac{Ci}{ATE_i}$$

where:
Ci = concentration of ingredient i
n ingredients and i is running from 1 to n
ATEi = acute toxicity estimate of ingredient i.

A.1.3.6.2 Data are not available for one or more ingredients of the mixture

A.1.3.6.2.1 Where an ATE is not available for an individual ingredient of the mixture, but available information provides a derived conversion value, the formula in A.1.3.6.1 may be applied. This information may include evaluation of:

(a) Extrapolation between oral, dermal and inhalation acute toxicity estimates. Such an evaluation requires appropriate pharmacodynamic and pharmacokinetic data;

(b) Evidence from human exposure that indicates toxic effects but does not provide lethal dose data;

(c) Evidence from any other toxicity tests/assays available on the substance that indicates toxic acute effects but does not necessarily provide lethal dose data; or

(d) Data from closely analogous substances using structure/activity relationships.

A.1.3.6.2.2 This approach requires substantial supplemental technical information, and a highly trained and experienced expert, to reliably estimate acute toxicity. If sufficient information is not available to reliably estimate acute toxicity, proceed to the provisions of A.1.3.6.2.3.

A.1.3.6.2.3 In the event that an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture has not been classified based on testing of the mixture as a whole, the mixture cannot be attributed a definitive acute toxicity estimate. In this situation the mixture is classified based on the known ingredients only. (Note: A statement that x percent of the mixture consists of ingredient(s) of unknown toxicity is required on the label and safety data sheet in such cases; see Appendix C, Allocation of Label Elements and Appendix D, Safety Data Sheets.)

Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label and safety data sheet in such cases; see Appendix C, Allocation of Label Elements and Appendix D, Safety Data Sheets.)

A.1.3.6.2.4 If the total concentration of the relevant ingredient(s) with unknown acute toxicity is ≤ 10% then the formula presented in A.1.3.6.1 must be used. If the total concentration of the relevant ingredient(s) with unknown acute toxicity is < 10%, the formula presented in A.1.3.6.1 is corrected to adjust for the percentage of the unknown ingredient(s) as follows:

$$\frac{100 - (\Sigma C_{\text{unknown}} \text{ if} > 10\%)}{ATE_{mix}} = \sum_{n} \frac{Ci}{ATE_1}$$

Table A.1.2: Conversion from experimentally obtained acute toxicity range values (or acute toxicity hazard categories) to acute toxicity point estimates for use in the formulas for the classification of mixtures

Exposure routes	Classification category or experimentally obtained acute toxicity range estimate			Converted Acute Toxicity point estimate
Oral (mg/kg bodyweight)	0	< Category 1 ≤	5	0.5
	5	< Category 2 ≤	50	5
	50	< Category 3 ≤	300	100
	300	< Category 4 ≤	2000	500
Dermal (mg/kg bodyweight)	0	< Category 1 ≤	50	5
	50	< Category 2 ≤	200	50
	200	< Category 3 ≤	1000	300
	1000	< Category 4 ≤	2000	1100
Gases (ppmV)	0	< Category 1 ≤	100	10
	100	< Category 2 ≤	500	100
	500	< Category 3 ≤	2500	700
	2500	< Category 4 ≤	20000	4500
Vapors (mg/l)	0	< Category 1 ≤	0.5	0.05
	0.5	< Category 2 ≤	2.0	0.5
	2.0	< Category 3 ≤	10.0	3
	10.0	< Category 4 ≤	20.0	11
Dust/mist (mg/l)	0	< Category 1 ≤	0.05	0.005
	0.05	< Category 2 ≤	0.5	0.05
	0.5	< Category 3 ≤	1.0	0.5
	1.0	< Category 4 ≤	5.0	1.5

Note: Gas concentrations are expressed in parts per million per volume (ppmV).

A.2 SKIN CORROSION/IRRITATION

A.2.1 Definitions and general considerations

A.2.1.1 *Skin corrosion* is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Histopathology should be considered to evaluate questionable lesions.

Skin irritation is the production of reversible damage to the skin following the application of a test substance for up to 4 hours.

A.2.1.2 Skin corrosion/irritation shall be classified using a tiered approach as detailed in figure A.2.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of skin corrosion/irritation is considered together, including the results of appropriate scientifically validated in-vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.2.2 Classification criteria for substances using animal test data

A.2.2.1 Corrosion

A.2.2.1.1 A corrosive substance is a chemical that produces destruction of skin tissue, namely, visible necrosis through the epidermis and into the dermis, in at least 1 of 3 tested animals after exposure up to a 4-hour duration. Corrosive reactions are typified by ulcers, bleeding, bloody scabs and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia and scars. Histopathology should be considered to discern questionable lesions.

A.2.2.1.2 Three sub-categories of Category 1 are provided in Table A.2.1, all of which shall be regulated as Category 1.

Table A.2.1: Skin corrosion category and sub-categories

Category 1: Corrosive	Corrosive sub-categorie	Corrosive in ≥ 1 of 3 animals	
		Exposure	Observation
	1A	≤ 3 min	≤ 1 h
	1B	> 3 min ≤ 1 h	≤ 14 days
	1C	1 h ≤ 4 h	≤ 14 days

A.2.2.2 Irritation

A.2.2.2.1 A single irritant category (Category 2) is presented in the Table A.2.2. The major criterion for the irritant category is that at least 2 tested animals have a mean score of ≥ 2.3 ≥ 4.0.

Table A.2.2: Skin irritation category

	Criteria
Irritant (Category 2)	(1) Mean value of ≥ 2.3 ≥ 4.0 for erythema/eschar or for edema in at least 2 of 3 tested animals from gradings at 24, 48 and 72 hours after patch removal or, if reactions are delayed, from grades on 3 consecutive days after the onset of skin reactions; or (2) Inflammation that persists to the end of the observation period normally 14 days in at least 2 animals, particularly taking into account alopecia (limited area), hyperkeratosis, hyperplasia, and scaling; or (3) In some cases where there is pronounced variability of response among animals, with very definite positive effects related to chemical exposure in a single animal but less than the criteria above.

A.2.2.2.2 Animal irritant responses within a test can be quite variable, as they are with corrosion. A separate irritant criterion accommodates cases when there is a significant irritant response but less than the mean score criterion for a positive test. For example, a substance might be designated as an irritant if at least 1 of 3 tested animals shows a very elevated mean score throughout the study, including lesions persisting at the end of an observation period of normally 14 days. Other responses could also fulfill this criterion. However, it should be ascertained that the responses are the result of chemical exposure. Addition of this criterion increases the sensitivity of the classification system.

A.2.2.2.3 Reversibility of skin lesions is another consideration in evaluating irritant responses. When inflammation persists to the end of the observation period in 2 or more test animals, taking into consideration alopecia (limited area), hyperkeratosis, hyperplasia and scaling, then a chemical should be considered to be an irritant.

A.2.3 Classification Criteria for Substances Using Other Data Elements

A.2.3.1 Existing human and animal data including information from single or repeated exposure should be the first line of analysis, as they give information directly relevant to effects on the skin. If a substance is highly toxic by the dermal route, a skin corrosion/irritation study may not be practicable since the amount of test substance to be applied would considerably exceed the toxic dose and, consequently, would result in the death of the animals. When observations are made of skin corrosion/irritation in acute toxicity studies and are observed up through the limit dose, these data may be used for classification provided that the dilutions used and species tested are equivalent. *In vitro* alternatives that have been scientifically validated shall be used to make classification decisions. Solid substances (powders) may become corrosive or irritant when moistened or in contact with moist skin or mucous membranes. Likewise, pH extremes like ≤ 2 and ≥ 11.5 may indicate skin effects, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the skin. In the absence of any other information, a substance is considered corrosive (Skin Category 1) if it has a pH ≤ 2 or a pH ≥ 11.5. However, if consideration of alkali/acid reserve suggests the substance or mixture may not be corrosive despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.2.3.2 A *tiered approach* to the evaluation of initial information shall be used (Figure A.2.1) recognizing that all elements may not be relevant in certain cases.

A.2.3.3 The tiered approach explains how to organize information on a substance and to make a weight-of-evidence decision about hazard assessment and hazard classification.

A.2.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, there is merit in considering the totality of existing information and making an overall weight of evidence determination. This is especially true when there is information available on some but not all parameters. Emphasis shall be placed upon existing human experience and data, followed by animal experience and testing data, followed by other sources of information, but case-by-case determinations are necessary.

Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

Step	Parameter		Finding		Conclusion
1a:	Existing human or animal data[1]	→	Skin corrosive	→	Category 1[2]
	↓				
	Not corrosive or no data				
	↓				
1b:	Existing human or animal data[1]	→	Skin irritant	→	Category 2[2]
	↓				
	Not an irritant or no data				
	↓				
1c:	Existing human or animal data[1]	→	Not a skin corrosive or skin irritant	→	Not classfied
	↓				
	No/Insufficient data				
	↓				
2:	Other, existing skin data in animals[3]	→	Skin corrosive Skin irritant	→	Category 1[2] Category 2[2]
	↓				
	No/Insufficient data				
	↓				
3:	Existing skin corrosive *ex vivo/in vitro* data[4]	→	Positive: Skin corrosive	→	Category 1[2]
	↓				
	Not corrosive or no data				
	↓				
	Existing skin corrosive *ex vivo/in vitro* data[4]	→	Positive: Skin irritant	→	Category 2[2]
	↓	↘	Negative: Not a skin irritant[5]		Not classified
	No/Insufficient data				
	↓				
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)[5]	→	ph≤ 2 or ≥11.5	→	Category 1[2]
	↓				
	Not a pH extreme, No pH data or extreme pH with low/no buffering capacity				
	↓				
5:	Validated Structure/Activity Relationship (SAR) models	→	Skin corrosive	→	Category 1[2]
	↓	↘	Skin irritant		Category 2[2]
	No/Insufficient data				
	↓				
6:	Consideration of the total Weight of Evidence[6]	→	Skin corrosive	→	Category 1[2]
	↓	↘	Skin irritant		Category 2[2]
	No concern based on consideration of the sum of available data				

Figure A.2.1: Tiered evaluation of skin corrosion and irritation potential

Step	Parameter		Finding		Conclusion
7:	**Not Classified**		⟶		Not classified

Notes to Figure A.2.1:

1. Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods (at present, there is no internationally accepted test method for human skin irritation testing).

2. Classify in the appropriate harmonized category, as shown in Tables A.2.1 and A.2.2.

3. Pre-existing animal data (e.g. from an acute dermal toxicity test or a sensitisation test) should be carefully reviewed to determine if sufficient skin corrosion/irritation evidence is available through other, similar information. For example, classification/categorization may be done on the basis of whether a chemical has or has not produced any skin irritation in an acute dermal toxicity test in animals at the limit dose, or produces very toxic effects in an acute dermal toxicity test in animals. In the latter case, the chemical would be classified as being very hazardous by the dermal route for acute toxicity, and it would be moot whether the chemical is also irritating or corrosive on the skin. It should be kept in mind in evaluating acute dermal toxicity information that the reporting of dermal lesions may be incomplete, testing and observations may be made on a species other than the rabbit, and species may differ in sensitivity in their responses.

4. Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of scientifically validated test methods for skin corrosion include OECD TG 430 (Transcutaneous Electrical Resistance Test (TER)), 431 (Human Skin Model Test), and 435 (Membrane Barrier Test Method). OECD TG 439 (Reconstructed Human Epidermis Test Method) is a scientifically validated in vitro test method for skin irritation.

5. Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable. Presently, there is no scientifically validated and internationally accepted method for assessing this parameter.

6. All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. Professional judgment should be exercised in making such a determination.

A.2.4 Classification criteria for mixtures

A.2.4.1 Classification of mixtures when data are available for the complete mixture

A.2.4.1.1 The mixture shall be classified using the criteria for substances (See A.2.3).

A.2.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.2.4.2.1 Where the mixture itself has not been tested to determine its skin corrosion/irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.2.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.2.4.3.1 For purposes of classifying the skin corrosion/irritation hazards of mixtures in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for skin corrosion/irritation, that ingredient shall also be considered relevant.

A.2.4.3.2 In general, the approach to classification of mixtures as irritant or corrosive to skin when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as corrosive or irritant when the sum of the concentrations of such ingredients exceeds a cut-off value/concentration limit.

A.2.4.3.3 Table A.2.3 below provides the cut-off value/concentration limits to be used to determine if the mixture is considered to be an irritant or a corrosive to the skin.

A.2.4.3.4 Particular care shall be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.2.4.3.1 and A.2.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases the pH should be used as classification criteria since pH will be a better indicator of corrosion than the concentration limits of Table A.2.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach shown in Table A.2.3, due to chemical characteristics that make this approach unworkable, should be classified as Skin Category 1 if it contains ≥ 1% of a corrosive ingredient and as Skin Category 2 when it contains ≥ 3% of an irritant ingredient. Classification of mixtures with ingredients for which the approach in Table A.2.3 does not apply is summarized in Table A.2.4 below.

A.2.4.3.5 On occasion, reliable data may show that the skin corrosion/irritation of an ingredient will not be evident when present at a level above the generic concentration cut-off values mentioned in Tables A.2.3 and A.2.4. In these cases the mixture could be classified according to those data (See *Use of cut-off values/concentration limits*, paragraph A.0.4.3 of this Appendix).

A.2.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture shall be classified accordingly (See *Use of cut-off values /concentration limits*, paragraph A.0.4.3 of this Appendix).

Table A.2.3: Concentration of ingredients of a mixture classified as skin Category 1 or 2 that would trigger classification of the mixture as hazardous to skin (Category 1 or 2)

	Concentration triggering classification of a mixture as:	
Sum of ingredients classified as:	**Skin corrosive**	**Skin irritant**
	Category 1	**Category 2**
Skin Category 1	≥ 5%	≥ 1% but < 5%
Skin Category 2		≥ 10%
10 x Skin Category 1) + Skin Category 2		≥ 10%

Table A.2.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin

Ingredient:	**Concentration:**	**Mixture classified as: Skin**
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3%	Category 2

A.3 SERIOUS EYE DAMAGE /EYE IRRITATION

A.3.1 Definitions and general considerations

A.3.1.1 *Serious eye damage* is the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

Eye irritation is the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

A.3.1.2 Serious eye damage/eye irritation shall be classified using a tiered approach as detailed in figure A.3.1. Emphasis shall be placed upon existing human data (See A.0.2.6), followed by animal data, followed by other sources of information. Classification results directly when the data satisfy the criteria in this section. In case the criteria cannot be directly applied, classification of a substance or a mixture is made on the basis of the total weight of evidence (See A.0.3.1). This means that all available information bearing on the determination of serious eye damage/eye irritation is considered together, including the results of appropriate scientifically validated in vitro tests, relevant animal data, and human data such as epidemiological and clinical studies and well-documented case reports and observations.

A.3.2 Classification criteria for substances using animal test data

A.3.2.1 Irreversible effects on the eye/serious damage to eyes (Category 1)

A single hazard category is provided in Table A.3.1, for substances that have the potential to seriously damage the eyes. Category 1, irreversible effects on the eye, includes the criteria listed below. These observations include animals with grade 4 cornea lesions and other severe reactions (e.g. destruction of cornea) observed at any time during the test, as well as persistent corneal opacity, discoloration of the cornea by a dye substance, adhesion, pannus, and interference with the function of the iris or other effects that impair sight. In this context, persistent lesions are considered those which are not fully reversible within an observation period of normally 21 days. Category 1 also contains substances fulfilling the criteria of corneal opacity ≥ 3 and/or iritis > 1.5 detected in a Draize eye test with rabbits, because severe lesions like these usually do not reverse within a 21-day observation period.

Table A.3.1: Irreversible eye effects

A substance is classified as Serious **Eye Damage Category 1 (irreversible effects on the eye)** when it produces:

(a) at least in one tested animal, effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 days; and/or

(b) at least in 2 of 3 tested animals, a positive response of:

(i) corneal opacity ≥ 3; and/or

(ii) iritis > 1.5;

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance.

A.3.2.2 Reversible effects on the eye (Category 2)

A single category is provided in Table A.3.2 for substances that have the potential to induce reversible eye irritation.

Table A.3.2: Reversible eye effects

A substance is classified as **Eye irritant Category 2A (irritating to eyes)** when it produces in at least in 2 of 3 tested animals a positive response of:

(i) corneal opacity ≥ 1; and/or

(ii) iritis ≥ 1; and/or

(iii) conjunctival redness ≥ 2; and/or

(iv) conjunctival edema (chemosis) ≥ 2

calculated as the mean scores following grading at 24, 48 and 72 hours after instillation of the substance, and which fully reverses within an observation period of normally 21 days.

An eye irritant is considered **mildly irritating to eyes (Category 2B)** when the effects listed above are fully reversible within 7 days of observation.

A.3.2.3 For those chemicals where there is pronounced variability among animal responses, this information may be taken into account in determining the classification.

A.3.3 Classification Criteria for Substances Using Other Data Elements

A.3.3.1 Existing human and animal data should be the first line of analysis, as they give information directly relevant to effects on the eye. Possible skin corrosion shall be evaluated prior to consideration of serious eye damage/eye irritation in order to avoid testing for local effects on eyes with skin corrosive substances. *In vitro* alternatives that have been scientifically validated and accepted shall be used to make classification decisions. Likewise, pH extremes like ≤ 2 and ≥ 11.5, may indicate serious eye damage, especially when associated with significant buffering capacity. Generally, such substances are expected to produce significant effects on the eyes. In the absence of any other information, a mixture/substance is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance may not have the potential to cause serious eye damage

despite the low or high pH value, then further evaluation may be necessary. In some cases enough information may be available from structurally related compounds to make classification decisions.

A.3.3.2 A tiered approach to the evaluation of initial information shall be used where applicable, recognizing that all elements may not be relevant in certain cases (Figure A.3.1).

A.3.3.3 The tiered approach explains how to organize existing information on a substance and to make a weight-of-evidence decision, where appropriate, about hazard assessment and hazard classification.

A.3.3.4 All the above information that is available on a substance shall be evaluated. Although information might be gained from the evaluation of single parameters within a tier, consideration should be given to the totality of existing information and making an overall weight of evidence determination. This is especially true when there is conflict in information available on some parameters.

Figure A.3.1: Evaluation strategy for serious eye damage and eye irritation (see also Figure A.2.1)

Step	Parameter		Finding		Conclusion
1a:	Existing human or animal data[1]	→	Serious Eye Damage	→	Category 1[2]
	↓	↘	Eye Irritant	→	Category 2[2]
	No/Insufficient data or unknown				
	↓				
1b:	Existing human or animal data, skin corrosion	→	Skin corrosive	→	Category 1[2]
	↓				
	No/Insufficient data or unknown				
	↓				
1c:	Existing human or animal data, eye[1]	→	Existing data that show that a substance does not cause serious eye damage or eye irritation	→	Not Classified
	↓				
	No/Insufficient data				
	↓				
2:	Other, existing skin/eye data in animals[3]	→	Yes, existing data that show that a substance does not cause serious eye damage or eye irritation	→	Category[1] or Category 2[2]
	↓				
	No/Insufficient data				
	↓				
3:	Existing *ex vivo/in vitro* data[4]	→	Positive: serious eye damage	→	Category[1]
	↓	↘	Positive: eye irritant	→	Category 2[2]
	No/Insufficient data/negative response				
	↓				
4:	pH-Based assessment (with consideration of buffering capacity of the chemical, or no buffering capacity data)[5]	→	pH≤ 2 or ≥11.5	→	Category 1[2]
	↓				
	Not pH extreme, no pH data, or extreme pH with low/no buffering capacity				
	↓				
5:	Validated structure/activity relationship (SAR) models	→	Skin corrosive	→	Category[2]
	↓	↘	Skin irritant		Category 2[2]
	No/Insufficient data				

Figure A.3.1: Evaluation strategy for serious eye damage and eye irritation (see also Figure A.2.1)					
	↓				
6:	Consideration of the total Weight of Evidence[6]	→	Serious Eye Damage	→	Category 1[2]
		↘	Eye irritant		Category 2[2]
	↓				
	No concern based on consideration of the sum of available data				
	↓				
7:	**Not Classified**		→		Not classified

Notes to Figure A.3.1:

1. Evidence of existing human or animal data may be derived from single or repeated exposure(s) in occupational, consumer, transportation, or emergency response scenarios; from ethically-conducted human clinical studies; or from purposely-generated data from animal studies conducted according to scientifically validated test methods. At present, there are no internationally accepted test methods for human skin or eye irritation testing.

2. Classify in the appropriate harmonized category, as shown in Tables A.3.1 and A.3.2.

3. Pre-existing animal data should be carefully reviewed to determine if sufficient skin or eye corrosion/irritation evidence is available through other, similar information.

4. Evidence from studies using scientifically validated protocols with isolated human/animal tissues or other, non-tissue-based, though scientifically validated, protocols should be assessed. Examples of, scientifically validated test methods for identifying eye corrosives and severe irritants (i.e., Serious Eye Damage) include OECD TG 437 (Bovine Corneal Opacity and Permeability (BCOP)) and TG 438 (Isolated Chicken Eye). Positive test results from a scientifically validated in vitro test for skin corrosion would likely also lead to a conclusion to classify as causing Serious Eye Damage.

5. Measurement of pH alone may be adequate, but assessment of acid or alkali reserve (buffering capacity) would be preferable.

6. All information that is available on a chemical should be considered and an overall determination made on the total weight of evidence. This is especially true when there is conflict in information available on some parameters. The weight of evidence including information on skin irritation could lead to classification of eye irritation. It is recognized that not all skin irritants are eye irritants as well. Professional judgment should be exercised in making such a determination.

A.3.4 Classification criteria for mixtures

A.3.4.1 Classification of mixtures when data are available for the complete mixture

A.3.4.1.1 The mixture will be classified using the criteria for substances

A.3.4.1.2 Unlike other hazard classes, there are alternative tests available for skin corrosivity of certain types of chemicals that can give an accurate result for classification purposes, as well as being simple and relatively inexpensive to perform. When considering testing of the mixture, chemical manufacturers are encouraged to use a tiered weight of evidence strategy as included in the criteria for classification of substances for skin corrosion and serious eye damage and eye irritation to help ensure an accurate classification, as well as avoid unnecessary animal testing. In the absence of any other information, a mixture is considered to cause serious eye damage (Eye Category 1) if it has a pH ≤ 2 or ≥ 11.5. However, if consideration of acid/alkaline reserve suggests the substance or mixture may not have the potential to cause serious eye damage despite the low or high pH value, then further evaluation may be necessary.

A.3.4.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.3.4.2.1 Where the mixture itself has not been tested to determine its skin corrosivity or potential to cause serious eye damage or eye irritation, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles, as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, and Aerosols.

A.3.4.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.3.4.3.1 For purposes of classifying the eye corrosion/irritation hazards of mixtures in the tiered approach:

The "relevant ingredients" of a mixture are those which are present in concentrations ≥1% (weight/weight for solids, liquids, dusts, mists and vapors and volume/volume for gases.) If the classifier has reason to suspect that an ingredient present at a concentration <1% will affect classification of the mixture for eye corrosion/irritation, that ingredient shall also be considered relevant.

A.3.4.3.2 In general, the approach to classification of mixtures as seriously damaging to the eye or eye irritant when data are available on the ingredients, but not on the mixture as a whole, is based on the theory of additivity, such that each corrosive or irritant ingredient contributes to the overall irritant or corrosive properties of the mixture in proportion to its potency and concentration. A weighting factor of 10 is used for corrosive ingredients when they are present at a concentration below the concentration limit for classification with Category 1, but are at a concentration that will contribute to the classification of the mixture as an irritant. The mixture is classified as seriously damaging to the eye or eye irritant when the sum of the concentrations of such ingredients exceeds a threshold cut-off value/concentration limit.

A.3.4.3.3 Table A.3.3 provides the cut-off value/concentration limits to be used to determine if the mixture should be classified as seriously damaging to the eye or an eye irritant.

A.3.4.3.4 Particular care must be taken when classifying certain types of chemicals such as acids and bases, inorganic salts, aldehydes, phenols, and surfactants. The approach explained in A.3.4.3.1 and A.3.4.3.2 might not work given that many of such substances are corrosive or irritant at concentrations < 1%. For mixtures containing strong acids or bases, the pH should be used as classification criteria (See A.3.4.1) since pH will be a better indicator of serious eye damage than the concentration limits of Table A.3.3. A mixture containing corrosive or irritant ingredients that cannot be classified based on the additivity approach applied in Table A.3.3 due to chemical characteristics that make this approach unworkable, should be classified as Eye Category 1 if it contains ≥ 1% of a corrosive ingredient and as Eye Category 2 when it contains ≥ 3% of an irritant

ingredient. Classification of mixtures with ingredients for which the approach in Table A.3.3 does not apply is summarized in Table A.3.4.

A.3.4.3.5 On occasion, reliable data may show that the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic cut-off values/concentration limits mentioned in Tables A.3.3 and A.3.4. In these cases the mixture could be classified according to those data (See also A.0.4.3 *Use of cut-off values/concentration limits*"). On occasion, when it is expected that the skin corrosion/irritation or the reversible/irreversible eye effects of an ingredient will not be evident when present at a level above the generic concentration/cut-off levels mentioned in Tables A.3.3 and A.3.4, testing of the mixture may be considered. In those cases, the tiered weight of evidence strategy should be applied as referred to in section A.3.3, Figure A.3.1 and explained in detail in this chapter.

A.3.4.3.6 If there are data showing that (an) ingredient(s) may be corrosive or irritant at a concentration of < 1% (corrosive) or < 3% (irritant), the mixture should be classified accordingly (See also paragraph A.0.4.3, *Use of cut-off values/concentration limits*).

Table A.3.3: Concentration of ingredients of a mixture classified as Skin Category 1 and/or Eye Category 1 or 2 that would trigger classification of the mixtures as hazardous to the eye

Sum of ingredients classified as	Concentration triggering classification of a mixture as	
	Irreversible eye effects	Reversible eye effects
	Category 1	Category 2
Eye or Skin Category 1	≥ 3%	≥ 1% but < 3%
Eye Category 2		≥ 10%
(10 x Eye Category 1) + Eye Category 2		≥ 10%
Skin Category 1 + Eye Category 1	≥ 3%	≥ 1% but < 3%
10 x (Skin Category 1 + Eye Category 1) + Eye Category 2		≥ 10%

Note: A mixture may be classified as Eye Category 2B in cases when all relevant ingredients are classified as Eye Category 2B.

Table A.3.4: Concentration of ingredients of a mixture for which the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤ 2	≥ 1%	Category 1
Base with pH ≥ 11.5	≥ 1%	Category 1
Other corrosive (Category 1) ingredients for which additivity does not apply	≥ 1%	Category 1
Other irritant (Category 2) ingredients for which additivity does not apply, including acids and bases	≥ 3%	Category 2

A.4 RESPIRATORY OR SKIN SENSITIZATION

A.4.1 Definitions and general considerations

A.4.1.1 *Respiratory sensitizer* means a chemical that will lead to hypersensitivity of the airways following inhalation of the chemical.

Skin sensitizer means a chemical that will lead to an allergic response following skin contact.

A.4.1.2 For the purpose of this chapter, sensitization includes two phases: the first phase is induction of specialized immunological memory in an individual by exposure to an allergen. The second phase is elicitation, i.e., production of a cell-mediated or antibody-mediated allergic response by exposure of a sensitized individual to an allergen.

A.4.1.3 For respiratory sensitization, the pattern of induction followed by elicitation phases is shared in common with skin sensitization. For skin sensitization, an induction phase is required in which the immune system learns to react; clinical symptoms can then arise when subsequent exposure is sufficient to elicit a visible skin reaction (elicitation phase). As a consequence, predictive tests usually follow this pattern in which there is an induction phase, the response to which is measured by a standardized elicitation phase, typically involving a patch test. The local lymph node assay is the exception, directly measuring the induction response. Evidence of skin sensitization in humans normally is assessed by a diagnostic patch test.

A.4.1.4 Usually, for both skin and respiratory sensitization, lower levels are necessary for elicitation than are required for induction.

A.4.1.5 The hazard class "respiratory or skin sensitization" is differentiated into:

(a) Respiratory sensitization; and

(b) Skin sensitization

A.4.2 Classification criteria for substances

A.4.2.1 Respiratory sensitizers

A.4.2.1.1 Hazard categories

A.4.2.1.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for respiratory sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.1 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals.

A.4.2.1.1.2 Where data are not sufficient for sub-categorization, respiratory sensitizers shall be classified in Category 1.

Table A.4.1: Hazard category and sub-categories for respiratory sensitizers

Category 1:	Respiratory sensitizer
	A substance is classified as a respiratory sensitizer (a) if there is evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests.[1] Severity of reaction may also be considered.

A.4.2.1.2 Human evidence

A.4.2.1.2.1 Evidence that a substance can lead to specific respiratory hypersensitivity will normally be based on human experience. In this context, hypersensitivity is normally seen as asthma, but other hypersensitivity reactions such as rhinitis/conjunctivitis and alveolitis are also considered. The condition will have the clinical character of an allergic reaction. However, immunological mechanisms do not have to be demonstrated.

A.4.2.1.2.2 When considering the human evidence, it is necessary that in addition to the evidence from the cases, the following be taken into account:

(a) the size of the population exposed;

(b) the extent of exposure.

A.4.2.1.2.3 The evidence referred to above could be:

(a) clinical history and data from appropriate lung function tests related to exposure to the substance, confirmed by other supportive evidence which may include:

(i) in vivo immunological test (e.g., skin prick test);

(ii) in vitro immunological test (e.g., serological analysis);

(iii) studies that may indicate other specific hypersensitivity reactions where immunological mechanisms of action have not been proven, e.g., repeated low-level irritation, pharmacologically mediated effects;

(iv) a chemical structure related to substances known to cause respiratory hypersensitivity;

(b) data from positive bronchial challenge tests with the substance conducted according to accepted guidelines for the determination of a specific hypersensitivity reaction.

A.4.2.1.2.4 Clinical history should include both medical and occupational history to determine a relationship between exposure to a specific substance and development of respiratory hypersensitivity. Relevant information includes aggravating factors both in the home and workplace, the onset and progress of the disease, family history and medical history of the patient in question. The medical history should also include a note of other allergic or airway disorders from childhood and smoking history.

A.4.2.1.2.5 The results of positive bronchial challenge tests are considered to provide sufficient evidence for classification on their own. It is, however, recognized that in practice many of the examinations listed above will already have been carried out.

A.4.2.1.3 Animal studies

A.4.2.1.3.1 Data from appropriate animal studies which may be indicative of the potential of a substance to cause sensitization by inhalation in humans may include:

(a) measurements of Immunoglobulin E (IgE) and other specific immunological parameters, for example in mice

(b) specific pulmonary responses in guinea pigs.

A.4.2.2 Skin sensitizers

A.4.2.2.1 Hazard categories

A.4.2.2.1.1 Effects seen in either humans or animals will normally justify classification in a weight of evidence approach for skin sensitizers. Substances may be allocated to one of the two sub-categories 1A or 1B using a weight of evidence approach in accordance with the criteria given in Table A.4.2 and on the basis of reliable and good quality evidence from human cases or epidemiological studies and/or observations from appropriate studies in experimental animals according to the guidance values provided in A.4.2.2.2.1 and A.4.2.2.3.2 for sub-category 1A and in A.4.2.2.2.2 and A.4.2.2.3.3 for sub-category 1B.

A.4.2.2.1.2 Where data are not sufficient for sub-categorization, skin sensitizers shall be classified in Category 1.

Table A.4.2: Hazard category and sub-categories for skin sensitizers

Category 1:	**Skin sensitizer**
	A substance is classified as a skin sensitizer (a) if there is evidence in humans that the substance can lead to sensitization by skin contact in a substantial number of persons, or (b) if there are positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals can be presumed to have the potential to produce significant sensitization in humans. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals can be presumed to have the potential to produce sensitization in humans. Severity of reaction may also be considered.

A.4.2.2.2 Human evidence

A.4.2.2.2.1 Human evidence for sub-category 1A may include:

(a) positive responses at ≤ 500 μg/cm^2 (Human Repeat Insult Patch Test (HRIPT), Human Maximization Test (HMT) – induction threshold);

(b) diagnostic patch test data where there is a relatively high and substantial incidence of reactions in a defined population in relation to relatively low exposure;

(c) other epidemiological evidence where there is a relatively high and substantial incidence of allergic contact dermatitis in relation to relatively low exposure.

A.4.2.2.2.2 Human evidence for sub-category 1B may include:

(a) positive responses at > 500 μg/cm^2 (HRIPT, HMT – induction threshold);

(b) diagnostic patch test data where there is a relatively low but substantial incidence of reactions in a defined population in relation to relatively high exposure;

(c) other epidemiological evidence where there is a relatively low but substantial incidence of allergic contact dermatitis in relation to relatively high exposure.

A.4.2.2.3 Animal studies

A.4.2.2.3.1 For Category 1, when an adjuvant type test method for skin sensitization is used, a response of at least 30% of the animals is considered as positive. For a non-adjuvant Guinea pig test method a response of at least 15% of the animals is considered positive. For Category 1, a stimulation index of three or more is considered a positive response in the local lymph node assay.

A.4.2.2.3.2 Animal test results for sub-category 1A can include data with values indicated in Table A.4.3 below:

Table A.4.3: Animal test results for sub-category 1A

Assay	Criteria
Local lymph node assay	EC3 value ≤ 2%
Guinea pig maximization test	≥ 30% responding at ≤ 0.1% intradermal induction dose or ≥ 60% responding at > 0.1% to ≤ 1% intradermal induction dose
Buehler assay	≥ 15% responding at ≤ 0.2% topical induction dose or ≥ 60% responding at > 0.2% to ≤ 20% topical induction dose

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.3.3 Animal test results for sub-category 1B can include data with values indicated in Table A.4.4 below:

Table A.4.4: Animal test results for sub-category 1B

Assay	Criteria
Local lymph node assay	EC3 value > 2%
Guinea pig maximization test	≥ 30% to < 60% responding at > 0.1% to ≤ 1% intradermal induction dose or ≥ 30% responding at > 1% intradermal induction dose
Buehler assay	≥ 15% to < 60% responding at > 0.2% to ≤ 20% topical induction dose or ≥ 15% responding at > 20% topical induction dose

Note: EC3 refers to the estimated concentration of test chemical required to induce a stimulation index of 3 in the local lymph node assay.

A.4.2.2.4 Specific considerations

A.4.2.2.4.1 For classification of a substance, evidence shall include one or more of the following using a weight of evidence approach:

(a) Positive data from patch testing, normally obtained in more than one dermatology clinic;

(b) Epidemiological studies showing allergic contact dermatitis caused by the substance. Situations in which a high proportion of those exposed exhibit characteristic symptoms are to be looked at with special concern, even if the number of cases is small;

(c) Positive data from appropriate animal studies;

(d) Positive data from experimental studies in man (See paragraph A.0.2.6 of this Appendix);

(e) Well documented episodes of allergic contact dermatitis, normally obtained in more than one dermatology clinic;

(f) Severity of reaction.

A.4.2.2.4.2 Evidence from animal studies is usually much more reliable than evidence from human exposure. However, in cases where evidence is available from both sources, and there is conflict between the results, the quality and reliability of the evidence from both sources must be assessed in order to resolve the question of classification on a case-by-case basis. Normally, human data are not generated in controlled experiments with volunteers for the purpose of hazard classification but rather as part of risk assessment to confirm lack of effects seen in animal tests. Consequently, positive human data on skin sensitization are usually derived from case-control or other, less defined studies. Evaluation of human data must, therefore, be carried out with caution as the frequency of cases reflect, in addition to the inherent properties of the substances, factors such as the exposure situation, bioavailability, individual predisposition and preventive measures taken. Negative human data should not normally be used to negate positive results from animal studies. For both animal and human data, consideration should be given to the impact of vehicle.

A.4.2.2.4.3 If none of the above-mentioned conditions are met, the *substance* need not be classified as a skin sensitizer. However, a combination of two or more indicators of skin sensitization, as listed below, may alter the decision. This shall be considered on a case-by-case basis.

(a) Isolated episodes of allergic contact dermatitis;

(b) Epidemiological studies of limited power, e.g., where chance, bias or confounders have not been ruled out fully with reasonable confidence;

(c) Data from animal tests, performed according to existing guidelines, which do not meet the criteria for a positive result described in A.4.2.2.3, but which are sufficiently close to the limit to be considered significant;

(d) Positive data from non-standard methods;

(e) Positive results from close structural analogues.

A.4.2.2.4.4 Immunological contact urticaria

A.4.2.2.4.4.1 Substances meeting the criteria for classification as respiratory sensitizers may, in addition, cause immunological contact urticaria. Consideration shall be given to classifying these substances as skin sensitizers.

A.4.2.2.4.4.2 Substances which cause immunological contact urticaria without meeting the criteria for respiratory sensitizers shall be considered for classification as skin sensitizers.

A.4.2.2.4.4.3 There is no recognized animal model available to identify substances which cause immunological contact urticaria. Therefore, classification will normally be based on human evidence, similar to that for skin sensitization.

A.4.3 Classification criteria for mixtures

A.4.3.1 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence, as described in the criteria for substances, from human experience or appropriate studies in experimental animals, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care must be exercised in evaluating data on mixtures that the dose used does not render the results inconclusive.

A.4.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.4.3.2.1 Where the mixture itself has not been tested to determine its sensitizing properties, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following agreed bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation, Substantially similar mixtures, and Aerosols.

A.4.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

The mixture shall be classified as a respiratory or skin sensitizer when at least one ingredient has been classified as a respiratory or skin sensitizer and is present at or above the appropriate cut-off value/concentration limit for the specific endpoint as shown in Table A.4.5.

Table A.4.5: Cut-off values/concentration limits of ingredients of a mixture classified as either respiratory sensitizers or skin sensitizers that would trigger classification of the mixture

Ingredient classified as:	Cut-off values/concentration limits triggering classification of a mixture as:		
	Respiratory Sensitizer Category 1		Skin Sensitizer Category 1
	Solid/Liquid	Gas	All physical states
Respiratory Sensitizer Category 1	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1A	≥ 0.1%	≥ 0.1%	
Respiratory Sensitizer Sub-category 1B	≥ 0.1%	≥ 0.2%	
Skin Sensitizer Category 1			≥ 0.1%
Skin Sensitizer Sub-category 1A			≥ 0.1%
Skin Sensitizer Sub-category 1B			≥ 1.0%

A.5 GERM CELL MUTAGENICITY

A.5.1 Definitions and general considerations

A.5.1.1 A *mutation* is defined as a permanent change in the amount or structure of the genetic material in a cell. The term *mutation* applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The term *mutagenic* and *mutagen* will be used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

A.5.1.2 The more general terms *genotoxic* and *genotoxicity* apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Genotoxicity test results are usually taken as indicators for mutagenic effects.

A.5.1.3 This hazard class is primarily concerned with chemicals that may cause mutations in the germ cells of humans that can be transmitted to the progeny. However, mutagenicity/genotoxicity tests in vitro and in mammalian somatic cells *in vivo* are also considered in classifying substances and mixtures within this hazard class.

A.5.2 Classification criteria for substances

A.5.2.1 The classification system provides for two different categories of germ cell mutagens to accommodate the weight of evidence available. The two-category system is described in the Figure A.5.1.

Figure A.5.1: Hazard categories for germ cell mutagens

Category 1:	**Substances known to induce heritable mutations or to be regarded as if they induce heritable mutation in the germ cells of humans**
Category 1A:	**Substances known to induce heritable mutation in germ cells of humans** Positive evidence from human epidemiological studies.
Category 1B:	**Substances which should be regarded as if they induce heritable mutations in the germ cells of humans** (a) Positive result(s) from *in vivo* heritable germ cell mutagenicity tests in mammals; or (b) Positive result(s) from *in vivo* somatic cell mutagenicity tests in mammals, in combination with some evidence that the substance has potential to cause mutations to germ cells. This supporting evidence may, for example, be derived from mutagenicity/genotoxicity tests in germ cells *in vivo*, or by demonstrating the ability of the substance or its metabolite(s) to interact with the genetic material of germ cells; or (c) Positive results from tests showing mutagenic effects in the germ cells of humans, without demonstration of transmission to progeny; for example, an increase in the frequency of aneuploidy in sperm cells of exposed people.
Category 2:	**Substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans** Positive evidence obtained from experiments in mammals and/or in some cases from *in vitro* experiments, obtained from: (a) Somatic cell mutagenicity tests *in vivo*, in mammals; or (b) Other *in vivo* somatic cell genotoxicity tests which are supported by positive results from in vitro mutagenicity assays. *Note: Substances which are positive in* in vitro *mammalian mutagenicity assays, and which also show chemical structure activity relationship to known germ cell mutagens, should be considered for classification as Category 2 mutagens.*

A.5.2.2 Specific considerations for classification of substances as germ cell mutagens:

A.5.2.2.1 To arrive at a classification, test results are considered from experiments determining mutagenic and/or genotoxic effects in germ and/or somatic cells of exposed animals. Mutagenic and/or genotoxic effects determined in in vitro tests shall also be considered.

A.5.2.2.2 The system is hazard based, classifying chemicals on the basis of their intrinsic ability to induce mutations in germ cells. The scheme is, therefore, not meant for the (quantitative) risk assessment of chemical substances.

A.5.2.2.3 Classification for heritable effects in human germ cells is made on the basis of scientifically validated tests. Evaluation of the test results shall be done using expert judgment and all the available evidence shall be weighed for classification.

A.5.2.2.4 The classification of substances shall be based on the total weight of evidence available, using expert judgment. In those instances where a single well-conducted test is used for classification, it shall provide clear and unambiguously positive results. The relevance of the route of exposure used in the study of the substance compared to the route of human exposure should also be taken into account.

A.5.3 Classification criteria for mixtures

A.5.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.5.3.1.1 Classification of mixtures shall be based on the available test data for the individual ingredients of the mixture using cut-off values/ concentration limits for the ingredients classified as germ cell mutagens.

A.5.3.1.2 The mixture will be classified as a mutagen when at least one ingredient has been classified as a Category 1A, Category 1B or Category 2 mutagen and is present at or above the appropriate cut-off value/ concentration limit as shown in Table A.5.1 below for Category 1 and 2 respectively.

Table A.5.1: Cut-off values/concentration limits of ingredients of a mixture classified as germ cell mutagens that would trigger classification of the mixture

	Cut-off/concentration limits triggering classification of a mixture as:	
Ingredient classified as:	**Category 1 mutagen**	**Category 2 mutagen**
Category 1A/B mutagen	≥ 0.1 %	—
Category 2 mutagen	—	≥ 1.0 %
Note: The cut-off values/concentration limits in the table above apply to solids and liquids (w/w units) as well as gases (v/v units).		

A.5.3.2 Classification of mixtures when data are available for the mixture itself

The classification may be modified on a case-by-case basis based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g. statistical analysis, test sensitivity) of germ cell mutagenicity test systems.

A.5.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.5.3.3.1 Where the mixture itself has not been tested to determine its germ cell mutagenicity hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.5.4 Examples of scientifically validated test methods:

A.5.4.1 Examples of *in vivo* heritable germ cell mutagenicity tests are:

(a) Rodent dominant lethal mutation test (OECD 478)

(b) Mouse heritable translocation assay (OECD 485)

(c) Mouse specific locus test

A.5.4.2 Examples of *in vivo* somatic cell mutagenicity tests are:

(a) Mammalian bone marrow chromosome aberration test (OECD 475)

(b) Mouse spot test (OECD 484)

(c) Mammalian erythrocyte micronucleus test (OECD 474)

A.5.4.3 Examples of mutagenicity/genotoxicity tests in germ cells are:

(a) Mutagenicity tests:

(i) Mammalian spermatogonial chromosome aberration test (OECD 483)

(ii) Spermatid micronucleus assay

(b) Genotoxicity tests:

(i) Sister chromatid exchange analysis in spermatogonia

(ii) Unscheduled DNA synthesis test (UDS) in testicular cells

A.5.4.4 Examples of genotoxicity tests in somatic cells are:

(a) Liver Unscheduled DNA Synthesis (UDS) *in vivo* (OECD 486)

(b) Mammalian bone marrow Sister Chromatid Exchanges (SCE)

A.5.4.5 Examples of *in vitro* mutagenicity tests are:

(a) *In vitro* mammalian chromosome aberration test (OECD 473)

(b) *In vitro* mammalian cell gene mutation test (OECD 476)

(c) Bacterial reverse mutation tests (OECD 471)

A.5.4.6 As new, scientifically validated tests arise, these may also be used in the total weight of evidence to be considered.

A.6 CARCINOGENICITY

A.6.1 Definitions

Carcinogen means a substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

Classification of a substance or mixture as posing a carcinogenic hazard is based on its inherent properties and does not provide information on the level of the human cancer risk which the use of the substance or mixture may represent.

A.6.2 Classification criteria for substances

A.6.2.1 For the purpose of classification for carcinogenicity, substances are allocated to one of two categories based on strength of evidence and additional weight of evidence considerations. In certain instances, route-specific classification may be warranted.

Figure A.6.1: Hazard categories for carcinogens	
Category 1:	**Known or presumed human carcinogens** The classification of a substance as a Category 1 carcinogen is done on the basis of epidemiological and/or animal data. This classification is further distinguished on the basis of whether the evidence for classification is largely from human data (Category 1A) or from animal data (Category 1B):
Category 1A:	**Known to have carcinogenic potential for humans. Classification in this category is largely based on human evidence.**
Category 1B:	**Presumed to have carcinogenic potential for humans. Classification in this category is largely based on animal evidence.** The classification of a substance in Category 1A and 1B is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be derived from: — human studies that establish a causal relationship between human exposure to a substance and the development of cancer (known human carcinogen); or — animal experiments for which there is sufficient evidence to demonstrate animal carcinogenicity (presumed human carcinogen). In addition, on a case by case basis, scientific judgment may warrant a decision of presumed human carcinogenicity derived from studies showing limited evidence of carcinogenicity in humans together with limited evidence of carcinogenicity in experimental animals.
Category 2:	**Suspected human carcinogens** The classification of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or B. This classification is based on strength of evidence together with weight of evidence considerations (See paragraph A.6.2.5). Such evidence may be from either limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies.
Other considerations:	Where the weight of evidence for the carcinogenicity of a substance does not meet the above criteria, any positive study conducted in accordance with established scientific principles, and which reports statistically significant findings regarding the carcinogenic potential of the substance, must be noted on the safety data sheet.

A.6.2.2 Classification as a carcinogen is made on the basis of evidence from reliable and acceptable methods, and is intended to be used for substances which have an intrinsic property to produce such toxic effects. The evaluations are to be based on all existing data, peer-reviewed published studies and additional data accepted by regulatory agencies.

A.6.2.3 *Carcinogen classification* is a one-step, criterion-based process that involves two interrelated determinations: evaluations of strength of evidence and consideration of all other relevant information to place substances with human cancer potential into hazard categories.

A.6.2.4 *Strength of evidence* involves the enumeration of tumors in human and animal studies and determination of their level of statistical significance. Sufficient human evidence demonstrates causality between human exposure and the development of cancer, whereas sufficient evidence in animals shows a causal relationship between the agent and an increased incidence of tumors. Limited evidence in humans is demonstrated by a positive association between exposure and cancer, but a causal relationship cannot be stated. Limited evidence in animals is provided when data suggest a carcinogenic effect, but are less than sufficient. (Guidance on consideration of important factors in the classification of carcinogenicity and a more detailed description of the terms "limited" and "sufficient" have been developed by the International Agency for Research on Cancer (IARC) and are provided in non-mandatory Appendix F.)

A.6.2.5 *Weight of evidence*: Beyond the determination of the strength of evidence for carcinogenicity, a number of other factors should be considered that influence the overall likelihood that an agent may pose a carcinogenic hazard in humans. The full list of factors that influence this determination is very lengthy, but some of the important ones are considered here.

A.6.2.5.1 These factors can be viewed as either increasing or decreasing the level of concern for human carcinogenicity. The relative emphasis accorded to each factor depends upon the amount and coherence of evidence bearing on each. Generally there is a requirement for more complete information to decrease than to increase the level of concern. Additional considerations should be used in evaluating the tumor findings and the other factors in a case-by-case manner.

A.6.2.5.2 Some important factors which may be taken into consideration, when assessing the overall level of concern are:

(a) Tumor type and background incidence;

(b) Multisite responses;

(c) Progression of lesions to malignancy;

(d) Reduced tumor latency;

Additional factors which may increase or decrease the level of concern include:

(e) Whether responses are in single or both sexes;

(f) Whether responses are in a single species or several species;

(g) Structural similarity or not to a substance(s) for which there is good evidence of carcinogenicity;

(h) Routes of exposure;

(i) Comparison of absorption, distribution, metabolism and excretion between test animals and humans;

(j) The possibility of a confounding effect of excessive toxicity at test doses; and,

(k) Mode of action and its relevance for humans, such as mutagenicity, cytotoxicity with growth stimulation, mitogenesis, immunosuppression.

Mutagenicity: It is recognized that genetic events are central in the overall process of cancer development. Therefore evidence of mutagenic activity in vivo may indicate that a substance has a potential for carcinogenic effects.

A.6.2.5.3 A substance that has not been tested for carcinogenicity may in certain instances be classified in Category 1A, Category 1B, or Category 2 based on tumor data from a structural analogue together with substantial support from consideration of other important factors such as formation of common significant metabolites, e.g., for benzidine congener dyes.

A.6.2.5.4 The classification should also take into consideration whether or not the substance is absorbed by a given route(s); or whether there are only local tumors at the site of administration for the tested route(s), and adequate testing by other major route(s) show lack of carcinogenicity.

A.6.2.5.5 It is important that whatever is known of the physico-chemical, toxicokinetic and toxicodynamic properties of the substances, as well as any available relevant information on chemical analogues, i.e., structure

activity relationship, is taken into consideration when undertaking classification.

A.6.3 Classification criteria for mixtures

A.6.3.1 The mixture shall be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or Category 2 carcinogen and is present at or above the appropriate cut-off value/concentration limit as shown in Table A.6.1.

Table A.6.1: Cut-off values/concentration limits of ingredients of a mixture classified as carcinogen that would trigger classification of the mixture

Ingredient classified as:	Category 1 carcinogen	Category 2 carcinogen
Category 1 carcinogen	≥ 0.1 %	
Category 2 carcinogen		≥ 0.1% (note 1)

Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product. However, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ≥1%, both an SDS and a label is required and the information must be included on each.

A.6.3.2 Classification of mixtures when data are available for the complete mixture

A mixture may be classified based on the available test data for the mixture as a whole. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of carcinogenicity test systems.

A.6.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

Where the mixture itself has not been tested to determine its carcinogenic hazard, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data will be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; and Substantially similar mixtures.

A.6.4 Classification of carcinogenicity

A.6.4.1 Chemical manufacturers, importers and employers evaluating chemicals may treat the following sources as establishing that a substance is a carcinogen or potential carcinogen for hazard communication purposes in lieu of applying the criteria described herein:

A.6.4.1.1 National Toxicology Program (NTP), "Report on Carcinogens" (latest edition);

A.6.4.1.2 International Agency for Research on Cancer (IARC) "Monographs on the Evaluation of Carcinogenic Risks to Humans" (latest editions)

A.6.4.2 Where OSHA has included cancer as a health hazard to be considered by classifiers for a chemical covered by 29 CFR Part 1910, Subpart Z, Toxic and Hazardous Substances, chemical manufacturers, importers, and employers shall classify the chemical as a carcinogen.

A.7 REPRODUCTIVE TOXICITY

A.7.1 Definitions and general considerations

A.7.1.1 *Reproductive toxicity* includes *adverse effects on sexual function and fertility* in adult males and females, as well as *adverse effects on development of the offspring*. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in *Germ cell mutagenicity* (See A.5).

A.7.1.2 *Adverse effects on sexual function and fertility* means any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behaviour, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

A.7.1.3 *Adverse effects on development of the offspring* means any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

A.7.1.4 Adverse effects on or via lactation are also included in reproductive toxicity, but for classification purposes, such effects are treated separately (See A.7.2.1).

A.7.2 Classification criteria for substances

A.7.2.1 For the purpose of classification for reproductive toxicity, substances shall be classified in one of two categories in accordance with Figure A.7.1(a). Effects on sexual function and fertility, and on development, shall be considered. In addition, effects on or via lactation shall be classified in a separate hazard category in accordance with Figure A.7.1(b).

Figure A.7.1(a): Hazard categories for reproductive toxicants	
Category 1:	**Known or presumed human reproductive toxicant** Substance shall be classified in Category 1 for reproductive toxicity when they are known to have produced an adverse effect on sexual function and fertility or on development in humans or when there is evidence from animal studies, possibly supplemented with other information, to provide a strong presumption that the substance has the capacity to interfere with reproduction in humans. The classification of a substance is further distinguished on the basis of whether the evidence for classification is primarily from human data (Category 1A) or from animal data (Category 1B).
Category 1A:	**Known human reproductive toxicant** The classification of a substance in this category is largely based on evidence from humans.
Category 1B:	**Presumed human reproductive toxicant** The classification of a substance in this category is largely based on evidence from experimental animals. Data from animal studies shall provide sufficient evidence of an adverse effect on sexual function and fertility or on development in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of other toxic effects. However, when there is mechanistic information that raises doubt about the relevance of the effect for humans, classification in Category 2 may be more appropriate.
Category 2:	**Suspected human reproductive toxicant** Substances shall be classified in Category 2 for reproductive toxicity when there is some evidence from humans or experimental animals, possibly supplemented with other information, of an adverse effect on sexual function and fertility, or on development, in the absence of other toxic effects, or if occurring together with other toxic effects the adverse effect on reproduction is considered not to be a secondary non-specific consequence of the other toxic effects, and where the evidence is not sufficiently convincing to place the substance in Category 1. For instance, deficiencies in the study may make the quality of evidence less convincing, and in view of this, Category 2 would be the more appropriate classification.

Figure A.7.1(b): Hazard category for effects on or via lactation

Effects On Or Via Lactation

Effects on or via lactation shall be classified in a separate single category. Chemicals that are absorbed by women and have been shown to interfere with lactation or that may be present (including metabolites) in breast milk in amounts sufficient to cause concern for the health of a breastfed child, shall be classified to indicate this property hazardous to breastfed babies. This classification shall be assigned on the basis of:

(a) absorption, metabolism, distribution and excretion studies that indicate the likelihood the substance would be present in potentially toxic levels in breast milk; and/or

(b) results of one or two generation studies in animals which provide clear evidence of adverse effect in the offspring due to transfer in the milk or adverse effect on the quality of the milk; and/or

(c) human evidence indicating a hazard to babies during the lactation period.

A.7.2.2 Basis of classification

A.7.2.2.1 Classification is made on the basis of the criteria, outlined above, an assessment of the total weight of evidence, and the use of expert judgment. Classification as a reproductive toxicant is intended to be used for substances which have an intrinsic, specific property to produce an adverse effect on reproduction and substances should not be so classified if such an effect is produced solely as a non-specific secondary consequence of other toxic effects.

A.7.2.2.2 In the evaluation of toxic effects on the developing offspring, it is important to consider the possible influence of maternal toxicity.

A.7.2.2.3 For human evidence to provide the primary basis for a Category 1A classification there must be reliable evidence of an adverse effect on reproduction in humans. Evidence used for classification shall be from well conducted epidemiological studies, if available, which include the use of appropriate controls, balanced assessment, and due consideration of bias or confounding factors. Less rigorous data from studies in humans may be sufficient for a Category 1A classification if supplemented with adequate data from studies in experimental animals, but classification in Category 1B may also be considered.

A.7.2.3 Weight of evidence

A.7.2.3.1 Classification as a reproductive toxicant is made on the basis of an assessment of the total weight of evidence using expert judgment. This means that all available information that bears on the determination of reproductive toxicity is considered together. Included is information such as epidemiological studies and case reports in humans and specific reproduction studies along with sub-chronic, chronic and special study results in animals that provide relevant information regarding toxicity to reproductive and related endocrine organs. Evaluation of substances chemically related to the material under study may also be included, particularly when information on the material is scarce. The weight given to the available evidence will be influenced by factors such as the quality of the studies, consistency of results, nature and severity of effects, level of statistical significance for intergroup differences, number of endpoints affected, relevance of route of administration to humans and freedom from bias. Both positive and negative results are considered together in a weight of evidence determination. However, a single, positive study performed according to good scientific principles and with statistically or biologically significant positive results may justify classification (See also A.7.2.2.3).

A.7.2.3.2 Toxicokinetic studies in animals and humans, site of action and mechanism or mode of action study results may provide relevant information, which could reduce or increase concerns about the hazard to human health. If it is conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a chemical which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.3.3 In some reproductive toxicity studies in experimental animals the only effects recorded may be considered of low or minimal toxicological significance and classification may not necessarily be the outcome. These effects include, for example, small changes in semen parameters or in the incidence of spontaneous defects in the fetus, small changes in the proportions of common fetal variants such as are observed in skeletal examinations, or in fetal weights, or small differences in postnatal developmental assessments.

A.7.2.3.4 Data from animal studies shall provide sufficient evidence of specific reproductive toxicity in the absence of other systemic toxic effects. However, if developmental toxicity occurs together with other toxic effects in the dam (mother), the potential influence of the generalized adverse effects should be assessed to the extent possible. The preferred approach is to consider adverse effects in the embryo/fetus first, and then evaluate maternal toxicity, along with any other factors which are likely to have influenced these effects, as part of the weight of evidence. In general, developmental effects that are observed at maternally toxic doses should not be automatically discounted. Discounting developmental effects that

are observed at maternally toxic doses can only be done on a case-by-case basis when a causal relationship is established or refuted.

A.7.2.3.5 If appropriate information is available it is important to try to determine whether developmental toxicity is due to a specific maternally mediated mechanism or to a non-specific secondary mechanism, like maternal stress and the disruption of homeostasis. Generally, the presence of maternal toxicity should not be used to negate findings of embryo/fetal effects, unless it can be clearly demonstrated that the effects are secondary non-specific effects. This is especially the case when the effects in the offspring are significant, e.g., irreversible effects such as structural malformations. In some situations it is reasonable to assume that reproductive toxicity is due to a secondary consequence of maternal toxicity and discount the effects, for example if the chemical is so toxic that dams fail to thrive and there is severe inanition; they are incapable of nursing pups; or they are prostrate or dying.

A.7.2.4 Maternal toxicity

A.7.2.4.1 Development of the offspring throughout gestation and during the early postnatal stages can be influenced by toxic effects in the mother either through non-specific mechanisms related to stress and the disruption of maternal homeostasis, or by specific maternally-mediated mechanisms. So, in the interpretation of the developmental outcome to decide classification for developmental effects it is important to consider the possible influence of maternal toxicity. This is a complex issue because of uncertainties surrounding the relationship between maternal toxicity and developmental outcome. Expert judgment and a weight of evidence approach, using all available studies, shall be used to determine the degree of influence to be attributed to maternal toxicity when interpreting the criteria for classification for developmental effects. The adverse effects in the embryo/fetus shall be first considered, and then maternal toxicity, along with any other factors which are likely to have influenced these effects, as weight of evidence, to help reach a conclusion about classification.

A.7.2.4.2 Based on pragmatic observation, it is believed that maternal toxicity may, depending on severity, influence development via non-specific secondary mechanisms, producing effects such as depressed fetal weight, retarded ossification, and possibly resorptions and certain malformations in some strains of certain species. However, the limited numbers of studies which have investigated the relationship between developmental effects and general maternal toxicity have failed to demonstrate a consistent, reproducible relationship across species. Developmental effects which occur even in the presence of maternal toxicity are considered to be evidence of developmental toxicity, unless it can be unequivocally demonstrated on a case by case basis that the developmental effects are secondary to maternal toxicity. Moreover, classification shall be considered where there is a significant toxic effect in the offspring, e.g., irreversible effects such as structural malformations, embryo/fetal lethality, or significant post-natal functional deficiencies.

A.7.2.4.3 Classification shall not automatically be discounted for chemicals that produce developmental toxicity only in association with maternal toxicity, even if a specific maternally-mediated mechanism has been demonstrated. In such a case, classification in Category 2 may be considered more appropriate than Category 1. However, when a chemical is so toxic that maternal death or severe inanition results, or the dams (mothers) are prostrate and incapable of nursing the pups, it is reasonable to assume that developmental toxicity is produced solely as a secondary consequence of maternal toxicity and discount the developmental effects. Classification is not necessarily the outcome in the case of minor developmental changes, e.g., a small reduction in fetal/pup body weight or retardation of ossification when seen in association with maternal toxicity.

A.7.2.4.4 Some of the endpoints used to assess maternal toxicity are provided below. Data on these endpoints, if available, shall be evaluated in light of their statistical or biological significance and dose-response relationship.

(a) Maternal mortality: An increased incidence of mortality among the treated dams over the controls shall be considered evidence of maternal toxicity if the increase occurs in a dose-related manner and can be attributed to the systemic toxicity of the test material. Maternal mortality greater than 10% is considered excessive and the data for that dose level shall not normally be considered to need further evaluation.

(b) Mating index (Number of animals with seminal plugs or sperm/ Number of mated x 100)

(c) Fertility index (Number of animals with implants/Number of matings x 100)

(d) Gestation length (If allowed to deliver)

(e) Body weight and body weight change: Consideration of the maternal body weight change and/or adjusted (corrected) maternal body weight shall be included in the evaluation of maternal toxicity whenever such data are available. The calculation of an adjusted (corrected) mean maternal body weight change, which is the difference between the initial and terminal body weight minus the gravid uterine weight (or alternatively, the sum of the weights of the fetuses), may indicate whether the effect is maternal or intrauterine. In rabbits, the body weight gain may not be a useful indicator of maternal toxicity because of normal fluctuations in body weight during pregnancy.

(f) Food and water consumption (if relevant): The observation of a significant decrease in the average food or water consumption in treated dams (mothers) compared to the control group may be useful in evaluating maternal toxicity, particularly when the test material is administered in the diet or drinking water. Changes in food or water consumption must be evaluated in conjunction with maternal body weights when determining if the effects noted are reflective of maternal toxicity or more simply, unpalatability of the test material in feed or water.

(g) Clinical evaluations (including clinical signs, markers, and hematology and clinical chemistry studies): The observation of increased incidence of significant clinical signs of toxicity in treated dams (mothers) relative to the control group is useful in evaluating maternal toxicity. If this is to be used as the basis for the assessment of maternal toxicity, the types, incidence, degree and duration of clinical signs shall be reported in the study. Clinical signs of maternal intoxication include, but are not limited to: coma, prostration, hyperactivity, loss of righting reflex, ataxia, or labored breathing.

(h) Post-mortem data: Increased incidence and/or severity of post-mortem findings may be indicative of maternal toxicity. This can include gross or microscopic pathological findings or organ weight data, including absolute organ weight, organ to body weight ratio, or organ to brain weight ratio. When supported by findings of adverse histopathological effects in the affected organ(s), the observation of a significant change in the average weight of suspected target organ(s) of treated dams (mothers), compared to those in the control group, may be considered evidence of maternal toxicity.

A.7.2.5 Animal and experimental data

A.7.2.5.1 A number of scientifically validated test methods are available, including methods for developmental toxicity testing (e.g., OECD Test

Guideline 414, ICH Guideline S5A, 1993), methods for peri- and post-natal toxicity testing (e.g., ICH S5B, 1995), and methods for one or two-generation toxicity testing (e.g., OECD Test Guidelines 415, 416)

A.7.2.5.2 Results obtained from screening tests (e.g., OECD Guidelines 421 - Reproduction/ Developmental Toxicity Screening Test, and 422 - Combined Repeated Dose Toxicity Study with Reproduction/ Development Toxicity Screening Test) can also be used to justify classification, although the quality of this evidence is less reliable than that obtained through full studies.

A.7.2.5.3 Adverse effects or changes, seen in short- or long-term repeated dose toxicity studies, which are judged likely to impair reproductive function and which occur in the absence of significant generalized toxicity, may be used as a basis for classification, e.g., histopathological changes in the gonads.

A.7.2.5.4 Evidence from *in vitro* assays, or non-mammalian tests, and from analogous substances using structure-activity relationship (SAR), can contribute to the procedure for classification. In all cases of this nature, expert judgment must be used to assess the adequacy of the data. Inadequate data shall not be used as a primary support for classification.

A.7.2.5.5 It is preferable that animal studies are conducted using appropriate routes of administration which relate to the potential route of human exposure. However, in practice, reproductive toxicity studies are commonly conducted using the oral route, and such studies will normally be suitable for evaluating the hazardous properties of the substance with respect to reproductive toxicity. However, if it can be conclusively demonstrated that the clearly identified mechanism or mode of action has no relevance for humans or when the toxicokinetic differences are so marked that it is certain that the hazardous property will not be expressed in humans then a substance which produces an adverse effect on reproduction in experimental animals should not be classified.

A.7.2.5.6 Studies involving routes of administration such as intravenous or intraperitoneal injection, which may result in exposure of the reproductive organs to unrealistically high levels of the test substance, or elicit local damage to the reproductive organs, e.g., by irritation, must be interpreted with extreme caution and on their own are not normally the basis for classification.

A.7.2.5.7 There is general agreement about the concept of a limit dose, above which the production of an adverse effect may be considered to be outside the criteria which lead to classification. Some test guidelines specify a limit dose, other test guidelines qualify the limit dose with a statement that higher doses may be necessary if anticipated human exposure is sufficiently high that an adequate margin of exposure would not be achieved. Also, due to species differences in toxicokinetics, establishing a specific limit dose may not be adequate for situations where humans are more sensitive than the animal model.

A.7.2.5.8 In principle, adverse effects on reproduction seen only at very high dose levels in animal studies (for example doses that induce prostration, severe inappetence, excessive mortality) do not normally lead to classification, unless other information is available, for example, toxicokinetics information indicating that humans may be more susceptible than animals, to suggest that classification is appropriate.

A.7.2.5.9 However, specification of the actual "limit dose" will depend upon the test method that has been employed to provide the test results.

A.7.3 Classification criteria for mixtures

A.7.3.1 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.7.3.1.1 The mixture shall be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1 or Category 2 reproductive toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.7.1 for Category 1 and 2, respectively.

A.7.3.1.2 The mixture shall be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the appropriate cut-off value/ concentration limit specified in Table A.7.1 for the additional category for effects on or via lactation.

Table A.7.1: Cut-off values/concentration limits of ingredients of a mixture classified as reproductive toxicants or for effects on or via lactation that trigger classification of the mixture

	Cut-off values/concentration limits triggering classification of a mixture as:		
Ingredients classified as:	**Category 1 reproductive toxicant**	**Category 2 reproductive toxicant**	**Additional category for effects on or via lactation**
Category 1 reproductive toxicant	≥ 0.1%		
Category 2 reproductive toxicant		≥ 0.1%	
Additional category for effects on or via lactation			≥ 0.1%

A.7.3.2 Classification of mixtures when data are available for the complete mixture

Available test data for the mixture as a whole may be used for classification on a case-by-case basis. In such cases, the test results for the mixture as a whole must be shown to be conclusive taking into account dose and other factors such as duration, observations and analysis (e.g., statistical analysis, test sensitivity) of reproduction test systems.

A.7.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.7.3.3.1 Where the mixture itself has not been tested to determine its reproductive toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, and Substantially similar mixtures.

A.8 SPECIFIC TARGET ORGAN TOXICITY

SINGLE EXPOSURE

A.8.1 Definitions and general considerations

A.8.1.1 *Specific target organ toxicity - single exposure, (STOT-SE)* means specific, non-lethal target organ toxicity arising from a single exposure to a chemical. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following repeated exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – REPEATED EXPOSURE* (A.9 of this Appendix) and is therefore not included here.

A.8.1.2 Classification identifies the chemical as being a specific target organ toxicant and, as such, it presents a potential for adverse health effects in people who are exposed to it.

A.8.1.3 The adverse health effects produced by a single exposure include consistent and identifiable toxic effects in humans; or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism, and these changes are relevant for human health. Human data is the primary source of evidence for this hazard class.

A.8.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.8.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, i.e., principally oral, dermal or inhalation.

A.8.1.6 The classification criteria for specific organ systemic toxicity single exposure are organized as criteria for substances Categories 1 and 2 (See A.8.2.1), criteria for substances Category 3 (See A.8.2.2) and criteria for mixtures (See A.8.3). See also Figure A.8.1.

A.8.2 Classification criteria for substances

A.8.2.1 Substances of Category 1 and Category 2

A.8.2.1.1 Substances shall be classified for immediate or delayed effects separately, by the use of expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values (See A.8.2.1.9). Substances shall then be classified in Category 1 or 2, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.8.1.

Figure A.8.1: Hazard categories for specific target organ toxicity following single exposure

Category 1:	**Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following single exposure** Substances are classified in Category 1 for STOT-SE on the basis of: (a) reliable and good quality evidence from human cases or epidemiological studies; or (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects of relevance to human health were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) to be used as part of weight-of-evidence evaluation.
Category 2:	**Substances that, on the basis of evidence from studies in experimental animals, can be presumed to have the potential to be harmful to human health following single exposure** Substances are classified in Category 2 for STOT-SE on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.8.2.1.9) in order to help in classification. In exceptional cases, human evidence can also be used to place a substance in Category 2 (See A.8.2.1.6).
Category 3:	**Transient target organ effects** There are target organ effects for which a substance does not meet the criteria to be classified in Categories 1 or 2 indicated above. These are effects which adversely alter human function for a short duration after exposure and from which humans may recover in a reasonable period without leaving significant alteration of structure or function. This category only includes narcotic effects and respiratory tract irritation. Substances are classified specifically for these effects as discussed in A.8.2.2.

Note: The primary target organ/system shall be identified where possible, and where this is not possible, the substance shall be identified as a general toxicant. The data shall be evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).

A.8.2.1.2 The relevant route(s) of exposure by which the classified substance produces damage shall be identified.

A.8.2.1.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.8.2.1.4 Weight of evidence of all available data, including human incidents, epidemiology, and studies conducted in experimental animals is used to substantiate specific target organ toxic effects that merit classification.

A.8.2.1.5 The information required to evaluate specific target organ toxicity comes either from single exposure in humans (e.g., exposure at home, in the workplace or environmentally), or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are acute toxicity studies which can include clinical observations and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Results of acute toxicity studies conducted in other species may also provide relevant information.

A.8.2.1.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the chemical shall be classified as Category 1.

A.8.2.1.7 Effects considered to support classification for Category 1 and 2

A.8.2.1.7.1 Classification is supported by evidence associating single exposure to the substance with a consistent and identifiable toxic effect.

A.8.2.1.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.8.2.1.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, and macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and evidence relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity resulting from single exposure;

(b) Significant functional changes, more than transient in nature, in the respiratory system, central or peripheral nervous systems, other organs or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction; and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.8.2.1.8 Effects considered not to support classification for Category 1 and 2

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and/or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant; and,

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.8.2.1.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals for Category 1 and 2

A.8.2.1.9.1 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration "guidance values" are provided for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged.

A.8.2.1.9.2 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the dose/concentration).

A.8.2.1.9.3 The guidance value (C) ranges for single-dose exposure which has produced a significant non-lethal toxic effect are those applicable to acute toxicity testing, as indicated in Table A.8.1.

Table A.8.1: Guidance value ranges for single-dose exposures

		Guidance value ranges for:		
Route of exposure	**Units**	**Category 1**	**Category 2**	**Category 3**
Oral (rat)	mg/kg body weight	C ≤ 300	2000 ≥ C > 300	Guidance values do not apply
Dermal (rat or rabbit)	mg/kg body weight	C ≤ 1000	2000 ≥ C > 1000	
Inhalation (rat) gas	ppmV/4h	C ≤ 2500	20,000 ≥ C > 2500	
Inhalation (rat) vapor	mg/1/4h	C ≤ 10	20 ≥ C > 10	
Inhalation (rat) dust/mist/ fume	mg/l/4h	C ≤ 1.0	5.0 ≥ C > 1.0	

A.8.2.1.9.4 The guidance values and ranges mentioned in Table A.8.1 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. Guidance values are not provided for Category 3 since this classification is primarily based on human data; animal data may be included in the weight of evidence evaluation.

A.8.2.1.9.5 Thus, it is feasible that a specific profile of toxicity occurs at a dose/concentration below the guidance value, e.g., < 2000 mg/kg body weight by the oral route, however the nature of the effect may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 2000 mg/kg body weight by the oral route, and in addition there is supplementary information from other sources, e.g., other single dose studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is the prudent action to take.

A.8.2.1.10 Other considerations

A.8.2.1.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.8.2.1.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to single exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because specific target organ toxicity observed was considered not relevant or significant to humans, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.8.2.1.10.3 A substance that has not been tested for specific target organ toxicity shall, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.8.2.2 Substances of Category 3

A.8.2.2.1 Criteria for respiratory tract irritation

The criteria for classifying substances as Category 3 for respiratory tract irritation are:

(a) Respiratory irritant effects (characterized by localized redness, edema, pruritis and/or pain) that impair function with symptoms such as cough, pain, choking, and breathing difficulties are included. It is recognized that this evaluation is based primarily on human data;

(b) Subjective human observations supported by objective measurements of clear respiratory tract irritation (RTI) (e.g., electrophysiological responses, biomarkers of inflammation in nasal or bronchoalveolar lavage fluids);

(c) The symptoms observed in humans shall also be typical of those that would be produced in the exposed population rather than being an isolated idiosyncratic reaction or response triggered only in individuals with hypersensitive airways. Ambiguous reports simply of "irritation" should be excluded as this term is commonly used to describe a wide range of sensations including those such as smell, unpleasant taste, a tickling sensation, and dryness, which are outside the scope of classification for respiratory tract irritation;

(d) There are currently no scientifically validated animal tests that deal specifically with RTI; however, useful information may be obtained from the single and repeated inhalation toxicity tests. For example, animal studies may provide useful information in terms of clinical signs of toxicity (dyspnoea, rhinitis etc) and histopathology (e.g., hyperemia, edema, minimal inflammation, thickened mucous layer) which are reversible and may be reflective of the characteristic clinical symptoms described above. Such animal studies can be used as part of weight of evidence evaluation; and,

(e) This special classification will occur only when more severe organ effects including the respiratory system are not observed as those effects would require a higher classification.

A.8.2.2.2 Criteria for narcotic effects

The criteria for classifying substances in Category 3 for narcotic effects are:

(a) Central nervous system depression including narcotic effects in humans such as drowsiness, narcosis, reduced alertness, loss of reflexes, lack of coordination, and vertigo are included. These effects can also be manifested as severe headache or nausea, and can lead to reduced judgment, dizziness, irritability, fatigue, impaired memory function, deficits in perception and coordination, reaction time, or sleepiness; and,

(b) Narcotic effects observed in animal studies may include lethargy, lack of coordination righting reflex, narcosis, and ataxia. If these effects are not transient in nature, then they shall be considered for classification as Category 1 or 2.

A.8.3 Classification criteria for mixtures

A.8.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.8.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of this data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.8.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.8.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution, Batching, Concentration of mixtures, Interpolation within one toxicity category, Substantially similar mixtures, or Aerosols.

A.8.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.8.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.8.2 for Categories 1 and 2, respectively.

Table A.8.2: Cut-off values/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

	Cut-off values/concentration limits triggering classification of a mixture as:	
Ingredients classified as:	**Category 1**	**Category 2**
Category 1 Target organ toxicant	≤ 1.0 %	
Category 2 Target organ toxicant		≤ 1.0 %

A.8.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.8.3.4.3 Mixtures shall be classified for either or both single and repeated dose toxicity independently.

A.8.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.8.3.4.5 Care shall be exercised when extrapolating the toxicity of a mixture that contains Category 3 ingredient(s). A cut-off value/concentration limit of 20%, considered as an additive of all Category 3 ingredients for each hazard endpoint, is appropriate; however, this cut-off value/concentration limit may be higher or lower depending on the Category 3 ingredient(s) involved and the fact that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value. Expert judgment shall be exercised. Respiratory tract irritation and narcotic effects are to be evaluated separately in accordance with the criteria given in A.8.2.2. When conducting classifications for these hazards, the contribution of each ingredient should be considered additive, unless there is evidence that the effects are not additive.

A.9 SPECIFIC TARGET ORGAN TOXICITY

REPEATED OR PROLONGED EXPOSURE

A.9.1 Definitions and general considerations

A.9.1.1 *Specific target organ toxicity - repeated exposure (STOT-RE)* means specific target organ toxicity arising from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in A.1 to A.7 and A.10 of this Appendix are included. Specific target organ toxicity following a single-event exposure is classified in accordance with *SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE* (A.8 of this Appendix) and is therefore not included here.

A.9.1.2 Classification identifies the substance or mixture as being a specific target organ toxicant and, as such, it may present a potential for adverse health effects in people who are exposed to it.

A.9.1.3 These adverse health effects produced by repeated exposure include consistent and identifiable toxic effects in humans, or, in experimental animals, toxicologically significant changes which have affected the function or morphology of a tissue/organ, or have produced serious changes to the biochemistry or hematology of the organism and these changes are relevant for human health. Human data will be the primary source of evidence for this hazard class.

A.9.1.4 Assessment shall take into consideration not only significant changes in a single organ or biological system but also generalized changes of a less severe nature involving several organs.

A.9.1.5 Specific target organ toxicity can occur by any route that is relevant for humans, e.g., principally oral, dermal or inhalation.

A.9.2 Classification criteria for substances

A.9.2.1 Substances shall be classified as STOT - RE by expert judgment on the basis of the weight of all evidence available, including the use of recommended guidance values which take into account the duration of exposure and the dose/concentration which produced the effect(s), (See A.9.2.9). Substances shall be placed in one of two categories, depending upon the nature and severity of the effect(s) observed, in accordance with Figure A.9.1.

Figure A.9.1: Hazard categories for specific target organ toxicity following repeated exposure

Category 1:	**Substances that have produced significant toxicity in humans, or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated or prolonged exposure** Substances are classified in Category 1 for specific target organ toxicity (repeated exposure) on the basis of: (a) reliable and good quality evidence from human cases or epidemiological studies; or, (b) observations from appropriate studies in experimental animals in which significant and/or severe toxic effects, of relevance to human health, were produced at generally low exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) to be used as part of weight-of-evidence evaluation.
Category 2:	**Substances that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to be harmful to human health following repeated or prolonged exposure** Substances are classified in Category 2 for specific target organ toxicity (repeated exposure) on the basis of observations from appropriate studies in experimental animals in which significant toxic effects, of relevance to human health, were produced at generally moderate exposure concentrations. Guidance dose/concentration values are provided below (See A.9.2.9) in order to help in classification. In exceptional cases human evidence can also be used to place a substance in Category 2 (See A.9.2.6).
Note: The primary target organ/system shall be identified where possible, or the substance shall be identified as a general toxicant. The data shall be carefully evaluated and, where possible, shall not include secondary effects (e.g., a hepatotoxicant can produce secondary effects in the nervous or gastro-intestinal systems).	

A.9.2.2 The relevant route of exposure by which the classified substance produces damage shall be identified.

A.9.2.3 Classification is determined by expert judgment, on the basis of the weight of all evidence available including the guidance presented below.

A.9.2.4 Weight of evidence of all data, including human incidents, epidemiology, and studies conducted in experimental animals, is used to substantiate specific target organ toxic effects that merit classification.

A.9.2.5 The information required to evaluate specific target organ toxicity comes either from repeated exposure in humans, e.g., exposure at home, in the workplace or environmentally, or from studies conducted in experimental animals. The standard animal studies in rats or mice that provide this information are 28 day, 90 day or lifetime studies (up to 2 years) that include hematological, clinico-chemical and detailed macroscopic and microscopic examination to enable the toxic effects on target tissues/organs to be identified. Data from repeat dose studies performed in other species may also be used. Other long-term exposure studies, e.g., for carcinogenicity, neurotoxicity or reproductive toxicity, may also provide evidence of specific target organ toxicity that could be used in the assessment of classification.

A.9.2.6 In exceptional cases, based on expert judgment, it may be appropriate to place certain substances with human evidence of specific target organ toxicity in Category 2: (a) when the weight of human evidence is not sufficiently convincing to warrant Category 1 classification, and/or (b) based on the nature and severity of effects. Dose/concentration levels in humans shall not be considered in the classification and any available evidence from animal studies shall be consistent with the Category 2 classification. In other words, if there are also animal data available on the substance that warrant Category 1 classification, the substance shall be classified as Category 1.

A.9.2.7 Effects considered to support classification

A.9.2.7.1 Classification is supported by reliable evidence associating repeated exposure to the substance with a consistent and identifiable toxic effect.

A.9.2.7.2 Evidence from human experience/incidents is usually restricted to reports of adverse health consequences, often with uncertainty about exposure conditions, and may not provide the scientific detail that can be obtained from well-conducted studies in experimental animals.

A.9.2.7.3 Evidence from appropriate studies in experimental animals can furnish much more detail, in the form of clinical observations, hematology, clinical chemistry, macroscopic and microscopic pathological examination and this can often reveal hazards that may not be life-threatening but could indicate functional impairment. Consequently all available evidence, and relevance to human health, must be taken into consideration in the classification process. Relevant toxic effects in humans and/or animals include, but are not limited to:

(a) Morbidity or death resulting from repeated or long-term exposure. Morbidity or death may result from repeated exposure, even to relatively low doses/concentrations, due to bioaccumulation of the substance or its metabolites, or due to the overwhelming of the de-toxification process by repeated exposure;

(b) Significant functional changes in the central or peripheral nervous systems or other organ systems, including signs of central nervous system depression and effects on special senses (e.g., sight, hearing and sense of smell);

(c) Any consistent and significant adverse change in clinical biochemistry, hematology, or urinalysis parameters;

(d) Significant organ damage that may be noted at necropsy and/or subsequently seen or confirmed at microscopic examination;

(e) Multi-focal or diffuse necrosis, fibrosis or granuloma formation in vital organs with regenerative capacity;

(f) Morphological changes that are potentially reversible but provide clear evidence of marked organ dysfunction (e.g., severe fatty change in the liver); and,

(g) Evidence of appreciable cell death (including cell degeneration and reduced cell number) in vital organs incapable of regeneration.

A.9.2.8 Effects considered not to support classification

Effects may be seen in humans and/or animals that do not justify classification. Such effects include, but are not limited to:

(a) Clinical observations or small changes in bodyweight gain, food consumption or water intake that may have some toxicological importance but that do not, by themselves, indicate "significant" toxicity;

(b) Small changes in clinical biochemistry, hematology or urinalysis parameters and /or transient effects, when such changes or effects are of doubtful or of minimal toxicological importance;

(c) Changes in organ weights with no evidence of organ dysfunction;

(d) Adaptive responses that are not considered toxicologically relevant;

(e) Substance-induced species-specific mechanisms of toxicity, i.e., demonstrated with reasonable certainty to be not relevant for human health, shall not justify classification.

A.9.2.9 Guidance values to assist with classification based on the results obtained from studies conducted in experimental animals

A.9.2.9.1 In studies conducted in experimental animals, reliance on observation of effects alone, without reference to the duration of experimental exposure and dose/concentration, omits a fundamental concept of toxicology, i.e., all substances are potentially toxic, and what determines the toxicity is a function of the dose/concentration and the duration of exposure. In most studies conducted in experimental animals the test guidelines use an upper limit dose value.

A.9.2.9.2 In order to help reach a decision about whether a substance shall be classified or not, and to what degree it shall be classified (Category 1 vs. Category 2), dose/concentration "guidance values" are provided in Table A.9.1 for consideration of the dose/concentration which has been shown to produce significant health effects. The principal argument for proposing such guidance values is that all chemicals are potentially toxic and there has to be a reasonable dose/concentration above which a degree of toxic effect is acknowledged. Also, repeated-dose studies conducted in experimental animals are designed to produce toxicity at the highest dose used in order to optimize the test objective and so most studies will reveal some toxic effect at least at this highest dose. What is therefore to be decided is not only what effects have been produced, but also at what dose/concentration they were produced and how relevant is that for humans.

A.9.2.9.3 Thus, in animal studies, when significant toxic effects are observed that indicate classification, consideration of the duration of experimental exposure and the dose/concentration at which these effects were seen, in relation to the suggested guidance values, provides useful information to help assess the need to classify (since the toxic effects are a consequence of the hazardous property(ies) and also the duration of exposure and the dose/concentration).

A.9.2.9.4 The decision to classify at all can be influenced by reference to the dose/concentration guidance values at or below which a significant toxic effect has been observed.

A.9.2.9.5 The guidance values refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Haber's rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment should be done on a case-by-case basis; for example, for a 28-day study the guidance values below would be increased by a factor of three.

A.9.2.9.6 Thus for Category 1 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur at or below the (suggested) guidance values (C) as indicated in Table A.9.1 would justify classification:

Table A.9.1: Guidance values to assist in Category 1 classification (applicable to a 90-day study)

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	C ≤ 10
Dermal (rat or rabbit)	mg/kg body weight/day	C ≤ 20
Inhalation (rat) gas	ppmV/6h/day	C ≤ 50
Inhalation (rat) vapor	mg/liter/6h/day	C ≤ 0.2
Inhalation (rat) dust/mist/ fume	mg/liter/6h/day	C ≤ 0.02

A.9.2.9.7 For Category 2 classification, significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals and seen to occur within the (suggested) guidance value ranges as indicated in Table A.9.2 would justify classification:

Table A.9.2: Guidance values to assist in Category 2 classification (applicable to a 90-day study)

Route of exposure	Units	Guidance values (dose/concentration)
Oral (rat)	mg/kg body weight/day	10 < C ≤ 100
Dermal (rat or rabbit)	mg/kg body weight/day	20 < C ≤ 200
Inhalation (rat) gas	ppmV/6h/day	50 < C ≤ 250
Inhalation (rat) vapor	mg/liter/6h/day	0.2 < C ≤ 1.0
Inhalation (rat) dust/mist/ fume	mg/liter/6h/day	0.02 < C ≤ 0.2

A.9.2.9.8 The guidance values and ranges mentioned in A.2.9.9.6 and A.2.9.9.7 are intended only for guidance purposes, i.e., to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values.

A.9.2.9.9 Thus, it is possible that a specific profile of toxicity occurs in repeat-dose animal studies at a dose/concentration below the guidance value, e.g., < 100 mg/kg body weight/day by the oral route, however the nature of the effect, e.g., nephrotoxicity seen only in male rats of a particular strain known to be susceptible to this effect, may result in the decision not to classify. Conversely, a specific profile of toxicity may be seen in animal studies occurring at above a guidance value, e.g., ≥ 100 mg/kg body weight/day by the oral route, and in addition there is supplementary information from other sources, e.g., other long-term administration studies, or human case experience, which supports a conclusion that, in view of the weight of evidence, classification is prudent.

A.9.2.10 Other considerations

A.9.2.10.1 When a substance is characterized only by use of animal data the classification process includes reference to dose/concentration guidance values as one of the elements that contribute to the weight of evidence approach.

A.9.2.10.2 When well-substantiated human data are available showing a specific target organ toxic effect that can be reliably attributed to repeated or prolonged exposure to a substance, the substance shall be classified. Positive human data, regardless of probable dose, predominates over animal data. Thus, if a substance is unclassified because no specific target organ toxicity was seen at or below the dose/concentration guidance value for animal testing, if subsequent human incident data become available showing a specific target organ toxic effect, the substance shall be classified.

A.9.2.10.3 A substance that has not been tested for specific target organ toxicity may in certain instances, where appropriate, be classified on the basis of data from a scientifically validated structure activity relationship and expert judgment-based extrapolation from a structural analogue that has previously been classified together with substantial support from consideration of other important factors such as formation of common significant metabolites.

A.9.3 Classification criteria for mixtures

A.9.3.1 Mixtures are classified using the same criteria as for substances, or alternatively as described below. As with substances, mixtures may be classified for specific target organ toxicity following single exposure, repeated exposure, or both.

A.9.3.2 Classification of mixtures when data are available for the complete mixture

When reliable and good quality evidence from human experience or appropriate studies in experimental animals, as described in the criteria for substances, is available for the mixture, then the mixture shall be classified by weight of evidence evaluation of these data. Care shall be exercised in evaluating data on mixtures, that the dose, duration, observation or analysis, do not render the results inconclusive.

A.9.3.3 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.9.3.3.1 Where the mixture itself has not been tested to determine its specific target organ toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazards of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; Substantially similar mixtures; and Aerosols.

A.9.3.4 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.9.3.4.1 Where there is no reliable evidence or test data for the specific mixture itself, and the bridging principles cannot be used to enable classification, then classification of the mixture is based on the classification of the ingredient substances. In this case, the mixture shall be classified as a specific target organ toxicant (specific organ specified), following single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant and is present at or above the appropriate cut-off value/concentration limit specified in Table A.9.3 for Category 1 and 2 respectively.

Table A.9.3: Cut-off value/concentration limits of ingredients of a mixture classified as a specific target organ toxicant that would trigger classification of the mixture as Category 1 or 2

	Cut-off values/concentration limits triggering classification of a mixture as:	
Ingredient classified as:	**Category 1**	**Category 2**
Category 1 Target organ toxicant	≥ 1.0 %	
Category 2 Target organ toxicant		≥ 1.0 %

A.9.3.4.2 These cut-off values and consequent classifications shall be applied equally and appropriately to both single- and repeated-dose target organ toxicants.

A.9.3.4.3 Mixtures shall be classified for either or both single- and repeated-dose toxicity independently.

A.9.3.4.4 Care shall be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at < 1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

A.10 ASPIRATION HAZARD

A.10.1 Definitions and general and specific considerations

A.10.1.1 *Aspiration* means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

A.10.1.2 Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.

A.10.1.3 Aspiration is initiated at the moment of inspiration, in the time required to take one breath, as the causative material lodges at the crossroad of the upper respiratory and digestive tracts in the laryngopharyngeal region.

A.10.1.4 Aspiration of a substance or mixture can occur as it is vomited following ingestion. This may have consequences for labeling, particularly where, due to acute toxicity, a recommendation may be considered to induce vomiting after ingestion. However, if the substance/mixture also presents an aspiration toxicity hazard, the recommendation to induce vomiting may need to be modified.

A.10.1.5 Specific considerations

A.10.1.5.1 The classification criteria refer to kinematic viscosity. The following provides the conversion between dynamic and kinematic viscosity:

$$\frac{\text{Dynamic viscocity (mPa•s)}}{\text{Density (g/cm3)}} = \text{Kinematic viscosity (mm}^2\text{/s)}$$

A.10.1.5.2 Although the definition of aspiration in A.10.1.1 includes the entry of solids into the respiratory system, classification according to (b) in table A.10.1 for Category 1 is intended to apply to liquid substances and mixtures only.

A.10.1.5.3 Classification of aerosol/mist products

Aerosol and mist products are usually dispensed in containers such as self-pressurized containers, trigger and pump sprayers. Classification for these products shall be considered if their use may form a pool of product in the mouth, which then may be aspirated. If the mist or aerosol from a pressurized container is fine, a pool may not be formed. On the other hand, if a pressurized container dispenses product in a stream, a pool may be formed that may then be aspirated. Usually, the mist produced by trigger and pump sprayers is coarse and therefore, a pool may be formed that then may be aspirated. When the pump mechanism may be removed and contents are available to be swallowed then the classification of the products should be considered.

A.10.2 Classification criteria for substances

Table A.10.1: Criteria for aspiration toxicity

Category	Criteria
Category 1: Chemicals known to cause human aspiration toxicity hazards or to be regarded as if they cause human aspiration toxicity hazard	A substance shall be classified in Category 1: (a) If reliable and good quality human evidence indicates that it causes aspiration toxicity (See note); or (b) If it is a hydrocarbon and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40° C.
Note: Examples of substances included in Category 1 are certain hydrocarbons, turpentine and pine oil.	

A.10.3 Classification criteria for mixtures

A.10.3.1 Classification when data are available for the complete mixture

A mixture shall be classified in Category 1 based on reliable and good quality human evidence.

A.10.3.2 Classification of mixtures when data are not available for the complete mixture: bridging principles

A.10.3.2.1 Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on both the individual ingredients and similar tested mixtures to adequately characterize the hazard of the mixture, these data shall be used in accordance with the following bridging principles as found in paragraph A.0.5 of this Appendix: Dilution; Batching; Concentration of mixtures; Interpolation within one toxicity category; and Substantially similar mixtures. For application of the dilution bridging principle, the concentration of aspiration toxicants shall not be less than 10%.

A.10.3.3 Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

A.10.3.3.1 A mixture which contains ≥ 10% of an ingredient or ingredients classified in Category 1, and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40 °C, shall be classified in Category 1.

A.10.3.3.2 In the case of a mixture which separates into two or more distinct layers, one of which contains ≥ 10 % of an ingredient or ingredients classified in Category 1 and has a kinematic viscosity ≤ 20.5 mm²/s, measured at 40 °C, then the entire mixture shall be classified in Category 1.

[77 FR 17786, 17790, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 78 FR 9313, Feb. 8, 2013]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200 Appendix B
Title: Physical Criteria (Mandatory)

B.1 EXPLOSIVES

B.1.1 Definitions and general considerations

B.1.1.1 An *explosive chemical* is a solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

A *pyrotechnic chemical* is a chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.

An *explosive item* is an item containing one or more explosive chemicals.

A *pyrotechnic item* is an item containing one or more pyrotechnic chemicals.

An *unstable explosive* is an explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.

An *intentional explosive* is a chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

B.1.1.2 The class of explosives comprises:

(a) Explosive chemicals;

(b) Explosive items, except devices containing explosive chemicals in such quantity or of such a character that their inadvertent or accidental ignition or initiation shall not cause any effect external to the device either by projection, fire, smoke, heat or loud noise; and

(c) Chemicals and items not included under (a) and (b) above which are manufactured with the view to producing a practical explosive or pyrotechnic effect.

B.1.2 Classification criteria

Chemicals and items of this class shall be classified as unstable explosives or shall be assigned to one of the following six divisions depending on the type of hazard they present:

(a) Division 1.1 - Chemicals and items which have a mass explosion hazard (a mass explosion is one which affects almost the entire quantity present virtually instantaneously);

(b) Division 1.2 - Chemicals and items which have a projection hazard but not a mass explosion hazard;

(c) Division 1.3 - Chemicals and items which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

(i) Combustion of which gives rise to considerable radiant heat; or

(ii) Which burn one after another, producing minor blast or projection effects or both;

(d) Division 1.4 - Chemicals and items which present no significant hazard: chemicals and items which present only a small hazard in the event of ignition or initiation. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of almost the entire contents of the package;

(e) Division 1.5 - Very insensitive chemicals which have a mass explosion hazard: chemicals which have a mass explosion hazard but are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions;

(f) Division 1.6 - Extremely insensitive items which do not have a mass explosion hazard: items which contain only extremely insensitive detonating chemicals and which demonstrate a negligible probability of accidental initiation or propagation.

B.1.3 Additional classification considerations

B.1.3.1 Explosives shall be classified as unstable explosives or shall be assigned to one of the six divisions identified in B.1.2 in accordance with the three step procedure in Part I of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6). The first step is to ascertain whether the substance or mixture has explosive effects (Test Series 1). The second step is the acceptance procedure (Test Series 2 to 4) and the third step is the assignment to a hazard division (Test Series 5 to 7). The assessment whether a candidate for "ammonium nitrate emulsion or suspension or gel, intermediate for blasting explosives (ANE)" is insensitive enough for inclusion as an oxidizing liquid (See B.13) or an oxidizing solid (See B.14) is determined by Test Series 8 tests.

NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.1.3.2 Explosive properties are associated with the presence of certain chemical groups in a molecule which can react to produce very rapid increases in temperature or pressure. The screening procedure in B.1.3.1 is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the chemical as a potential explosive, the acceptance procedure (See section 10.3 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)) is necessary for classification.

NOTE: Neither a Series 1 type (a) propagation of detonation test nor a Series 2 type (a) test of sensitivity to detonative shock is necessary if the exothermic decomposition energy of organic materials is less than 800 J/g.

B.1.3.3 If a mixture contains any known explosives, the acceptance procedure is necessary for classification.

B.1.3.4 A chemical is not classified as explosive if:

(a) There are no chemical groups associated with explosive properties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6); or

(b) The substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than -200.

The oxygen balance is calculated for the chemical reaction:

$C_xH_yO_z + [x + (y/4)-(z/2)] O2 \rightarrow x. CO_2 + (y/2) H_2O$

using the formula: oxygen balance = -1600 [2x +(y/2) -z]/molecular weight; or

(c) The organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500°C (932°F). The exothermic decomposition energy may be determined using a suitable calorimetric technique; or

(d) For mixtures of inorganic oxidizing substances with organic material(s), the concentration of the inorganic oxidizing substance is:

(i) less than 15%, by mass, if the oxidizing substance is assigned to Category 1 or 2;

(ii) less than 30%, by mass, if the oxidizing substance is assigned to Category 3.

B.2 FLAMMABLE GASES

B.2.1 Definition

Flammable gas means a gas having a flammable range with air at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

B.2.2 Classification criteria

A flammable gas shall be classified in one of the two categories for this class in accordance with Table B.2.1:

Table B.2.1: Criteria For Flammable Gases

Category	Criteria
1	Gases, which at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi): (a) are ignitable when in a mixture of 13% or less by volume in air; or (b) have a flammable range with air of at least 12 percentage points regardless of the lower flammable limit.
2	Gases, other than those of Category 1, which, at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi), have a flammable range while mixed in air.
Note: Aerosols should not be classified as flammable gases. See B.3.	

B.2.3 Additional classification considerations

Flammability shall be determined by tests or by calculation in accordance with ISO 10156 (incorporated by reference; See §1910.6). Where insufficient data are available to use this method, equivalent validated methods may be used.

B.3 FLAMMABLE AEROSOLS

B.3.1 Definition

Aerosol means any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

B.3.2 Classification criteria

B.3.2.1 Aerosols shall be considered for classification as flammable if they contain any component which is classified as flammable in accordance with this Appendix, i.e.:

Flammable liquids (See B.6);

Flammable gases (See B.2);

Flammable solids (See B.7).

NOTE 1: Flammable components do not include pyrophoric, self-heating or water-reactive chemicals.

NOTE 2: Flammable aerosols do not fall additionally within the scope of flammable gases, flammable liquids, or flammable solids.

B.3.2.2 A flammable aerosol shall be classified in one of the two categories for this class in accordance with Table B.3.1.

Table B.3.1: Criteria For Flammable Aerosols

Category	Criteria
1	Contains ≥ 85% flammable components and the chemical heat of combustion is ≥30 kJ/g; or (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥75 cm (29.5 in), or (b) For foam aerosols, in the aerosol foam flammability test (i) the flame height is ≥ 20 cm (7.87 in) and the flame duration ≥2 s; or (ii) the flame height is ≥ 4 cm (1.57 in) and the flame duration ≥7 s.
2	Contains > 1% flammable components, or the heat of combustion is ≥20 kJ/g; and (a) For spray aerosols, in the ignition distance test, ignition occurs at a distance ≥15 cm (5.9 in), or in the enclosed space ignition test, the (i) time equivalent is ≥300 s/m^3; or (ii) Deflagration density is ≥ 300 g/m^3 (b) For foam aerosols, in the aerosol foam flammability test, the flame height is ≥4 cm and the flame duration is ≥2 s and it does not meet the criteria for Category 1
Note: Aerosols not submitted to the flammability classification procedures in this Appendix shall be classified as extremely flammable (Category 1).	

B.3.3 Additional classification considerations

B.3.3.1 To classify a flammable aerosol, data on its flammable components, on its chemical heat of combustion and, if applicable, the results of the aerosol foam flammability test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols) are necessary.

B.3.3.2 The chemical heat of combustion (ΔHc), in kilojoules per gram (kJ/g), is the product of the theoretical heat of combustion (ΔHcomb), and a combustion efficiency, usually less than 1.0 (a typical combustion efficiency is 0.95 or 95%).

For a composite aerosol formulation, the chemical heat of combustion is the summation of the weighted heats of combustion for the individual components, as follows:

$$\Delta Hc\ (product) = \sum_{i}^{n} [\ wi\% \times \Delta Hc(i)\ ]$$

where:
ΔHc = chemical heat of combustion (kJ/g);
wi% = mass fraction of component i in the product;
ΔHc(i) = specific heat of combustion (kJ/g) of component i in the product;

The chemical heats of combustion shall be found in literature, calculated or determined by tests (See ASTM D240-02, ISO 13943, Sections 86.1 to 86.3, and NFPA 30B (incorporated by reference; See §1910.6)).

B.3.3.3 The Ignition Distance Test, Enclosed Space Ignition Test and Aerosol Foam Flammability Test shall be performed in accordance

with sub-sections 31.4, 31.5 and 31.6 of the of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.4 OXIDIZING GASES

B.4.1 Definition

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

NOTE: "Gases which cause or contribute to the combustion of other material more than air does" means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156 or 10156-2 (incorporated by reference, See §1910.6) or an equivalent testing method.)

B.4.2 Classification criteria

An oxidizing gas shall be classified in a single category for this class in accordance with Table B.4.1:

Table B.4.1: Criteria For Oxidizing Gases

Category	Criteria
1	Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

B.4.3 Additional classification considerations

Classification shall be in accordance with tests or calculation methods as described in ISO 10156 (incorporated by reference; See §1910.6) and ISO 10156-2 (incorporated by reference; See §1910.6).

B.5 GASES UNDER PRESSURE

B.5.1 Definition

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more, or which are liquefied or liquefied and refrigerated.

They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

B.5.2 Classification criteria

Gases under pressure shall be classified in one of four groups in accordance with Table B.5.1:

Table B.5.1: Criteria For Gases Under Pressure

Group	Criteria
Compressed gas	A gas which when under pressure is entirely gaseous at -50°C (-58°F), including all gases with a critical temperature[1] ≤ 50°C (-58°F).
Liquefied gas	A gas which when under pressure is partially liquid at temperatures above -50°C (-58°F). A distinction is made between: (a) High pressure liquefied gas: a gas with a critical temperature[1] between -50°C (-58°F) and +65°C (149°F); and (b) Low pressure liquefied gas: a gas with a critical temperature[1] above +65°C (149°F).
Refrigerated liquefied gas	A gas which is made partially liquid because of its low temperature.
Dissolved gas	A gas which when under pressure is dissolved in a liquid phase solvent.

[1] The critical temperature is the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression.

B.6 FLAMMABLE LIQUIDS

B.6.1 Definition

Flammable liquid means a liquid having a flash point of not more than 93°C (199.4°F).

Flash point means the minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Section B.6.3.

B.6.2 Classification criteria

A flammable liquid shall be classified in one of four categories in accordance with Table B.6.1:

Table B.6.1: Criteria For Flammable Liquids

Category	Criteria
1	Flash point < 23°C (73.4°F) and initial boiling point ≤ 35°C (95°F)
2	Flash point < 23°C (73.4°F) and initial boiling point > 35°C (95°F)
3	Flash point ≥ 23°C (73.4°F) and ≤ 60°C (140°F)
4	Flash point > 60°C (140°F) and ≤ 93°C (199.4°F)

B.6.3 Additional classification considerations

The flash point shall be determined in accordance with ASTM D56-05, ASTM D3278, ASTM D3828, ASTM D93-08 (incorporated by reference; See §1910.6), or any other method specified in GHS Revision 3, Chapter 2.6.

The initial boiling point shall be determined in accordance with ASTM D86-07a or ASTM D1078 (incorporated by reference; See §1910.6).

B.7 FLAMMABLE SOLIDS

B.7.1 Definitions

Flammable solid means a solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

Readily combustible solids are powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

B.7.2 Classification criteria

B.7.2.1 Powdered, granular or pasty chemicals shall be classified as flammable solids when the time of burning of one or more of the test runs, performed in accordance with the test method described in the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), Part III, sub-section 33.2.1, is less than 45 s or the rate of burning is more than 2.2 mm/s (0.0866 in/s).

B.7.2.2 Powders of metals or metal alloys shall be classified as flammable solids when they can be ignited and the reaction spreads over the whole length of the sample in 10 min or less.

B.7.2.3 Solids which may cause fire through friction shall be classified in this class by analogy with existing entries (e.g., matches) until definitive criteria are established.

B.7.2.4 A flammable solid shall be classified in one of the two categories for this class using Method N.1 as described in Part III, sub-section 33.2.1 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.7.1:

Table B.7.1: Criteria For Flammable Solids

Category	Criteria
1	Burning rate test: Chemicals other than metal powders: (a) wetted zone does not stop fire; and> (b) burning time <45 s or burning rate >2.2 mm/s Metal powders: burning time ≤5 min
2	Burning rate test: Chemicals other than metal powders: (a) wetted zone stops the fire for at least 4 min; and> (b) burning time <45 s or burning rate >2.2 mm/s Metal powders: burning time >5 min and ≤10 min

Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.8 SELF-REACTIVE CHEMICALS

B.8.1 Definitions

Self-reactive chemicals are thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under this section as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

A self-reactive chemical is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.8.2 Classification criteria

B.8.2.1 A self-reactive chemical shall be considered for classification in this class unless:

(a) It is classified as an explosive according to B.1 of this appendix;

(b) It is classified as an oxidizing liquid or an oxidizing solid according to B.13 or B.14 of this appendix, except that a mixture of oxidizing substances which contains 5% or more of combustible organic substances shall be classified as a self-reactive chemical according to the procedure defined in B.8.2.2;

(c) It is classified as an organic peroxide according to B.15 of this appendix;

(d) Its heat of decomposition is less than 300 J/g; or

(e) Its self-accelerating decomposition temperature (SADT) is greater than 75°C (167°F) for a 50 kg (110 lb) package.

B.8.2.2 Mixtures of oxidizing substances, meeting the criteria for classification as oxidizing liquids or oxidizing solids, which contain 5% or more of combustible organic substances and which do not meet the criteria mentioned in B.8.2.1 (a), (c), (d) or (e), shall be subjected to the self-reactive chemicals classification procedure in B.8.2.3. Such a mixture showing the properties of a self-reactive chemical type B to F shall be classified as a self-reactive chemical.

B.8.2.3 Self-reactive chemicals shall be classified in one of the seven categories of "types A to G" for this class, according to the following principles:

(a) Any self-reactive chemical which can detonate or deflagrate rapidly, as packaged, will be defined as self-reactive chemical TYPE A;

(b) Any self-reactive chemical possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package will be defined as self-reactive chemical TYPE B;

(c) Any self-reactive chemical possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion will be defined as self-reactive chemical TYPE C;

(d) Any self-reactive chemical which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) will be defined as self-reactive chemical TYPE D:

(i) Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) Does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any self-reactive chemical which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement will be defined as self-reactive chemical TYPE E;

(f) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power will be defined as self-reactive chemical TYPE F;

(g) Any self-reactive chemical which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C (140°F) to 75°C (167°F) for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point greater than or equal to 150°C (302°F) is used for desensitization will be defined as self-reactive chemical TYPE G. If the mixture is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, the mixture shall be defined as self-reactive chemical TYPE F.

B.8.3 Additional classification considerations

B.8.3.1 For purposes of classification, the properties of self-reactive chemicals shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.8.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10, Part II, section 28 (incorporated by reference; See §1910.6).

B.8.3.3 The classification procedures for self-reactive substances and mixtures need not be applied if:

(a) There are no chemical groups present in the molecule associated with explosive or self-reactive properties; examples of such groups are given in Tables A6.1 and A6.2 in the Appendix 6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6); or

(b) For a single organic substance or a homogeneous mixture of organic substances, the estimated SADT is greater than 75°C (167°F) or the exothermic decomposition energy is less than 300 J/g. The onset temperature and decomposition energy may be estimated using a suitable calorimetric technique (See 20.3.3.3 in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6)).

B.9 PYROPHORIC LIQUIDS

B.9.1 Definition

Pyrophoric liquid means a liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.9.2 Classification criteria

A pyrophoric liquid shall be classified in a single category for this class using test N.3 in Part III, sub-section 33.3.1.5 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.9.1:

Table B.9.1: Criteria For Pyrophoric Liquids

Category	Criteria
1	The liquid ignites within 5 min when added to an inert carrier and exposed to air, or it ignites or chars a filter paper on contact with air within 5 min.

B.9.3 Additional classification considerations

The classification procedure for pyrophoric liquids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the substance is known to be stable at room temperature for prolonged periods of time (days)).

B.10 PYROPHORIC SOLIDS

B.10.1 Definition

Pyrophoric solid means a solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

B.10.2 Classification criteria

A pyrophoric solid shall be classified in a single category for this class using test N.2 in Part III, sub-section 33.3.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.10.1:

Table B.10.1: Criteria For Pyrophoric Solids

Category	Criteria
1	The solid ignites within 5 min of coming into contact with air.
Note: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.	

B.10.3 Additional classification considerations

The classification procedure for pyrophoric solids need not be applied when experience in production or handling shows that the chemical does not ignite spontaneously on coming into contact with air at normal temperatures (i.e., the chemical is known to be stable at room temperature for prolonged periods of time (days)).

B.11 SELF-HEATING CHEMICALS

B.11.1 Definition

A *self-heating chemical* is a solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

NOTE: Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

B.11.2 Classification criteria

B.11.2.1 A self-heating chemical shall be classified in one of the two categories for this class if, in tests performed in accordance with test method N.4 in Part III, sub-section 33.3.1.6 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), the result meets the criteria shown in Table B.11.1.

Table B.11.1: Criteria For Self-Heating Chemicals

Category	Criteria
1	A positive result is obtained in a test using a 25 mm sample cube at 140°C (284°F)
2	A negative result is obtained in a test using a 25 mm cube sample at 140°C (284°F), a positive result is obtained in a test using a 100 mm sample cube at 140°C (284°F), and: (a) The unit volume of the chemical is more than 3 m^3; or (b) A positive result is obtained in a test using a 100 mm cube sample at 120°C (248°F) and the unit volume of the chemical is more than 450 liters; or (c) Apositive result is obtained in a test using a 100 mm cube sample at 100°C (212°F).

B.11.2.2 Chemicals with a temperature of spontaneous combustion higher than 50°C (122°F) for a volume of 27 m3 shall not be classified as self-heating chemicals.

B.11.2.3 Chemicals with a spontaneous ignition temperature higher than 50°C (122°F) for a volume of 450 liters shall not be classified in Category 1 of this class.

B.11.3 Additional classification considerations

B.11.3.1 The classification procedure for self-heating chemicals need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied.

B.11.3.2 Examples of screening tests are:

(a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, Test methods for the Determination of the Safety Characteristics of Dusts) with an onset temperature 80°K above the reference temperature for a volume of 1 /;

(b) The Bulk Powder Screening Test (Gibson, N. Harper, D. J. Rogers, R. Evaluation of the fire and explosion risks in drying powders, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60°K above the reference temperature for a volume of 1 /.

B.12 CHEMICALS WHICH, IN CONTACT WITH WATER, EMIT FLAMMABLE GASES

B.12.1 Definition

Chemicals which, in contact with water, emit flammable gases are solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

B.12.2 Classification criteria

B.12.2.1 A chemical which, in contact with water, emits flammable gases shall be classified in one of the three categories for this class, using test N.5 in Part III, sub-section 33.4.1.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.12.1:

Table B.12.1: Criteria For Chemicals Which, In Contact With Water, Emit Flammable Gases

Category	Criteria
1	Any chemical which reacts vigorously with water at ambient temperatures and demonstrates generally a tendency for the gas produced to ignite spontaneously, or which reacts readily with water at ambient temperatures such that the rate of evolution of flammable gas is equal to or greater than 10 liters per kilogram of chemical over any one minute.
2	Any chemical which reacts readily with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 20 liters per kilogram of chemical per hour, and which does not meet the criteria for Category 1.
3	Any chemical which reacts slowly with water at ambient temperatures such that the maximum rate of evolution of flammable gas is equal to or greater than 1 liter per kilogram of chemical per hour, and which does not meet the criteria for Categories 1 and 2.
NOTE: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.	

B.12.2.2 A chemical is classified as a chemical which, in contact with water, emits flammable gases if spontaneous ignition takes place in any step of the test procedure.

B.12.3 Additional classification considerations

The classification procedure for this class need not be applied if:

(a) The chemical structure of the chemical does not contain metals or metalloids;

(b) Experience in production or handling shows that the chemical does not react with water, (e.g., the chemical is manufactured with water or washed with water); or

(c) The chemical is known to be soluble in water to form a stable mixture.

B.13 OXIDIZING LIQUIDS

B.13.1 Definition

Oxidizing liquid means a liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.13.2 Classification criteria

An oxidizing liquid shall be classified in one of the three categories for this class using test O.2 in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.13.1:

Table B.13.1: Criteria For Oxidizing Liquids

Category	Criteria
1	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, spontaneously ignites; or the mean pressure rise time of a 1:1 mixture, by mass, of chemical and cellulose is less than that of a 1:1 mixture, by mass, of 50% perchloric acid and cellulose;
2	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 40% aqueous sodium chlorate solution and cellulose; and the criteria for Category 1 are not met;
3	Any chemical which, in the 1:1 mixture, by mass, of chemical and cellulose tested, exhibits a mean pressure rise time less than or equal to the mean pressure rise time of a 1:1 mixture, by mass, of 65% aqueous nitric acid and cellulose; and the criteria for Categories 1 and 2 are not met.

B.13.3 Additional classification considerations

B.13.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.13.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.13.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgments based on known experience shall take precedence over test results.

B.13.3.4 In cases where chemicals generate a pressure rise (too high or too low), caused by chemical reactions not characterizing the oxidizing properties of the chemical, the test described in Part III, sub-section 34.4.2 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6) shall be repeated with an inert substance (e.g., diatomite (kieselguhr)) in place of the cellulose in order to clarify the nature of the reaction.

B.14 OXIDIZING SOLIDS

B.14.1 Definition

Oxidizing solid means a solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

B.14.2 Classification criteria

An oxidizing solid shall be classified in one of the three categories for this class using test O.1 in Part III, sub-section 34.4.1 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.14.1:

Table B.14.1: Criteria For Oxidizing Solids

Category	Criteria
1	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time less than the mean burning time of a 3:2 mixture, by mass, of potassium bromate and cellulose.
2	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 2:3 mixture (by mass) of potassium bromate and cellulose and the criteria for Category 1 are not met.
3	Any chemical which, in the 4:1 or 1:1 sample-to-cellulose ratio (by mass) tested, exhibits a mean burning time equal to or less than the mean burning time of a 3:7 mixture (by mass) of potassium bromate and cellulose and the criteria for Categories 1 and 2 are not met.

Note: 1: Some oxidizing solids may present explosion hazards under certain conditions (e.g., when stored in large quantities). For example, some types of ammonium nitrate may give rise to an explosion hazard under extreme conditions and the "Resistance to detonation test" (IMO: Code of Safe Practice for Solid Bulk Cargoes, 2005, Annex 3, Test 5) may be used to assess this hazard. When information indicates that an oxidizing solid may present an explosion hazard, it shall be indicated on the Safety Data Sheet.

Note:2: Classification of solid chemicals shall be based on tests performed on the chemical as presented. If, for example, for the purposes of supply or transport, the same chemical is to be presented in a physical form different from that which was tested and which is considered likely to materially alter its performance in a classification test, classification must be based on testing of the chemical in the new form.

B.14.3 Additional classification considerations

B.14.3.1 For organic chemicals, the classification procedure for this class shall not be applied if:

(a) The chemical does not contain oxygen, fluorine or chlorine; or

(b) The chemical contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen.

B.14.3.2 For inorganic chemicals, the classification procedure for this class shall not be applied if the chemical does not contain oxygen or halogen atoms.

B.14.3.3 In the event of divergence between test results and known experience in the handling and use of chemicals which shows them to be oxidizing, judgements based on known experience shall take precedence over test results.

B.15 ORGANIC PEROXIDES

B.15.1 Definition

B.15.1.1 *Organic peroxide* means a liquid or solid organic chemical which contains the bivalent -0-0- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

(a) Be liable to explosive decomposition;

(b) Burn rapidly;

(c) Be sensitive to impact or friction;

(d) React dangerously with other substances.

B.15.1.2 An organic peroxide is regarded as possessing explosive properties when in laboratory testing the formulation is liable to detonate, to deflagrate rapidly or to show a violent effect when heated under confinement.

B.15.2 Classification criteria

B.15.2.1 Any organic peroxide shall be considered for classification in this class, unless it contains:

(a) Not more than 1.0% available oxygen from the organic peroxides when containing not more than 1.0% hydrogen peroxide; or

(b) Not more than 0.5% available oxygen from the organic peroxides when containing more than 1.0% but not more than 7.0% hydrogen peroxide.

NOTE: The available oxygen content (%) of an organic peroxide mixture is given by the formula:

$$16 \times \sum_{i}^{n} \frac{(n_i \times c_i)}{m_i}$$

Where:
n_i = number of peroxygen groups per molecule of organic peroxide *i*;
c_i = concentration (mass %) of organic peroxide *i*;
m_i = molecular mass of organic peroxide *i*.

B.15.2.2 Organic peroxides shall be classified in one of the seven categories of "Types A to G" for this class, according to the following principles:

(a) Any organic peroxide which, as packaged, can detonate or deflagrate rapidly shall be defined as organic peroxide TYPE A;

(b) Any organic peroxide possessing explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package shall be defined as organic peroxide TYPE B;

(c) Any organic peroxide possessing explosive properties when the chemical as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion shall be defined as organic peroxide TYPE C;

(d) Any organic peroxide which in laboratory testing meets the criteria in (d)(i), (ii), or (iii) shall be defined as organic peroxide TYPE D:

(i) detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or

(ii) does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or

(iii) does not detonate or deflagrate at all and shows a medium effect when heated under confinement;

(e) Any organic peroxide which, in laboratory testing, neither detonates nor deflagrates at all and shows low or no effect when heated under confinement shall be defined as organic peroxide TYPE E;

(f) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power shall be defined as organic peroxide TYPE F;

(g) Any organic peroxide which, in laboratory testing, neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is

thermally stable (self-accelerating decomposition temperature is 60°C (140°F) or higher for a 50 kg (110 lb) package), and, for liquid mixtures, a diluent having a boiling point of not less than 150°C (302°F) is used for desensitization, shall be defined as organic peroxide TYPE G. If the organic peroxide is not thermally stable or a diluent having a boiling point less than 150°C (302°F) is used for desensitization, it shall be defined as organic peroxide TYPE F.

B.15.3 Additional classification considerations

B.15.3.1 For purposes of classification, the properties of organic peroxides shall be determined in accordance with test series A to H as described in Part II of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6).

B.15.3.2 Self-accelerating decomposition temperature (SADT) shall be determined in accordance with the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), Part II, section 28.

B.15.3.3 Mixtures of organic peroxides may be classified as the same type of organic peroxide as that of the most dangerous ingredient. However, as two stable ingredients can form a thermally less stable mixture, the SADT of the mixture shall be determined.

B.16 CORROSIVE TO METALS

B.16.1 Definition

A *chemical which is corrosive to metals* means a chemical which by chemical action will materially damage, or even destroy, metals.

B.16.2 Classification criteria

A chemical which is corrosive to metals shall be classified in a single category for this class, using the test in Part III, sub-section 37.4 of the UN ST/SG/AC.10 (incorporated by reference; See §1910.6), in accordance with Table B.16.1:

Table B.16.1: Criteria For Chemicals Corrosive To Metal

Category	Criteria
1	Corrosion rate on either steel or aluminium surfaces exceeding 6.25 mm per year at a test temperature of 55°C (131°F) when tested on both materials.

Note: Where an initial test on either steel or aluminium indicates the chemical being tested is corrosive the follow-up test on the other metal is not necessary.

B.16.3 Additional classification considerations

The specimen to be used for the test shall be made of the following materials:

(a) For the purposes of testing steel, steel types S235JR+CR (1.0037 resp.St 37-2), S275J2G3+CR (1.0144 resp.St 44-3), ISO 3574, Unified Numbering System (UNS) G 10200, or SAE 1020;

(b) For the purposes of testing aluminium: non-clad types 7075-T6 or AZ5GU-T6.

[77 FR 17786, 17817, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 78 FR 9313, Feb. 8, 2013]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200 Appendix C
Title: Allocation Of Label Elements (Mandatory)

C.1 The label for each hazardous chemical shall include the product identifier used on the safety data sheet.

C.1.1 The labels on shipped containers shall also include the name, address, and telephone number of the chemical manufacturer, importer, or responsible party.

C.2 The label for each hazardous chemical that is classified shall include the signal word, hazard statement(s), pictogram(s), and precautionary statement(s) specified in C.4 for each hazard class and associated hazard category, except as provided for in C.2.1 through C.2.4.

C.2.1 Precedence of hazard information

C.2.1.1 If the signal word "Danger" is included, the signal word "Warning" shall not appear;

C.2.1.2 If the skull and crossbones pictogram is included, the exclamation mark pictogram shall not appear where it is used for acute toxicity;

C.2.1.3 If the corrosive pictogram is included, the exclamation mark pictogram shall not appear where it is used for skin or eye irritation;

C.2.1.4 If the health hazard pictogram is included for respiratory sensitization, the exclamation mark pictogram shall not appear where it is used for skin sensitization or for skin or eye irritation.

C.2.2 Hazard statement text

C.2.2.1 The text of all applicable hazard statements shall appear on the label, except as otherwise specified. The information in italics shall be included as part of the hazard statement as provided. For example: "causes damage to organs *(state all organs affected)* through prolonged or repeated exposure *(state route of exposure if no other routes of exposure cause the hazard)*". Hazard statements may be combined where appropriate to reduce the information on the label and improve readability, as long as all of the hazards are conveyed as required.

C.2.2.2 If the chemical manufacturer, importer, or responsible party can demonstrate that all or part of the hazard statement is inappropriate to a specific substance or mixture, the corresponding statement may be omitted from the label.

C.2.3 Pictograms

C.2.3.1 Pictograms shall be in the shape of a square set at a point and shall include a black hazard symbol on a white background with a red frame sufficiently wide to be clearly visible. A square red frame set at a point without a hazard symbol is not a pictogram and is not permitted on the label.

C.2.3.2 One of eight standard hazard symbols shall be used in each pictogram. The eight hazard symbols are depicted in Figure C.1. A pictogram using the exclamation mark symbol is presented in Figure C.2, for the purpose of illustration.

Figure C.1: Hazard Symbols and Classes

Flame		Flammables Self Reactives Pyrophorics Self-heating Emits Flammable Gas Organic Peroxides
Flame Over Circle		Oxidizers
Exclamation Mark		Irritant Dermal Sensitizer Acute Toxicity (harmful) Narcotic Effects Respiratory Tract Irritation
Exploding Bomb		Explosives Self Reactives Organic Peroxides
Corrosion		Corrosives
Gas Cylinder		Gases Under Pressure
Health Hazard		Carcinogen Respiratory Sensitizer Reproductive Toxicity Target Organ Toxicity Mutagenicity Aspiration Toxicity
Skull and Crossbones		Acute Toxicity (severe)

Figure C.2: Exclamation Mark Pictogram

C.2.3.3 Where a pictogram required by the Department of Transportation under Title 49 of the Code of Federal Regulations appears on a shipped container, the pictogram specified in C.4 for the same hazard shall not appear.

C.2.4 Precautionary statement text

C.2.4.1 There are four types of precautionary statements presented, "prevention," "response," "storage," and "disposal." The core part of the precautionary statement is presented in bold print. This is the text, except as otherwise specified, that shall appear on the label. Where additional information is required, it is indicated in plain text.

C.2.4.2 When a backslash or diagonal mark (/) appears in the precautionary statement text, it indicates that a choice has to be made between the separated phrases. In such cases, the chemical manufacturer, importer, or responsible party can choose the most appropriate phrase(s). For example, "Wear protective gloves/protective clothing/eye protection/face protection" could read "wear eye protection".

C.2.4.3 When three full stops (...) appear in the precautionary statement text, they indicate that all applicable conditions are not listed. For example, in "Use explosion-proof electrical/ventilating/lighting/.../equipment", the use of "..." indicates that other equipment may need to be specified. In such cases, the chemical manufacturer, importer, or responsible party can choose the other conditions to be specified.

C.2.4.4 When text in *italics* is used in a precautionary statement, this indicates specific conditions applying to the use or allocation of the precautionary statement. For example, "Use explosion-proof electrical/ventilating/lighting/.../equipment" is only required for flammable solids *"if dust clouds can occur"*. Text in italics is intended to be an explanatory, conditional note and is not intended to appear on the label.

C.2.4.5 Where square brackets ([ ]) appear around text in a precautionary statement, this indicates that the text in square brackets is not appropriate in every case and should be used only in certain circumstances. In these cases, conditions for use explaining when the text should be used are provided. For example, one precautionary statement states: "[In case of inadequate ventilation] wear respiratory protection." This statement is given with the condition for use "– text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use". This means that, if additional information is provided with the chemical explaining what type of ventilation would be adequate for safe use, the text in square brackets should be used and the statement would read: "In case of inadequate ventilation wear respiratory protection." However, if the chemical is supplied without such ventilation information, the text in square brackets should not be used, and the precautionary statement should read: "Wear respiratory protection. "

C.2.4.6 Precautionary statements may be combined or consolidated to save label space and improve readability. For example, Keep away from heat, sparks and open flame, " "Store in a well-ventilated place" and "Keep cool" can be combined to read "Keep away from heat, sparks and open flame and store in a cool, well-ventilated place. "

C.2.4.7 In most cases, the precautionary statements are independent (e.g., the phrases for explosive hazards do not modify those related to certain health hazards, and products that are classified for both hazard classes shall bear appropriate precautionary statements for both). Where a chemical is classified for a number of hazards, and the precautionary statements are similar, the most stringent shall be included on the label (this will be applicable mainly to preventive measures). An order of precedence may be imposed by the chemical manufacturer, importer or responsible party in situations where phrases concern "Response." Rapid action may be crucial. For example, if a chemical is carcinogenic and acutely toxic, rapid action may be crucial, and first aid measures for acute toxicity will take precedence over those for long-term effects. In

addition, medical attention to delayed health effects may be required in cases of incidental exposure, even if not associated with immediate symptoms of intoxication.

C.2.4.8 If the chemical manufacturer, importer, or responsible party can demonstrate that a precautionary statement is inappropriate to a specific substance or mixture, the precautionary statement may be omitted from the label.

C.3 Supplementary hazard information

C.3.1 To ensure that non-standardized information does not lead to unnecessarily wide variation or undermine the required information, supplementary information on the label is limited to when it provides further detail and does not contradict or cast doubt on the validity of the standardized hazard information.

C.3.2 Where the chemical manufacturer, importer, or distributor chooses to add supplementary information on the label, the placement of supplemental information shall not impede identification of information required by this section.

C.3.3 Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥ 1%, and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required on the label.

C.4 REQUIREMENTS FOR SIGNAL WORDS, HAZARD STATEMENTS, PICTOGRAMS, AND PRECAUTIONARY STATEMENTS

<table>
<tr><th colspan="4">C.4.1: Acute Toxicity — Oral
(Classified in Accordance with Appendix A.1)</th></tr>
<tr><th>Hazard category</th><th>Signal word</th><th>Hazard statement</th><th>Pictogram</th></tr>
<tr><td>1</td><td>Danger</td><td>Fatal if swallowed</td><td rowspan="2">Skull and Crossbones
  </td></tr>
<tr><td>2</td><td>Danger</td><td>Fatal if swallowed</td></tr>
<tr><td colspan="4">Precautionary statements</td></tr>
<tr><th>Prevention</th><th>Response</th><th>Storage</th><th>Disposal</th></tr>
<tr><td>Wash …thoroughly after handling.
… Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.
Do not eat, drink or smoke when using this product.</td><td>If swallowed: Immediately call a poison center/doctor/…
… Chemical manufacturer, importer,or distributor to specify the appropriate source of emergency medical advice.
Specific treatment (see … on this label)
… Reference to supplemental first aid instruction.
— if immediate administration of antidote is required.
Rinse mouth.</td><td>Store locked up.</td><td>Dispose of contents/container to…
... in accordance with local/regional/national/international regulations (to be specified).</td></tr>
</table>

C.4.1: Acute Toxicity — Oral (Classified in Accordance with Appendix A.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
3	Danger	Toxic if swallowed	Skull and Crossbones 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If swallowed: Immediately call a poison center/doctor/...** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if immediate administration of antidote is required.* **Rinse mouth.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified)
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
4	Warning	Harmful if swallowed	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product**	**If swallowed: Call a poison center/doctor/…/ if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Rinse mouth.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.2: Acute Toxicity — Dermal (Classified in Accordance with Appendix A.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Fatal in contact with skin	Skull and Crossbones 
2	Danger	Fatal in contact with skin	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not get in eyes, on skin, or on clothing. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.** **Wear protective gloves/ protective clothing.** Chemical manufacturer, importer, or distributor to specify type of equipment. If on skin:	**Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Immediately call a poison center/ doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if immediate measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
3	Danger	Toxic in contact with skin	Skull and Crossbones 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing. Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of water/…** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/ if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if measures such as specific cleansing agent is advised.* **Take off immediately all contaminated clothing and wash it before reuse.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.2: Acute Toxicity — Dermal (Classified in Accordance with Appendix A.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
4	Warning	Harmful in contact with skin	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear protective gloves/protective clothing Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if measures such as specific cleansing agent is advised.* **Take off contaminated clothing and wash it before reuse.**		**Dispose of contents/container to..** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.3 Acute Toxicity — Inhalation (Classified in Accordance with Appendix A.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Fatal if inhaled	Skull and Crossbones 
2	Danger	Fatal if inhaled	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.** **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify equipment. *— Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/ doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment is urgent (see ... on this label)** ... Reference to supplemental first aid instruction. *— if immediate administration of antidote is required.*	**Store in a well-ventilated place. Keep container tightly closed.** *— if product is volatile as to generate hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.3 Acute Toxicity — Inhalation (Classified in Accordance with Appendix A.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
3	Danger	Toxic if inhaled	Skull and Crossbones 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/...** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if immediate specific measures are required.*	**Store in a well-ventilated place. Keep container tightly closed.** — if product is volatile so as to generate hazardous atmosphere. **Store locked up.**	**Dispose of content/container to…** … in accordance with local/regional/national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
4	Warning	Harmful if inhaled	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.4: Skin Corrosion/Irritation (Classified in Accordance with Appendix A.2)			
Hazard category	**Signal word**	**Hazard statement**	**Corrosion**
1A to 1C	Danger	Causes severe skin burns and eye damage	Corrosion 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dusts or mists. *— if inhalable particles of dusts or mists may occur during use.* **Wash …thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves/protective clothing/eye protection/ face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If swallowed: Rinse mouth. Do NOT induce vomiting.** **If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.** **Wash contaminated clothing before reuse.** **If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Immediately call a poison center/ doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.4: Skin Corrosion/Irritation (Classified in Accordance with Appendix A.2)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2	Warning	Causes skin irritation	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear protective gloves.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **If skin irritation occurs: Get medical advice/attention.** **Take off contaminated clothing and wash it before reuse.**		

C.4.5: Eye Damage/Irritation (Classified in Accordance with Appendix A.3)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Causes serious eye damage	Corrosion 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear eye protection/face protection. Chemical manufacturer, importer, or distributor to specify type of equipment.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **Immediately call a poison center/ doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		

C.4.5: Eye Damage/Irritation (Classified in Accordance with Appendix A.3)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2A	Warning	Causes serious eye irritation	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Wear eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.**		
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2B	Warning	Causes eye irritation	*No Pictogram*
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wash … thoroughly after handling. … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling.	**If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** **If eye irritation persists: Get medical advice/attention.**		

C.4.6: Sensitization — Respiratory (Classified in Accordance with Appendix A.4)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1 (including both sub-categories 1A and 1B)	Danger	May cause allergy or asthma symptoms or breathing difficulties if inhaled	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/ mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **[In case of inadequate ventilation] wear respiratory protection.** Chemical manufacturer, importer, or distributor to specify applicable conditions. *— Text in square brackets may be used if additional information is provided with the chemical at the point of use that explains what type of ventilation would be adequate for safe use.*	**If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.** **If experiencing respiratory symptoms: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.		**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.7: Sensitization — Skin (Classified in Accordance with Appendix A.4)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1 (including both sub-categories 1A and 1B)	Warning	May cause an allergic skin reaction	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Contaminated work clothing must not be allowed out of the workplace.** **Wear protective gloves.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Wash with plenty of water/...** … Chemical manufacturer, importer, or distributor may specify a cleansing agent if appropriate, or may recommend an alternative agent in exceptional cases if water is clearly inappropriate. **If skin irritation or rash occurs: Get medical advice/attention.** **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— Manufacturer, importer, or distributor may specify a cleansing agent if appropriate.* **Wash contaminated clothing before reuse.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.8: Germ Cell Mutagenicity (Classified in Accordance with Appendix A.5)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1A and 1B	Danger	May cause genetic defects <...>	Health Hazard 
2	Warning	Suspected of causing genetic defects <...> *(state route of exposure if no other routes of exposure cause the hazard)*	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.9: Carcinogenicity (Classified in Accordance with Appendix A.6)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1A and 1B	Danger	May cause cancer <...>	Health Hazard 
2	Warning	Suspected of causing cancer <...> *(state route of exposure if no other routes of exposure cause the hazard)*	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).
Note: If a Category 2 carcinogen ingredient is present in the mixture at a concentration between 0.1% and 1%, information is required on the SDS for a product; however, a label warning is optional. If a Category 2 carcinogen ingredient is present in the mixture at a concentration of ³ 1%, both an SDS and a label is required and the information must be included on each.			

C.4.10: Toxic To Reproduction (Classified in Accordance with Appendix A.7)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1A and 1B	Danger	May damage fertility or the unborn child <...> <<...>>	Health Hazard 
2	Warning	Suspected of damaging fertility or the unborn child <...> <<...>> *(state specific effect if known)* *(state route of exposure if no other routes of exposure cause the hazard)*	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear protective gloves/protective clothing/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**If exposed or concerned: Get medical advice/attention.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.10: Toxic To Reproduction (Classified in Accordance with Appendix A.7) (Effects On Or Via Lactation)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
No designated number (See Table A.7.1 in Appendix A.7)	No signal word	May cause harm to breast-fed children	No Pictogram
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Obtain special instructions before use. **Do not breathe dusts or mists.** *— if inhalable particles of dusts or mists may occur during use.* **Wash … thoroughly after handling.** **Avoid contact during pregnancy/ while nursing.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Get medical advice/attention.**		

C.4.11: Specific Target Organ Toxicity (Single Exposure) (Classified in Accordance with Appendix A.8)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Causes damage to organs <...> <<...> <...> *(or state all organs affected if known)* <<...>> *(state route of exposure if no other routes of exposure cause the hazard)*	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash …thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed:** **Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Specific treatment (see ... on this label)** ... Reference to supplemental first aid instruction. *— if immediate measures are required.*	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.11: Specific Target Organ Toxicity (Single Exposure) (Classified in Accordance with Appendix A.8)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2	Warning	May cause damage to organs <...> <<...>> *<...> (or state all organs affected, if known)* *<<...>> (state route of exposure if no other routes of exposure cause the hazard)*	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** … Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**If exposed or concerned: Call a poison center/doctor/…** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
3	Warning	May cause respiratory irritation; or May cause drowsiness or dizziness	Exclamation Mark 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Avoid breathing dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Use only outdoors or in a well-ventilated area.**	**If inhaled: Remove person to fresh air and keep comfortable for breathing.** **Call a poison center/doctor/…/ if you feel unwell.** … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice.	**Store in a well-ventilated place. Keep container tightly closed.** *— if product is volatile so as to generate hazardous atmosphere.* **Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.12: Specific Target Organ Toxicity (Repeated Exposure) (Classified in Accordance with Appendix A.9)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Causes damage to organs <...> through prolonged or repeated exposure <<...>> *<...> (state all organs affected, if known)* *<<...>> (state route of exposure if no other routes of exposure cause the hazard)*	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/ vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions. **Wash … thoroughly after handling.** …Chemical manufacturer, importer, or distributor to specify parts of the body to be washed after handling. **Do not eat, drink or smoke when using this product.**	**Get medical advice/attention if you feel unwell.**		**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.12: Specific Target Organ Toxicity (Repeated Exposure) (Classified in Accordance with Appendix A.9)			
Hazard category	**Signal word**	**Hazard statement**	**Health Hazard Pictogram**
2	Warning	May cause damage to organs <...> through prolonged or repeated exposure <<...>> *<...> (state all organs affected, if known)* *<<...>> (state route of exposure if no other routes of exposure cause the hazard)*	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not breathe dust/fume/gas/mist/vapors/spray. Chemical manufacturer, importer, or distributor to specify applicable conditions.	**Get medical advice/attention if you feel unwell.**		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.13: Aspiration Hazard (Classified in Accordance with Appendix A.10)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	May be fatal if swallowed and enters airways	Health Hazard 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
	If swallowed: Immediately call a poison center/doctor/… … Chemical manufacturer, importer, or distributor to specify the appropriate source of emergency medical advice. **Do NOT induce vomiting.**	**Store locked up.**	**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.14: Explosives
(Classified in Accordance with Appendix B.1)

Hazard category	Signal word	Hazard statement	Pictogram
Unstable	Danger	Unstable explosive	Exploding Bomb 

Precautionary statements

Prevention	Response	Storage	Disposal
Obtain special instructions before use. **Do not handle until all safety precautions have been read and understood.** **Wear personal protective equipment/ face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment, as required.	**Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.** **Evacuate area.**	**Store ...** …in accordance with local/regional/ national/international regulations (to be specified).	**Dispose of contents/container to ...** …in accordance with local/regional/ national/international regulations (to be specified).

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.1	Danger	Explosive; mass explosion hazard	Exploding Bomb 
Division 1.2	Danger	Explosive; severe projection hazard	
Division 1.3	Danger	Explosive; fire, blast or projection	

Precautionary statements[1]

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep wetted with...** … Chemical manufacturer, importer, or distributor to specify appropriate material. *— if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).* **Ground/bond container and receiving equipment.** *— if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/ friction.** …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: evacuate area.** **Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.**	**Store ...** …in accordance with local/regional/ national/ international regulations (to be specified).	**Dispose of contents/container to ...** … in accordance with local/ regional/ national/international regulations (to be specified).

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14: Explosives
(Classified in Accordance with Appendix B.1)

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.4	Warning	Fire or projection hazard	Exploding Bomb[1] 

Precautionary statements[1]

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/bond container and receiving equipment.** — if the explosive is electrostatically sensitive. **Do not subject to grinding/shock/…/ friction.** Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Evacuate area.** **Explosion risk in case of fire.** *— except if explosives are 1.4S ammunition and components thereof.* **Do NOT fight fire when fire reaches explosives.** **Fight fire with normal precautions from a reasonable distance** *— if explosives are 1.4S ammunition and components thereof.*	**Store ...** …in accordance with local/regional/ national/international regulations (to be specified).	**Dispose of contents/container to...** … in accordance with local/regional/ national/international regulations (to be specified).

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.[1]

Hazard category	Signal word	Hazard statement	Pictogram
Division 1.5	Danger	May mass explode in fire	No Pictogram

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep wetted with...** … Chemical manufacturer, importer, or distributor to specify appropriate material. *— if drying out increases explosion hazard, except as needed for manufacturing or operating processes (e.g., nitrocellulose).* **Ground/bond container and receiving equipment** *— if the explosive is electrostatically sensitive.* **Do not subject to grinding/shock/…/ friction.** …Chemical manufacturer, importer, or distributor to specify applicable rough handling. **Wear face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Evacuate area.** **Explosion risk in case of fire.** **Do NOT fight fire when fire reaches explosives.**	**Store ...** …in accordance with local/regional/ national/international regulations (to be specified).	**Dispose of contents/container to ...** … in accordance with local/regional/ national/international regulations (to be specified).

Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.

C.4.14: Explosives (Classified in Accordance with Appendix B.1)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Division 1.6	No signal word	No hazard statement	No Pictogram
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
None assigned	None assigned	None assigned	None assigned
Note: Unpackaged explosives or explosives repacked in packagings other than the original or similar packaging shall have the label elements assigned to Division 1.1 unless the hazard is shown to correspond to one of the hazard categories in Appendix B.1, in which case the corresponding symbol, signal word and/or the hazard statement shall be assigned.			

C.4.15: Flammable Gases (Classified in Accordance with Appendix B.2)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Extremely flammable gas	Flame 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s).	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** **Eliminate all ignition sources if safe to do so.**	**Store in well-ventilated place.**	
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2	Warning	Flammable gas	No Pictogram
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s).	**Leaking gas fire: Do not extinguish, unless leak can be stopped safely.** Eliminate all ignition sources if safe to do so.	**Store in well-ventilated place.**	

C.4.16: Flammable Aerosols (Classified in Accordance with Appendix B.3)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Extremely flammable aerosol	Flame 
2	Warning	Flammable aerosol	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s). **Do not spray on an open flame or other ignition source.** **Pressurized container: Do not pierce or burn, even after use.**		**Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.**	

C.4.17: Oxidizing Gases (Classified in Accordance with Appendix B.4)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	May cause or intensify fire; oxidizer	Flame Over Circle 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep/Store away from clothing/…/ combustible materials. …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep reduction valves/valves and fittings free from oil and grease.**	**In case of fire: Stop leak if safe to do so.**	**Store in well-ventilated place.**	

C.4.18: Gases Under Pressure (Classified in Accordance with Appendix B.5)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Compressed gas Liquefied gas Dissolved gas	Warning Warning Warning	Contains gas under pressure; may explode if heated Contains gas under pressure; may explode if heated Contains gas under pressure; may explode if heated	Gas Cylinder 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
		Protect from sunlight. Store in a well-ventilated place.	
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Refrigerated liquefied gas	Warning	Contains refrigerated gas; may cause cryogenic burns or injury	Gas Cylinder 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Wear cold insulating gloves/face shield/eye protection.	**Thaw frosted parts with lukewarm water. Do not rub affected area.** **Get immediate medical advice/ attention.**	**Store in well-ventilated place.**	

C.4.19: Flammable Liquids (Classified in Accordance with Appendix B.6)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Extremely flammable liquid and vapor	Flame 
2	Danger	Highly flammable liquid and vapor	
3	Warning	Flammable liquid and vapor	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/Bond container and receiving equipment.** *— if electrostatically sensitive material is for reloading.* *-— f product is volatile so as to generate hazardous atmosphere.* **Use explosion-proof electrical/ ventilating/ lighting/.../equipment.** ... Chemical manufacturer, importer, or distributor to specify other equipment. **Use only non-sparking tools.** **Take precautionary measures against static discharge.** **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.** **In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store in a well-ventilated place. Keep cool.**	**Dispose of contents/container to...** … in accordance with local/regional/ national/ international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
4	Warning	Combustible liquid	No Pictogram
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from flames and hot surfaces. No smoking. **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store in a well-ventilated place. Keep cool.**	**Dispose of contents/container to...** in accordance with local/regional/ national/international regulations (to be specified).

C.4.20: Flammable Solids (Classified in Accordance with Appendix B.7)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Flammable solid	Flame 
2	Warning	Flammable solid	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Ground/Bond container and receiving equipment.** *— if electrostatically sensitive material is for reloading.* **Use explosion-proof electrical/ ventilating/ lighting/... /equipment.** ... Chemical manufacturer, importer, or distributor to specify other equipment. *— if dust clouds can occur.* **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*		

C.4.21: Self-Reactive Substances And Mixtures (Classified in Accordance with Appendix B.8)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Type A	Danger	Heating may cause an explosion	Flame 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/ combustible materials.** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.* **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to...** … in accordance with local/regional/ national/international regulations (to be specified).

C.4.21: Self-Reactive Substances And Mixtures
(Classified in Accordance with Appendix B.8)

Hazard category	Signal word	Hazard statement	Pictogram
Type B	Danger	Heating may cause a fire or explosion	Flame  Exploding Bomb 

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/.../ combustible materials.** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.* **In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.**	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).

Hazard category	Signal word	Hazard statement	Pictogram
Type C	Danger	Heating may cause a fire	Flame 
Type D	Danger	Heating may cause a fire	
Type E	Warning	Heating may cause a fire	
Type F	Warning	Heating may cause a fire	

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/ combustible materials.** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store in a well-ventilated place. Keep cool.** **Store at temperatures not exceeding …°C/…°F.** ...Chemical manufacturer, importer, or distributor to specify temperature. **Store away from other materials.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).

C.4.22: Pyrophoric Liquids (Classified in Accordance with Appendix B.9)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Catches fire spontaneously if exposed to air	Flame 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition sources(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**If on skin: Immerse in cool water/ wrap with wet bandages** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store contents under ...** ... Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.	

C.4.23: Pyrophoric Solids (Classified in Accordance with Appendix B.10)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Catches fire spontaneously if exposed to air	Flame 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Do not allow contact with air.** **Wear protective gloves/eye protection/face protection** Chemical manufacturer, importer, or distributor to specify type of equipment.	**Brush off loose particles from skin. Immerse in cool water/wrap in wet bandages.** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store contents under ...** …Chemical manufacturer, importer, or distributor to specify appropriate liquid or inert gas.	

C.4.24: Self-Heating Substances And Mixtures (Classified in Accordance with Appendix B.11)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	Self-heating; may catch fire	Flame 
2	Warning	Self-heating in large quantities; may catch fire	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep cool. Protect from sunlight. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Maintain air gap between stacks/ pallets.** **Store bulk masses greater than … kg/…lbs at temperatures not exceeding …°C/…°F.** ... Chemical manufacturer, importer, or distributor to specify mass and temperature. **Store away from other materials.**	

C.4.25: Substances And Mixtures Which, In Contact With Water, Emit Flammable Gases (Classified in Accordance with Appendix B.12)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	In contact with water releases flammable gases, which may ignite spontaneously	Flame 
2	Danger	In contact with water releases flammable gas	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Do not allow contact with water. **Handle under inert gas. Protect from moisture.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**Brush off loose particles from skin and immerse in cool water/wrap in wet bandages.** **In case of fire: Use ... to extinguish** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store in a dry place. Store in a closed container.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
3	Warning	In contact with water releases flammable gas	Flame 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Handle under inert gas. Protect from moisture. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*	**Store in a dry place. Store in a closed container.**	**Dispose of contents/container to...** …in accordance with local/regional/ national/ international regulations (to be specified).

C.4.26: Oxidizing Liquids (Classified in Accordance with Appendix B.13)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Danger	May cause fire or explosion; strong oxidizer	Flame Over Circle 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat. **Keep/Store away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves /eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment. **Wear fire/flame resistant/retardant clothing.**	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*		**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
2	Danger	May intensify fire; oxidizer	Flame Over Circle 
3	Warning	May intensify fire; oxidizer	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat. **Keep/Store away from clothing/…/ combustible materials.** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Take any precaution to avoid mixing with combustibles/...** ... Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*		**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified).

C.4.27: Oxidizing Solids
(Classified in Accordance with Appendix B.14)

Hazard category	Signal word	Hazard statement	Pictogram
1	Danger	May cause fire or explosion; strong oxidizer	Flame Over Circle 

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat. **Keep away from clothing and other combustible materials.** **Take any precaution to avoid mixing with combustibles/...** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment. **Wear fire/flame resistant/retardant clothing.**	**If on clothing: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes.** **In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.** **In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*		**Dispose of contents/container to...** …in accordance with local/regional/national/international regulations (to be specified).

Hazard category	Signal word	Hazard statement	Pictogram
2	Danger	May intensify fire; oxidizer	Flame Over Circle 
3	Warning	May intensify fire; oxidizer	

Precautionary statements

Prevention	Response	Storage	Disposal
Keep away from heat. **Keep/Store away from clothing/…/ combustible materials.** … Chemical manufacturer, importer, or distributor to specify incompatible materials. **Take any precaution to avoid mixing with combustibles/...** …Chemical manufacturer, importer, or distributor to specify other incompatible materials. **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.	**In case of fire: Use ... to extinguish.** ... Chemical manufacturer, importer, or distributor to specify appropriate media. *— if water increases risk.*		**Dispose of contents/container to...** ... in accordance with local/regional/national/international regulations (to be specified).

C.4.28: Organic Peroxides (Classified in Accordance with Appendix B.15)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Type A	Danger	Heating may cause an explosion	Exploding Bomb 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep/Store away from clothing/…/ combustible materials.** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** ... Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Type B	Danger	Heating may cause an explosion	Flame  Exploding Bomb 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep /Store away from clothing/.../ combustible materials.** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.28: Organic Peroxides (Classified in Accordance with Appendix B.15)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Type C	Danger	Heating may cause a fire	Flame 
Type D	Danger	Heating may cause a fire	
Type E	Warning	Heating may cause a fire	
Type F	Warning	Heating may cause a fire	
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep away from heat/sparks/open flames/hot surfaces. No smoking. Chemical manufacturer, importer, or distributor to specify applicable ignition source(s). **Keep /Store away from clothing/.../ combustible materials.** ... Chemical manufacturer, importer, or distributor to specify incompatible materials. **Keep only in original container.** **Wear protective gloves/eye protection/face protection.** Chemical manufacturer, importer, or distributor to specify type of equipment.		**Store at temperatures not exceeding …°C/…°F. Keep cool.** Chemical manufacturer, importer, or distributor to specify temperature. **Protect from sunlight.** **Store away from other materials.**	**Dispose of contents/container to...** ... in accordance with local/regional/ national/international regulations (to be specified).

C.4.29: Corrosive To Metals (Classified in Accordance with Appendix B.16)			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
1	Warning	May be corrosive to metals	Corrosion 
Precautionary statements			
Prevention	**Response**	**Storage**	**Disposal**
Keep only in original container.	**Absorb spillage to prevent material damage.**	**Store in corrosive resistant/... container with a resistant inner liner.** ... Chemical manufacturer, importer, or distributor to specify other compatible materials.	

C.4.30: Label Elements for OSHA Defined Hazards			
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Pyrophoric Gas	Danger	Catches fire spontaneously if exposed to air	Flame 
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Simple Asphyxiant	Warning	May displace oxygen and cause rapid suffocation	No Pictogram
Hazard category	**Signal word**	**Hazard statement**	**Pictogram**
Combustible Dust[2]	Warning	May form combustible dust concentrations in air	No Pictogram
1 Except no pictogram is required for explosives that are 1.4S small arms ammunition and components thereof. Labels for 1.4S small arms ammunition and components shall include appropriate precautionary statements.			
2 The chemical manufacturer or importer shall label chemicals that are shipped in dust form, and present a combustible dust hazard in that form when used downstream, under paragraph (f)(1); 2) the chemical manufacturer or importer shipping chemicals that are in a form that is not yet a dust must provide a label to customers under paragraph (f)(4) if, under normal conditions of use, the chemicals are processed in a downstream workplace in such a way that they present a combustible dust hazard; and 3) the employer shall follow the workplace labeling requirements under paragraph (f)(6) where combustible dust hazards are present.			

[77 FR 17786, 17824, March 26, 2012; 77 FR 62433, Oct. 15, 2012]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200 Appendix D
Title: Safety Data Sheets (Mandatory)

A safety data sheet (SDS) shall include the information specified in Table D.1 under the section number and heading indicated for sections 1-11 and 16. If no relevant information is found for any given subheading within a section, the SDS shall clearly indicate that no applicable information is available. Sections 12-15 may be included in the SDS, but are not mandatory.

Table D.1: Minimum Information for an SDS

Heading	Subheading
1. Identification	(a) Product identifier used on the label; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party; (e) Emergency phone number.
2. Hazard(s) identification	(a) Classification of the chemical in accordance with paragraph (d) of §1910.1200; (b) Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200. (Hazard symbols may be provided as graphical reproductions in black and white or the name of the symbol, e.g., flame, skull and crossbones); (c) Describe any hazards not otherwise classified that have been identified during the classification process; (d) Where an ingredient with unknown acute toxicity is used in a mixture at a concentration ≥1% and the mixture is not classified based on testing of the mixture as a whole, a statement that X% of the mixture consists of ingredient(s) of unknown acute toxicity is required.
3. Composition/information on ingredients	Except as provided for in paragraph (i) of §1910.1200 on trade secrets: For Substances (a) Chemical name; (b) Common name and synonyms; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. For Mixtures In addition to the information required for substances: (a) The chemical name and concentration (exact percentage) or concentration ranges of all ingredients which are classified as health hazards in accordance with paragraph (d) of §1910.1200 and (1) Are present above their cut-off/concentration limits; or (2) Present a health risk below the cut-off/concentration limits. (b) The concentration (exact percentage) shall be specified unless a trade secret claim is made in accordance with paragraph (i) of §1910.1200, when there is batch-to-batch variability in the production of a mixture, or for a group of substantially similar mixtures (See A.0.5.1.2) with similar chemical composition. In these cases, concentration ranges may be used. For All Chemicals Where a Trade Secret is Claimed Where a trade secret is claimed in accordance with paragraph (i) of §1910.1200, a statement that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret is required.
4. First-aid measures	(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed. (c) Indication of immediate medical attention and special treatment needed, if necessary.
5. Fire-fighting measures	(a) Suitable (and unsuitable) extinguishing media. (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products). (c) Special protective equipment and precautions for fire-fighters.
6. Accidental release measures	(a) Personal precautions, protective equipment, and emergency procedures. (b) Methods and materials for containment and cleaning up.

Table D.1: Minimum Information for an SDS	
7. Handling and storage	(a) Precautions for safe handling. (b) Conditions for safe storage, including any incompatibilities.
8. Exposure controls/personal protection	(a) OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available. (b) Appropriate engineering controls. (c) Individual protection measures, such as personal protective equipment.
9. Physical and chemical properties	(a) Appearance (physical state, color, etc.); (b) Odor; (c) Odor threshold; (d) pH; (e) Melting point/freezing point; (f) Initial boiling point and boiling range; (g) Flash point; (h) Evaporation rate; (i) Flammability (solid, gas); (j) Upper/lower flammability or explosive limits; (k) Vapor pressure; (l) Vapor density; (m) Relative density; (n) Solubility(ies); (o) Partition coefficient: n-octanol/water; (p) Auto-ignition temperature; (q) Decomposition temperature; (r) Viscosity.
10. Stability and reactivity	(a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions; (d) Conditions to avoid (e.g., static discharge, shock, or vibration); (e) Incompatible materials; (f) Hazardous decomposition products.
11. Toxicological information	Description of the various toxicological (health) effects and the available data used to identify those effects, including: (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic effects from short- and long-term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates). (e) Whether the hazardous chemical is listed in the National Toxicology Program (NTP) Report on Carcinogens (latest edition) or has been found to be a potential carcinogen in the International Agency for Research on Cancer (IARC) Monographs (latest edition), or by OSHA.
12. Ecological information (Non-mandatory)	(a) Ecotoxicity (aquatic and terrestrial, where available); (b) Persistence and degradability; (c) Bioaccumulative potential; (d) Mobility in soil; (e) Other adverse effects (such as hazardous to the ozone layer).
13. Disposal considerations (Non-mandatory)	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

Table D.1: Minimum Information for an SDS	
14. Transport information (Non-mandatory)	(a) UN number; (b) UN proper shipping name; (c) Transport hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (e.g., Marine pollutant (Yes/No)); (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code); (g) Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.
15. Regulatory information (Non-mandatory)	Safety, health and environmental regulations specific for the product in question.
16. Other information, including date of preparation or last revision	The date of preparation of the SDS or the last change to it.

[77 FR 17786, 17884, March 26, 2012; 77 FR 62433, Oct. 15, 2012]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1200 Appendix E
Title: Definition of "Trade Secret" (Mandatory)

The following is a reprint of the *Restatement of Torts* section 757, comment *b* (1939):

b. *Definition of trade secret*. A trade secret may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. It differs from other secret information in a business (see s759 of the Restatement of Torts which is not included in this Appendix) in that it is not simply information as to single or ephemeral events in the conduct of the business, as, for example, the amount or other terms of a secret bid for a contract or the salary of certain employees, or the security investments made or contemplated, or the date fixed for the announcement of a new policy or for bringing out a new model or the like. A trade secret is a process or device for continuous use in the operations of the business. Generally it relates to the production of goods, as, for example, a machine or formula for the production of an article. It may, however, relate to the sale of goods or to other operations in the business, such as a code for determining discounts, rebates or other concessions in a price list or catalogue, or a list of specialized customers, or a method of bookkeeping or other office management.

Secrecy. The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. Substantially, a trade secret is known only in the particular business in which it is used. It is not requisite that only the proprietor of the business know it. He may, without losing his protection, communicate it to employees involved in its use. He may likewise communicate it to others pledged to secrecy. Others may also know of it independently, as, for example, when they have discovered the process or formula by independent invention and are keeping it secret. Nevertheless, a substantial element of secrecy must exist, so that, except by the use of improper means, there would be difficulty in acquiring the information. An exact definition of a trade secret is not possible. Some factors to be considered in determining whether given information is one's trade secret are: (1) The extent to which the information is known outside of his business; (2) the extent to which it is known by employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to him and his competitors; (5) the amount of effort or money expended by him in developing the information; (6) the ease or difficulty with which the information could be properly acquired or duplicated by others.

Novelty and prior art. A trade secret may be a device or process which is patentable; but it need not be that. It may be a device or process which is clearly anticipated in the prior art or one which is merely a mechanical improvement that a good mechanic can make. Novelty and invention are not requisite for a trade secret as they are for patentability. These requirements are essential to patentability because a patent protects against unlicensed use of the patented device or process even by one who discovers it properly through independent research. The patent monopoly is a reward to the inventor. But such is not the case with a trade secret. Its protection is not based on a policy of rewarding or otherwise encouraging the development of secret processes or devices. The protection is merely against breach of faith and reprehensible means of learning another's secret. For this limited protection it is not appropriate to require also the kind of novelty and invention which is a requisite of patentability. The nature of the secret is, however, an important factor in determining the kind of relief that is appropriate against one who is subject to liability under the rule stated in this Section. Thus, if the secret consists of a device or process which is a novel invention, one who acquires the secret wrongfully is ordinarily enjoined from further use of it and is required to account for the profits derived from his past use. If, on the other hand, the secret consists of mechanical improvements that a good mechanic can make without resort to the secret, the wrongdoer's liability may be limited to damages, and an injunction against future use of the improvements made with the aid of the secret may be inappropriate.

[59 FR 6180, Feb. 9, 1994; 77 FR 17786, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 78 FR 9313, Feb. 8, 2013]

Formaldehyde

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048
Title: Formaldehyde.
Appendix: A, B, C, D, E

1910.1048(a)
Scope and application. This Standard applies to all occupational exposures to formaldehyde, i.e. from formaldehyde gas, its solutions, and materials that release formaldehyde.

1910.1048(b)
Definitions. For purposes of this Standard, the following definitions shall apply:

Action level means a concentration of 0.5 part formaldehyde per million parts of air (0.5 ppm) calculated as an eight (8)-hour time-weighted average (TWA) concentration.

Assistant Secretary means the Assistant Secretary of Labor for the Occupational Safety and Health Administration, U.S. Department of Labor, or designee.

Authorized Person means any person required by work duties to be present in regulated areas, or authorized to do so by the employer, by this section, or by the OSH Act of 1970.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designee.

Emergency is any occurrence, such as but not limited to equipment failure, rupture of containers, or failure of control equipment that results in an uncontrolled release of a significant amount of formaldehyde.

Employee exposure means the exposure to airborne formaldehyde which would occur without corrections for protection provided by any respirator that is in use.

Formaldehyde means the chemical substance, HCHO, Chemical Abstracts Service Registry No. 50-00-0.

1910.1048(c)
Permissible Exposure Limit (PEL).

1910.1048(c)(1)
TWA: The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds 0.75 parts formaldehyde per million parts of air (0.75 ppm) as an 8-hour TWA.

1910.1048(c)(2)
Short Term Exposure Limit (STEL): The employer shall assure that no employee is exposed to an airborne concentration of formaldehyde which exceeds two parts formaldehyde per million parts of air (2 ppm) as a 15-minute STEL.

1910.1048(d)
Exposure monitoring.

1910.1048(d)(1)
General.

1910.1048(d)(1)(i)
Each employer who has a workplace covered by this Standard shall monitor employees to determine their exposure to formaldehyde.

1910.1048(d)(1)(ii)
Exception. Where the employer documents, using objective data, that the presence of formaldehyde or formaldehyde-releasing products in the workplace cannot result in airborne concentrations of formaldehyde that would cause any employee to be exposed at or above the action level or the STEL under foreseeable conditions of use, the employer will not be required to measure employee exposure to formaldehyde.

1910.1048(d)(1)(iii)
When an employee's exposure is determined from representative sampling, the measurements used shall be representative of the employee's full shift or short-term exposure to formaldehyde, as appropriate.

1910.1048(d)(1)(iv)
Representative samples for each job classification in each work area shall be taken for each shift unless the employer can document with objective data that exposure levels for a given job classification are equivalent for different work shifts.

1910.1048(d)(2)
Initial monitoring. The employer shall identify all employees who may be exposed at or above the action level or at or above the STEL and accurately determine the exposure of each employee so identified.

1910.1048(d)(2)(i)
Unless the employer chooses to measure the exposure of each employee potentially exposed to formaldehyde, the employer shall develop a representative sampling strategy and measure sufficient exposures within each job classification for each workshift to correctly characterize and not underestimate the exposure of any employee within each exposure group.

1910.1048(d)(2)(ii)
The initial monitoring process shall be repeated each time there is a change in production, equipment, process, personnel, or control measures which may result in new or additional exposure to formaldehyde.

1910.1048(d)(2)(iii)
If the employer receives reports of signs or symptoms of respiratory or dermal conditions associated with formaldehyde exposure, the employer shall promptly monitor the affected employee's exposure.

1910.1048(d)(3)
Periodic monitoring.

1910.1048(d)(3)(i)
The employer shall periodically measure and accurately determine exposure to formaldehyde for employees shown by the initial monitoring to be exposed at or above the action level or at or above the STEL.

1910.1048(d)(3)(ii)
If the last monitoring results reveal employee exposure at or above the action level, the employer shall repeat monitoring of the employees at least every 6 months.

1910.1048(d)(3)(iii)
If the last monitoring results reveal employee exposure at or above the STEL, the employer shall repeat monitoring of the employees at least once a year under worst conditions.

1910.1048(d)(4)
Termination of monitoring. The employer may discontinue periodic monitoring for employees if results from two consecutive sampling periods taken at least 7 days apart show that employee exposure is below the action level and the STEL. The results must be statistically representative and consistent with the employer's knowledge of the job and work operation.

1910.1048(d)(5)
Accuracy of monitoring. Monitoring shall be accurate, at the 95 percent confidence level, to within plus or minus 25 percent for airborne concentrations of formaldehyde at the TWA and the STEL and to within plus or minus 35 percent for airborne concentrations of formaldehyde at the action level.

1910.1048(d)(6)
Employee notification of monitoring results. The employer must, within 15 working days after the receipt of the results of any monitoring performed under this section, notify each affected employee of these results either individually in writing or by posting the results in an appropriate location that is accessible to employees. If employee exposure is above the PEL, affected employees shall be provided with a description of the corrective actions being taken by the employer to decrease exposure.

1910.1048(d)(7)
Observation of monitoring.

1910.1048(d)(7)(i)
The employer shall provide affected employees or their designated representatives an opportunity to observe any monitoring of employee exposure to formaldehyde required by this Standard.

1910.1048(d)(7)(ii)
When observation of the monitoring of employee exposure to formaldehyde requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the clothing and equipment to the observer, require the observer to use such clothing and equipment, and assure that the observer complies with all other applicable safety and health procedures.

1910.1048(e)
Regulated areas.

1910.1048(e)(1)
Signs.

1910.1048(e)(1)(i)
The employer shall establish regulated areas where the concentration of airborne formaldehyde exceeds either the TWA or the STEL and post all entrances and access ways with signs bearing the following legend:

DANGER
FORMALDEHYDE
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
AUTHORIZED PERSONNEL ONLY

1910.1048(e)(1)(ii)
Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (e)(1)(i) of this section:

DANGER
FORMALDEHYDE
IRRITANT AND POTENTIAL CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

1910.1048(e)(2)
The employer shall limit access to regulated areas to authorized persons who have been trained to recognize the hazards of formaldehyde.

1910.1048(e)(3)
An employer at a multiemployer worksite who establishes a regulated area shall communicate the access restrictions and locations of these areas to other employers with work operations at that worksite.

1910.1048(f)
Methods of compliance.

1910.1048(f)(1)
Engineering controls and work practices. The employer shall institute engineering and work practice controls to reduce and maintain employee exposures to formaldehyde at or below the TWA and the STEL.

1910.1048(f)(2)
Exception. Whenever the employer has established that feasible engineering and work practice controls cannot reduce employee exposure to or below either of the PELs, the employer shall apply these controls to reduce employee exposures to the extent feasible and shall supplement them with respirators which satisfy this Standard.

1910.1048(g)
Respiratory protection.

1910.1048(g)(1)
General. For employees who use respirators required by this section, the employer must provide each employee an appropriate respirator that complies with the requirements of this paragraph. Respirators must be used during:

1910.1048(g)(1)(i)
Periods necessary to install or implement feasible engineering and work-practice controls.

1910.1048(g)(1)(ii)
Work operations, such as maintenance and repair activities or vessel cleaning, for which the employer establishes that engineering and work-practice controls are not feasible.

1910.1048(g)(1)(iii)
Work operations for which feasible engineering and work- practice controls are not yet sufficient to reduce employee exposure to or below the PELs.

1910.1048(g)(1)(iv)
Emergencies.

1910.1048(g)(2)
Respirator program.

1910.1048(g)(2)(i)
The employer must implement a respiratory protection program in accordance with § 1910.134(b) through (d) (except (d)(1)(iii), (d)(3)(iii)(b)(1), and (2)), and (f) through (m), which covers each employee required by this section to use a respirator.

1910.1048(g)(2)(ii)
When employees use air-purifying respirators with chemical cartridges or canisters that do not contain end-of-service-life indicators approved by the National Institute for Occupational Safety and Health, employers must replace these cartridges or canisters as specified by paragraphs (d)(3)(iii)(B)(1) and (B)(2) of 29 CFR 1910.134, or at the end of the workshift, whichever condition occurs first.

1910.1048(g)(2)(ii)(A)
Replace the cartridge after three (3) hours of use or at the end of the workshift, whichever occurs first, unless the cartridge contains a NIOSH-approved end-of-service-life indicator (ESLI) to show when breakthrough occurs.

1910.1048(g)(2)(ii)(B)
Unless the canister contains a NIOSH-approved ESLI to show when breakthrough occurs, replace canisters used in atmospheres up to 7.5 ppm (10xPEL) every four (4) hours and industrial-sized canisters used in atmospheres up to 75 ppm (100xPEL) every two (2) hours, or at the end of the workshift, whichever occurs first.

1910.1048(g)(3)
Respirator selection.

1910.1048(g)(3)(i)
Employers must:

1910.1048(g)(3)(i)(A)
Select, and provide to employees, the appropriate respirators specified in paragraph (d)(3)(i)(A) of 29 CFR 1910.134.

1910.1048(g)(3)(i)(B)
Equip each air-purifying, full facepiece respirator with a canister or cartridge approved for protection against formaldehyde.

1910.1048(g)(3)(i)(C)
For escape, provide employees with one of the following respirator options: A self-contained breathing apparatus operated in the demand or pressure-demand mode; or a full facepiece respirator having a chin-style, or a front-or back-mounted industrial-size, canister or cartridge approved for protection against formaldehyde.

1910.1048(g)(3)(ii)
Employers may substitute an air-purifying, half mask respirator for an air-purifying, full facepiece respirator when they equip the half mask respirator with a cartridge approved for protection against formaldehyde and provide the affected employee with effective gas-proof goggles.

1910.1048(g)(3)(iii)
Employers must provide employees who have difficulty using negative pressure respirators with powered air-purifying respirators permitted for use under paragraph (g)(3)(i)(A) of this Standard and that affords adequate protection against formaldehyde exposures.

1910.1048(h)
Protective equipment and clothing. Employers shall comply with the provisions of 29 CFR 1910.132 and 29 CFR 1910.133. When protective equipment or clothing is provided under these provisions, the employer shall provide these protective devices at no cost to the employee and assure that the employee wears them.

1910.1048(h)(1)
Selection. The employer shall select protective clothing and equipment based upon the form of formaldehyde to be encountered, the conditions of use, and the hazard to be prevented.

1910.1048(h)(1)(i)
All contact of the eyes and skin with liquids containing 1 percent or more formaldehyde shall be prevented by the use of chemical protective clothing made of material impervious to formaldehyde and the use of other personal protective equipment, such as goggles and face shields, as appropriate to the operation.

1910.1048(h)(1)(ii)
Contact with irritating or sensitizing materials shall be prevented to the extent necessary to eliminate the hazard.

1910.1048(h)(1)(iii)
Where a face shield is worn, chemical safety goggles are also required if there is a danger of formaldehyde reaching the area of the eye.

1910.1048(h)(1)(iv)
Full body protection shall be worn for entry into areas where concentrations exceed 100 ppm and for emergency reentry into areas of unknown concentration.

1910.1048(h)(2)
Maintenance of protective equipment and clothing.

1910.1048(h)(2)(i)
The employer shall assure that protective equipment and clothing that has become contaminated with formaldehyde is cleaned or laundered before its reuse.

1910.1048(h)(2)(ii)
When formaldehyde-contaminated clothing and equipment is ventilated, the employer shall establish storage areas so that employee exposure is minimized.

1910.1048(h)(2)(ii)(A)
Signs. Storage areas for contaminated clothing and equipment shall have signs bearing the following legend:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING]
EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

1910.1048(h)(2)(ii)(B)
Labels. The employer shall ensure containers for contaminated clothing and equipment are labeled consistent with the Hazard Communication Standard, Sec. 1910.1200, and shall, as a minimum, include the following:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING]
EQUIPMENT
MAY CAUSE CANCER
CAUSES SKIN, EYE, AND RESPIRATORY IRRITATION
DO NOT BREATHE VAPOR
DO NOT GET ON SKIN

1910.1048(h)(2)(ii)(C)
Prior to June 1, 2016, employers may use the following legend in lieu of that specified in paragraph (h)(2)(ii)(A) of this section:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING]
EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

1910.1048(h)(2)(ii)(D)
Prior to June 1, 2015, employers may include the following information on containers of protective clothing and equipment in lieu of the labeling requirements in paragraphs (h)(2)(ii)(B) of this section:

DANGER
FORMALDEHYDE-CONTAMINATED [CLOTHING]
EQUIPMENT
AVOID INHALATION AND SKIN CONTACT

1910.1048(h)(2)(iii)
The employer shall assure that only persons trained to recognize the hazards of formaldehyde remove the contaminated material from the storage area for purposes of cleaning, laundering, or disposal.

1910.1048(h)(2)(iv)
The employer shall assure that no employee takes home equipment or clothing that is contaminated with formaldehyde.

1910.1048(h)(2)(v)
The employer shall repair or replace all required protective clothing and equipment for each affected employee as necessary to assure its effectiveness.

1910.1048(h)(2)(vi)
The employer shall inform any person who launders, cleans, or repairs such clothing or equipment of formaldehyde's potentially harmful effects and of procedures to safely handle the clothing and equipment.

1910.1048(i)
Hygiene protection.

1910.1048(i)(1)
The employer shall provide change rooms, as described in 29 CFR 1910.141 for employees who are required to change from work clothing into protective clothing to prevent skin contact with formaldehyde.

1910.1048(i)(2)
If employees' skin may become splashed with solutions containing 1 percent or greater formaldehyde, for example, because of equipment failure or improper work practices, the employer shall provide conveniently located quick drench showers and assure that affected employees use these facilities immediately.

1910.1048(i)(3)
If there is any possibility that an employee's eyes may be splashed with solutions containing 0.1 percent or greater formaldehyde, the employer shall provide acceptable eyewash facilities within the immediate work area for emergency use.

1910.1048(j)
Housekeeping. For operations involving formaldehyde liquids or gas, the employer shall conduct a program to detect leaks and spills, including regular visual inspections.

1910.1048(j)(1)
Preventative maintenance of equipment, including surveys for leaks, shall be undertaken at regular intervals.

1910.1048(j)(2)
In work areas where spillage may occur, the employer shall make provisions to contain the spill, to decontaminate the work area, and to dispose of the waste.

1910.1048(j)(3)
The employer shall assure that all leaks are repaired and spills are cleaned promptly by employees wearing suitable protective equipment and trained in proper methods for cleanup and decontamination.

1910.1048(j)(4)
Formaldehyde-contaminated waste and debris resulting from leaks or spills shall be placed for disposal in sealed containers bearing a label warning of formaldehyde's presence and of the hazards associated with formaldehyde. The employer shall ensure that the labels are in accordance with paragraph (m) of this section.

1910.1048(k)
Emergencies. For each workplace where there is the possibility of an emergency involving formaldehyde, the employer shall assure appropriate procedures are adopted to minimize injury and loss of life. Appropriate procedures shall be implemented in the event of an emergency.

1910.1048(l)
Medical surveillance.

1910.1048(l)(1)
Employees covered.

1910.1048(l)(1)(i)
The employer shall institute medical surveillance programs for all employees exposed to formaldehyde at concentrations at or exceeding the action level or exceeding the STEL.

1910.1048(l)(1)(ii)
The employer shall make medical surveillance available for employees who develop signs and symptoms of overexposure to formaldehyde and for all employees exposed to formaldehyde in emergencies. When determining whether an employee may be experiencing signs and symptoms of possible overexposure to formaldehyde, the employer may rely on the evidence that signs and symptoms associated with formaldehyde exposure will occur only in exceptional circumstances when airborne exposure is less than 0.1 ppm and when formaldehyde is present in material in concentrations less than 0.1 percent.

1910.1048(l)(2)
Examination by a physician. All medical procedures, including administration of medical disease questionnaires, shall be performed by or under the supervision of a licensed physician and shall be provided without cost to the employee, without loss of pay, and at a reasonable time and place.

1910.1048(l)(3)
Medical disease questionnaire. The employer shall make the following medical surveillance available to employees prior to assignment to a job where formaldehyde exposure is at or above the action level or above the STEL and annually thereafter. The employer shall also make the following medical surveillance available promptly upon determining that an employee is experiencing signs and symptoms indicative of possible overexposure to formaldehyde.

1910.1048(l)(3)(i)
Administration of a medical disease questionnaire, such as in Appendix D, which is designed to elicit information on work history, smoking history, any evidence of eye, nose, or throat irritation; chronic airway problems or hyperreactive airway disease: allergic skin conditions or dermatitis; and upper or lower respiratory problems.

1910.1048(l)(3)(ii)
A determination by the physician, based on evaluation of the medical disease questionnaire, of whether a medical examination is necessary for employees not required to wear respirators to reduce exposure to formaldehyde.

1910.1048(l)(4)
Medical examinations. Medical examinations shall be given to any employee who the physician feels, based on information in the medical disease questionnaire, may be at increased risk from exposure to formaldehyde and at the time of initial assignment and at least annually thereafter to all employees required to wear a respirator to reduce exposure to formaldehyde. The medical examination shall include:

1910.1048(l)(4)(i)
A physical examination with emphasis on evidence of irritation or sensitization of the skin and respiratory system, shortness of breath, or irritation of the eyes.

1910.1048(l)(4)(ii)
Laboratory examinations for respirator wearers consisting of baseline and annual pulmonary function tests. As a minimum, these tests shall consist of forced vital capacity (FVC), forced expiratory volume in one second (FEV(1)), and forced expiratory flow (FEF).

1910.1048(l)(4)(iii)
Any other test which the examining physician deems necessary to complete the written opinion.

1910.1048(l)(4)(iv)
Counseling of employees having medical conditions that would be directly or indirectly aggravated by exposure to formaldehyde on the increased risk of impairment of their health.

1910.1048(l)(5)
Examinations for employees exposed in an emergency. The employer shall make medical examinations available as soon as possible to all employees who have been exposed to formaldehyde in an emergency.

1910.1048(l)(5)(i)
The examination shall include a medical and work history with emphasis on any evidence of upper or lower respiratory problems, allergic conditions, skin reaction or hypersensitivity, and any evidence of eye, nose, or throat irritation.

1910.1048(l)(5)(ii)
Other examinations shall consist of those elements considered appropriate by the examining physician.

1910.1048(l)(6)
Information provided to the physician. The employer shall provide the following information to the examining physician:

1910.1048(l)(6)(i)
A copy of this Standard and Appendix A, C, D, and E;

1910.1048(l)(6)(ii)
A description of the affected employee's job duties as they relate to the employee's exposure to formaldehyde;

1910.1048(l)(6)(iii)
The representative exposure level for the employee's job assignment;

1910.1048(l)(6)(iv)
Information concerning any personal protective equipment and respiratory protection used or to be used by the employee; and

1910.1048(l)(6)(v)
Information from previous medical examinations of the affected employee within the control of the employer.

1910.1048(l)(6)(vi)
In the event of a nonroutine examination because of an emergency, the employer shall provide to the physician as soon as possible: a description of how the emergency occurred and the exposure the victim may have received.

1910.1048(l)(7)
Physician's written opinion.

1910.1048(l)(7)(i)
For each examination required under this Standard, the employer shall obtain a written opinion from the examining physician. This written opinion shall contain the results of the medical examination except that it shall not reveal specific findings or diagnoses unrelated to occupational exposure to formaldehyde. The written opinion shall include:

1910.1048(l)(7)(i)(A)
The physician's opinion as to whether the employee has any medical condition that would place the employee at an increased risk of material impairment of health from exposure to formaldehyde;

1910.1048(l)(7)(i)(B)
Any recommended limitations on the employee's exposure or changes in the use of personal protective equipment, including respirators;

1910.1048(l)(7)(i)(C)
A statement that the employee has been informed by the physician of any medical conditions which would be aggravated by exposure to formaldehyde, whether these conditions may have resulted from past formaldehyde exposure or from exposure in an emergency, and whether there is a need for further examination or treatment.

1910.1048(l)(7)(ii)
The employer shall provide for retention of the results of the medical examination and tests conducted by the physician.

1910.1048(l)(7)(iii)
The employer shall provide a copy of the physician's written opinion to the affected employee within 15 days of its receipt.

1910.1048(l)(8)
Medical removal.

1910.1048(l)(8)(i)
The provisions of paragraph (l)(8) apply when an employee reports significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization attributed to workplace formaldehyde exposure. Medical removal provisions do not apply in the case of dermal irritation or dermal sensitization when the product suspected of causing the dermal condition contains less than 0.05 percent formaldehyde.

1910.1048(l)(8)(ii)
An employee's report of signs or symptoms of possible overexposure to formaldehyde shall be evaluated by a physician selected by the employer pursuant to paragraph (l)(3). If the physician determines that a medical examination is not necessary under paragraph (l)(3)(ii), there shall be a two-week evaluation and remediation period to permit the employer to ascertain whether the signs or symptoms subside untreated or with the use of creams, gloves, first aid treatment or personal protective equipment. Industrial hygiene measures that limit the employee's exposure to formaldehyde may also be implemented during this period. The employee shall be referred immediately to a physician prior to expiration of the two-week period if the signs or symptoms worsen. Earnings, seniority and benefits may not be altered during the two-week period by virtue of the report.

1910.1048(l)(8)(iii)
If the signs or symptoms have not subsided or been remedied by the end of the two-week period, or earlier if signs or symptoms warrant, the employee shall be examined by a physician selected by the employer. The physician shall presume, absent contrary evidence, that observed dermal irritation or dermal sensitization are not attributable to formaldehyde when products to which the affected employee is exposed contain less than 0.1 percent formaldehyde.

1910.1048(l)(8)(iv)
Medical examinations shall be conducted in compliance with the requirements of paragraph (l)(5)(i) and (ii). Additional guidelines for conducting medical exams are contained in Appendix C.

1910.1048(l)(8)(v)
If the physician finds that significant irritation of the mucosa of the eyes or of the upper airways, respiratory sensitization, dermal irritation, or dermal sensitization result from workplace formaldehyde exposure and recommends restrictions or removal, the employer shall promptly comply with the restrictions or recommendation of removal. In the event of a recommendation of removal, the employer shall remove the affected employee from the current formaldehyde exposure and if possible, transfer the employee to work having no or significantly less exposure to formaldehyde.

1910.1048(l)(8)(vi)
When an employee is removed pursuant to paragraph (l)(8)(v), the employer shall transfer the employee to comparable work for which the employee is qualified or can be trained in a short period (up to 6 months), where the formaldehyde exposures are as low as possible, but not higher than the action level. The employer shall maintain the employee's current earnings, seniority, and other benefits. If there is no such work available, the employer shall maintain the employee's current earnings, seniority and other benefits until such work becomes available, until the employee is determined to be unable to return to workplace formaldehyde exposure, until the employee is determined to be able to return to the original job status, or for six months, whichever comes first.

1910.1048(l)(8)(vii)
The employer shall arrange for a follow-up medical examination to take place within six months after the employee is removed pursuant to this paragraph. This examination shall determine if the employee can return to the original job status, or if the removal is to be permanent. The physician shall make a decision within six months of the date the employee was removed as to whether the employee can be returned to the original job status, or if the removal is to be permanent.

1910.1048(l)(8)(viii)
An employer's obligation to provide earnings, seniority and other benefits to a removed employee may be reduced to the extent that the employee receives compensation for earnings lost during the period of removal either from a publicly or employer-funded compensation program or from employment with another employer made possible by virtue of the employee's removal.

1910.1048(l)(8)(ix)
In making determinations of the formaldehyde content of materials under this paragraph the employer may rely on objective data.

1910.1048(l)(9)
Multiple physician review.

1910.1048(l)(9)(i)
After the employer selects the initial physician who conducts any medical examination or consultation to determine whether medical removal or restriction is appropriate, the employee may designate a second physician to review any findings, determinations or recommendations of the initial physician and to conduct such examinations, consultations,and laboratory tests as the second physician deems necessary and appropriate to evaluate the effects of formaldehyde exposure and to facilitate this review.

1910.1048(l)(9)(ii)
The employer shall promptly notify an employee of the right to seek a second medical opinion after each occasion that an initial physician conducts a medical examination or consultation for the purpose of medical removal or restriction.

1910.1048(l)(9)(iii)
The employer may condition its participation in, and payment for, the multiple physician review mechanism upon the employee doing the following within fifteen (15) days after receipt of the notification of the right to seek a second medical opinion, or receipt of the initial physician's written opinion, whichever is later;

1910.1048(l)(9)(iii)(A)
The employee informs the employer of the intention to seek a second medical opinion, and

1910.1048(l)(9)(iii)(B)
The employee initiates steps to make an appointment with a second physician.

1910.1048(l)(9)(iv)
If the findings, determinations or recommendations of the second physician differ from those of the initial physician, then the employer and the employee shall assure that efforts are made for the two physicians to resolve the disagreement. If the two physicians are unable to quickly resolve their disagreement, then the employer and the employee through their respective physicians shall designate a third physician who shall be a specialist in the field at issue:

1910.1048(l)(9)(iv)(A)
To review the findings, determinations or recommendations of the prior physicians; and

1910.1048(l)(9)(iv)(B)
To conduct such examinations, consultations, laboratory tests and discussions with the prior physicians as the third physician deems necessary to resolve the disagreement of the prior physicians.

1910.1048(l)(9)(v)
In the alternative, the employer and the employee or authorized employee representative may jointly designate such third physician.

1910.1048(l)(9)(vi)
The employer shall act consistent with the findings, determinations and recommendations of the third physician, unless the employer and the employee reach an agreement which is otherwise consistent with the recommendations of at least one of the three physicians.

1910.1048(m)
Communication of hazards.

1910.1048(m)(1)
Hazard communication—General.

1910.1048(m)(1)(i)
Chemical manufacturers, importers, distributors and employers shall comply with all requirements of the Hazard Communication Standard (HCS) (§ 1910.1200) for formaldehyde.

1910.1048(m)(1)(ii)
In classifying the hazards of formaldehyde at least the following hazards are to be addressed: Cancer; skin and respiratory sensitization; eye, skin and respiratory tract irritation; acute toxicity effects; and flammability.

1910.1048(m)(1)(iii)
Employers shall include formaldehyde in the hazard communication program established to comply with the HCS (§ 1910.1200). Employers shall ensure that each employee has access to labels on containers of formaldehyde and to safety data sheets, and is trained in accordance with the requirements of HCS and paragraph (n) of this section.

1910.1048(m)(1)(iv)
Paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this section apply to chemicals associated with formaldehyde gas, all mixtures or solutions composed of greater than 0.1 percent formaldehyde, and materials capable of releasing formaldehyde into the air at concentrations reaching or exceeding 0.1 ppm.

1910.1048(m)(1)(v)
In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

1910.1048(m)(2)(i)
In addition to the requirements in paragraphs (m)(1) through (m)(1)(iv) of this section, for materials listed in paragraph (m)(1)(iv) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in paragraph (d) of § 1910.1200 and Appendices A and B to § 1910.1200, including cancer and respiratory sensitization, and shall contain the hazard statement "May Cause Cancer."

1910.1048(m)(2)(ii)
As a minimum, for all materials listed in paragraph (m)(1)(i) and (iv) of this section capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from safety data sheets.

1910.1048(m)(2)(iii)
Prior to June 1, 2015, employers may include the phrase "Potential Cancer Hazard" in lieu of "May Cause Cancer" as specified in paragraph (m)(2)(i) of this section.

1910.1048(m)(3)
Labels.

1910.1048(m)(3)(i)
The employer shall assure that hazard warning labels complying with the requirements of 29 CFR 1910.1200(f) are affixed to all containers of materials listed in paragraph (m)(1)(i), except to the extent that 29 CFR 1910.1200(f) is inconsistent with this paragraph.

1910.1048(m)(3)(ii)
Information on labels. As a minimum, for all materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels of 0.1 ppm to 0.5 ppm, labels shall identify that the product contains formaldehyde; list the name and address of the responsible party; and state that physical and health hazard information is readily available from the employer and from material safety data sheets.

1910.1048(m)(3)(iii)
For materials listed in paragraph (m)(1)(i) capable of releasing formaldehyde at levels above 0.5 ppm, labels shall appropriately address all hazards as defined in 29 CFR 1910.1200 (d) and 29 CFR 1910.1200 Appendices A and B, including respiratory sensitization, and shall contain the words "Potential Cancer Hazard."

1910.1048(m)(3)(iv)
In making the determinations of anticipated levels of formaldehyde release, the employer may rely on objective data indicating the extent of potential formaldehyde release under reasonably foreseeable conditions of use.

1910.1048(m)(3)(v)
Substitute warning labels. The employer may use warning labels required by other statutes, regulations, or ordinances which impart the same information as the warning statements required by this paragraph.

1910.1048(m)(4)
Material safety data sheets.

1910.1048(m)(4)(i)
Any employer who uses formaldehyde-containing materials listed in paragraph (m)(1)(i) shall comply with the requirements of 29 CFR 1910.1200(g) with regard to the development and updating of material safety data sheets.

1910.1048(m)(4)(ii)
Manufacturers, importers, and distributors of formaldehyde-containing materials listed in paragraph (m)(1)(i) shall assure that material safety data sheets and updated information are provided to all employers purchasing such materials at the time of the initial shipment and at the time of the first shipment after a material safety data sheet is updated.

1910.1048(m)(5)
Written hazard communication program. The employer shall develop, implement, and maintain at the workplace, a written hazard communication program for formaldehyde exposures in the workplace, which at a minimum describes how the requirements specified in this paragraph for labels and other forms of warning and material safety data sheets, and paragraph (n) for employee information and training, will be met. Employers in multi-employer workplaces shall comply with the requirements of 29 CFR 1910.1200(e)(2).

1910.1048(n)
Employee information and training.

1910.1048(n)(1)
Participation. The employer shall assure that all employees who are assigned to workplaces where there is exposure to formaldehyde participate in a training program, except that where the employer can show, using objective data, that employees are not exposed to formaldehyde at or above 0.1 ppm, the employer is not required to provide training.

1910.1048(n)(2)
Frequency. Employers shall provide such information and training to employees at the time of initial assignment, and whenever a new exposure to formaldehyde is introduced into the work area. The training shall be repeated at least annually.

1910.1048(n)(3)
Training program. The training program shall be conducted in a manner which the employee is able to understand and shall include:

1910.1048(n)(3)(i)
A discussion of the contents of this regulation and the contents of the Material Safety Data Sheet.

1910.1048(n)(3)(ii)
The purpose for and a description of the medical surveillance program required by this Standard, including:

1910.1048(n)(3)(ii)(A)
A description of the potential health hazards associated with exposure to formaldehyde and a description of the signs and symptoms of exposure to formaldehyde.

1910.1048(n)(3)(ii)(B)
Instructions to immediately report to the employer the development of any adverse signs or symptoms that the employee suspects is attributable to formaldehyde exposure.

1910.1048(n)(3)(iii)
Description of operations in the work area where formaldehyde is present and an explanation of the safe work practices appropriate for limiting exposure to formaldehyde in each job;

1910.1048(n)(3)(iv)
The purpose for, proper use of, and limitations of personal protective clothing and equipment;

1910.1048(n)(3)(v)
Instructions for the handling of spills, emergencies, and clean-up procedures;

1910.1048(n)(3)(vi)
An explanation of the importance of engineering and work practice controls for employee protection and any necessary instruction in the use of these controls; and

1910.1048(n)(3)(vii)
A review of emergency procedures including the specific duties or assignments of each employee in the event of an emergency.

1910.1048(n)(4)
Access to training materials.

1910.1048(n)(4)(i)
The employer shall inform all affected employees of the location of written training materials and shall make these materials readily available, without cost, to the affected employees.

1910.1048(n)(4)(ii)
The employer shall provide, upon request, all training materials relating to the employee training program to the Assistant Secretary and the Director.

1910.1048(o)
Recordkeeping.

1910.1048(o)(1)
Exposure measurements. The employer shall establish and maintain an accurate record of all measurements taken to monitor employee exposure to formaldehyde. This record shall include:

1910.1048(o)(1)(i)
The date of measurement;

1910.1048(o)(1)(ii)
The operation being monitored;

1910.1048(o)(1)(iii)
The methods of sampling and analysis and evidence of their accuracy and precision;

1910.1048(o)(1)(iv)
The number, durations, time, and results of samples taken;

1910.1048(o)(1)(v)
The types of protective devices worn; and

1910.1048(o)(1)(vi)
The names, job classifications, and exposure estimates of the employees whose exposures are represented by the actual monitoring results.

1910.1048(o)(2)
Exposure determinations. Where the employer has determined that no monitoring is required under this Standard, the employer shall maintain a record of the objective data relied upon to support the determination that no employee is exposed to formaldehyde at or above the action level.

1910.1048(o)(3)
Medical surveillance. The employer shall establish and maintain an accurate record for each employee subject to medical surveillance under this Standard. This record shall include:

1910.1048(o)(3)(i)
The name of the employee;

1910.1048(o)(3)(ii)
The physician's written opinion;

1910.1048(o)(3)(iii)
A list of any employee health complaints that may be related to exposure to formaldehyde; and

1910.1048(o)(3)(iv)
A copy of the medical examination results, including medical disease questionnaires and results of any medical tests required by the Standard or mandated by the examining physician.

1910.1048(o)(4)
Respirator fit testing.

1910.1048(o)(4)(i)
The employer shall establish and maintain accurate records for employees subject to negative pressure respirator fit testing required by this Standard.

1910.1048(o)(4)(ii)
This record shall include:

1910.1048(o)(4)(ii)(A)
A copy of the protocol selected for respirator fit testing.

1910.1048(o)(4)(ii)(B)
A copy of the results of any fit testing performed.

1910.1048(o)(4)(ii)(C)
The size and manufacturer of the types of respirators available for selection.

1910.1048(o)(4)(ii)(D)
The date of the most recent fit testing, the name of each tested employee, and the respirator type and facepiece selected.

1910.1048(o)(5)
Record retention. The employer shall retain records required by this Standard for at least the following periods:

1910.1048(o)(5)(i)
Exposure records and determinations shall be kept for at least 30 years.

1910.1048(o)(5)(ii)
Medical records shall be kept for the duration of employment plus 30 years.

1910.1048(o)(5)(iii)
Respirator fit testing records shall be kept until replaced by a more recent record.

1910.1048(o)(6)
Availability of records.

1910.1048(o)(6)(i)
Upon request, the employer shall make all records maintained as a requirement of this Standard available for examination and copying to the Assistant Secretary and the Director.

1910.1048(o)(6)(ii)
The employer shall make employee exposure records, including estimates made from representative monitoring and available upon request for examination, and copying to the subject employee, or former employee, and employee representatives in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

1910.1048(o)(6)(iii)
Employee medical records required by this Standard shall be provided upon request for examination and copying, to the subject employee or former employee or to anyone having the specific written consent of the subject employee or former employee in accordance with 29 CFR 1910.1020 (a)-(e) and (g)-(i).

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990; 55 FR 32616, Aug. 10, 1990; 55 FR 51699, Dec. 17, 1990; 56 FR 10378, March 12, 1991; 56 FR 26909, June 12, 1991; 56 FR 37651, Aug. 8, 1991; 56 FR 57593, Nov. 13, 1991; 57 FR 2682, Jan. 23, 1992; 57 FR 19262, May 5, 1992; 57 FR 22307, 22310, May 27, 1992; 57 FR 24701, June 10, 1992; 57 FR 27161, June 18, 1992; 61 FR 5507, 5508, Feb. 13, 1996; 63 FR 1292, Jan. 8, 1998; 63 FR 20099, April 23, 1998; 70 FR 1143, Jan. 5, 2005; 71 FR 16672, 16673, April 3, 2006; 71 FR 50190, Aug. 24, 2006; 73 FR 75586, Dec. 12, 2008; 77 FR 17784, March 26, 2012; 77 FR 62433, Oct. 15, 2012; 84 FR 21597, May 14, 2019]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048 Appendix A
Title: Substance technical guidelines for formalin

The following Substance Technical Guideline for Formalin provides information on uninhibited formalin solution (37 percent formaldehyde, no methanol stabilizer). It is designed to inform employees at the production level of their rights and duties under the Formaldehyde Standard whether their job title defines them as workers or supervisors. Much of the information provided is general; however, some information is specific for formalin. When employee exposure to formaldehyde is from resins capable of releasing formaldehyde, the resin itself and other impurities or decomposition products may also be toxic, and employers should include this information as well when informing employees of the hazards associated with the materials they handle. The precise hazards associated with exposure to formaldehyde depend both on the form (solid, liquid, or gas) of the material and the concentration of formaldehyde present. For example, 37-50 percent solutions of formaldehyde present a much greater hazard to the skin and eyes from spills or splashes than solutions containing less than 1 percent formaldehyde. Individual Substance Technical Guidelines used by the employer for training employees should be modified to properly give information on the material actually being used.

Substance Identification
Chemical Name: Formaldehyde
Chemical Family: Aldehyde
Chemical Formula: HCHO
Molecular Weight: 30.03
Chemical Abstracts Service Number (CAS Number): 50-00-0

Synonyms: Formalin; Formic Aldehyde; Paraform; Formol; Formalin (Methanol-free); Fyde; Formalith; Methanal; Methyl Aldehyde; Methylene Glycol; Methylene Oxide; Tetraoxymethalene; Oxomethane; Oxymethylene

Components and Contaminants
Percent: 37.0 Formaldehyde
Percent: 63.0 Water

(Note-Inhibited solutions contain methanol.)
Other Contaminants: Formic acid (alcohol free) Exposure Limits: OSHA TWA-1 ppm; OSHA STEL-2 ppm

Physical Data
Description: Colorless liquid, pungent odor
Boiling point: 214 deg. F (101 deg. C)
Specific Gravity: 1.08 (H(2)O=1 at 20 deg. C)
pH: 2.8-4.0
Solubility in Water: Miscible
Solvent Solubility: Soluble in alcohol and acetone
Vapor Density: 1.04 (Air=1 at 20 deg. C)
Odor Threshold: 0.8-1 ppm

Fire and Explosion Hazard
Moderate fire and explosion hazard when exposed to heat or flame.

The flash point of 37 percent formaldehyde solutions is above normal room temperature, but the explosion range is very wide, from 7 to 73 percent by volume in air.

Reaction of formaldehyde with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid yields explosive compounds.

Flash Point: 185 deg. F (85 deg. C) closed cup
Lower Explosion Limit: 7 percent
Upper Explosion Limit: 73 percent
Autoignition Temperature: 806 deg. F (430 deg. C)
Flammability Class (OSHA): III A

Extinguishing Media: Use dry chemical, "alcohol foam", carbon dioxide, or water in flooding amounts as fog. Solid streams may not be effective. Cool fire-exposed containers with water from side until well after fire is out.

Use of water spray to flush spills can also dilute the spill to produce nonflammable mixtures. Water runoff, however, should be contained for treatment.

National Fire Protection Association Section 325M Designation:

Health: 2-Materials hazardous to health, but areas may be entered with full-faced mask self-contained breathing apparatus which provides eye protection.

Flammability: 2-Materials which must be moderately heated before ignition will occur. Water spray may be used to extinguish the fire because the material can be cooled below its flash point.

Reactivity: D-Materials which (in themselves) are normally stable even under fire exposure conditions and which are not reactive with water. Normal fire fighting procedures may be used.

Reactivity

Stability: Formaldehyde solutions may self-polymerize to form paraformaldehyde which precipitates.

Incompatibility (Materials to Avoid): Strong oxidizing agents, caustics, strong alkalies, isocyanates, anhydrides, oxides, and inorganic acids. Formaldehyde reacts with hydrochloric acid to form the potent carcinogen, bis-chloromethyl ether. Formaldehyde reacts with nitrogen dioxide, nitromethane, perchloric acid and aniline, or peroxyformic acid to yield explosive compounds. A violent reaction occurs when formaldehyde is mixed with strong oxidizers.

Hazardous Combustion or Decomposition Products: Oxygen from the air can oxidize formaldehyde to formic acid, especially when heated. Formic acid is corrosive.

Health Hazard Data

Acute Effects of Exposure

Ingestion (Swallowing): Liquids containing 10 to 40 percent formaldehyde cause severe irritation and inflammation of the mouth, throat, and stomach. Severe stomach pains will follow ingestion with possible loss of consciousness and death. Ingestion of dilute formaldehyde solutions (0.03-0.04 percent) may cause discomfort in the stomach and pharynx.

Inhalation (Breathing): Formaldehyde is highly irritating to the upper respiratory tract and eyes. Concentrations of 0.5 to 2.0 ppm may irritate the eyes, nose, and throat of some individuals. Concentrations of 3 to 5 ppm also cause tearing of the eyes and are intolerable to some persons. Concentrations of 10 to 20 ppm cause difficulty in breathing, burning of the nose and throat, cough, and heavy tearing of the eyes, and 25 to 30 ppm causes severe respiratory tract injury leading to pulmonary edema and pneumonitis. A concentration of 100 ppm is immediately dangerous to life and health. Deaths from accidental exposure to high concentrations of formaldehyde have been reported.

Skin (Dermal): Formalin is a severe skin irritant and a sensitizer. Contact with formalin causes white discoloration, smarting, drying, cracking, and scaling. Prolonged and repeated contact can cause numbness and a hardening or tanning of the skin. Previously exposed persons may react to future exposure with an allergic eczematous dermatitis or hives.

Eye Contact: Formaldehyde solutions splashed in the eye can cause injuries ranging from transient discomfort to severe, permanent corneal clouding and loss of vision. The severity of the effect depends on the concentration of formaldehyde in the solution and whether or not the eyes are flushed with water immediately after the accident.

Note. The perception of formaldehyde by odor and eye irritation becomes less sensitive with time as one adapts to formaldehyde. This can lead to overexposure if a worker is relying on formaldehyde's warning properties to alert him or her to the potential for exposure.

Acute Animal Toxicity:

Oral, rats: LD50=800 mg/kg
Oral, mouse: LD50=42 mg/kg
Inhalation, rats: LCLo=250 mg/kg
Inhalation, mouse: LCLo=900 mg/kg
Inhalation, rats: LC50=590 mg/kg

Chronic Effects of Exposure

Carcinogenicity: Formaldehyde has the potential to cause cancer in humans. Repeated and prolonged exposure increases the risk. Various animal experiments have conclusively shown formaldehyde to be a carcinogen in rats. In humans, formaldehyde exposure has been associated with cancers of the lung, nasopharynx and oropharynx, and nasal passages.

Mutagenicity: Formaldehyde is genotoxic in several in vitro test systems showing properties of both an initiator and a promoter.

Toxicity: Prolonged or repeated exposure to formaldehyde may result in respiratory impairment. Rats exposed to formaldehyde at 2 ppm developed benign nasal tumors and changes of the cell structure in the nose as well as inflamed mucous membranes of the nose. Structural changes in the epithelial cells in the human nose have also been observed. Some persons have developed asthma or bronchitis following exposure to formaldehyde, most often as the result of an accidental spill involving a single exposure to a high concentration of formaldehyde.

Emergency and First Aid Procedures

Ingestion (Swallowing): If the victim is conscious, dilute, inactivate, or absorb the ingested formaldehyde by giving milk, activated charcoal, or water. Any organic material will inactivate formaldehyde. Keep affected person warm and at rest. Get medical attention immediately. If vomiting occurs, keep head lower than hips.

Inhalation (Breathing): Remove the victim from the exposure area to fresh air immediately. Where the formaldehyde concentration may be very high, each rescuer must put on a self-contained breathing apparatus before attempting to remove the victim, and medical personnel should be informed of the formaldehyde exposure immediately. If breathing has stopped, give artificial respiration. Keep the affected person warm and at rest. Qualified first-aid or medical personnel should administer oxygen, if available, and maintain the patient's airways and blood pressure until the victim can be transported to a medical facility. If exposure results in a highly irritated upper respiratory tract and coughing continues for more than 10 minutes, the worker should be hospitalized for observation and treatment.

Skin Contact: Remove contaminated clothing (including shoes) immediately. Wash the affected area of your body with soap or mild detergent and large amounts of water until no evidence of the chemical remains (at least 15 to 20 minutes). If there are chemical burns, get first aid to cover the area with sterile, dry dressing, and bandages. Get medical attention if you experience appreciable eye or respiratory irritation.

Eye Contact: Wash the eyes immediately with large amounts of water occasionally lifting lower and upper lids, until no evidence of chemical remains (at least 15 to 20 minutes). In case of burns, apply sterile bandages loosely without medication. Get medical attention immediately. If you have experienced appreciable eye irritation from a splash or excessive exposure, you should be referred promptly to an opthamologist for evaluation.

Emergency Procedures

Emergencies: If you work in an area where a large amount of formaldehyde could be released in an accident or from equipment failure, your employer must develop procedures to be followed in event of an emergency. You should be trained in your specific duties in the event of an emergency, and it is important that you clearly understand these duties. Emergency equipment must be accessible and you should be trained to use any equipment that you might need. Formaldehyde contaminated equipment must be cleaned before reuse.

If a spill of appreciable quantity occurs, leave the area quickly unless you have specific emergency duties. Do not touch spilled material. Designated persons may stop the leak and shut off ignition sources if these procedures can be done without risk. Designated persons should isolate the hazard area and deny entry except for necessary people protected by suitable protective clothing and respirators adequate for the exposure. Use water spray to reduce vapors. Do not smoke, and prohibit all flames or flares in the hazard area.

Special Firefighting Procedures: Learn procedures and responsibilities in the event of a fire in your workplace. Become familiar with the appropriate equipment and supplies and their location. In firefighting, withdraw immediately in case of rising sound from venting safety device or any discoloration of storage tank due to fire.

Spill, Leak, and Disposal Procedures

Occupational Spill: For small containers, place the leaking container in a well ventilated area. Take up small spills with absorbent material and place the waste into properly labeled containers for later disposal. For larger spills, dike the spill to minimize contamination and facilitate salvage or disposal. You may be able to neutralize the spill with sodium hydroxide or sodium sulfite. Your employer must comply with EPA rules regarding the clean-up of toxic waste and notify state and local authorities, if required. If the spill is greater than 1,000 lb/day, it is reportable under EPA's Superfund legislation.

Waste Disposal: Your employer must dispose of waste containing formaldehyde in accordance with applicable local, state, and Federal law and in a manner that minimizes exposure of employees at the site and of the clean-up crew.

Monitoring and Measurement Procedures

Monitoring Requirements: If your exposure to formaldehyde exceeds the 0.5 ppm action level or the 2 ppm STEL, your employer must monitor your exposure. Your employer need not measure every exposure if a "high exposure" employee can be identified. This person usually spends the greatest amount of time nearest the process equipment. If you are a "representative employee", you will be asked to wear a sampling device to collect formaldehyde. This device may be a passive badge, a sorbent tube attached to a pump, or an impinger containing liquid. You should perform your work as usual, but inform the person who is conducting the monitoring of any difficulties you are having wearing the device.

Evaluation of 8-hour Exposure: Measurements taken for the purpose of determining time-weighted average (TWA) exposures are best taken with samples covering the full shift. Samples collected must be taken from the employee's breathing zone air.

Short-term Exposure Evaluation: If there are tasks that involve brief but intense exposure to formaldehyde, employee exposure must be measured to assure compliance with the STEL. Sample collections are for brief periods, only 15 minutes, but several samples may be needed to identify the peak exposure.

Monitoring Techniques: OSHA's only requirement for selecting a method for sampling and analysis is that the methods used accurately evaluate the concentration of formaldehyde in employees' breathing zones. Sampling and analysis may be performed by collection of formaldehyde on liquid or solid sorbents with subsequent chemical analysis. Sampling and analysis may also be performed by passive diffusion monitors and short-term exposure may be measured by instruments such as real-time continuous monitoring systems and portable direct reading instruments.

Notification of Results: Your employer must inform you of the results of exposure monitoring representative of your job. You may be informed in writing, but posting the results where you have ready access to them constitutes compliance with the Standard.

Protective Equipment and Clothing

[Material impervious to formaldehyde is needed if the employee handles formaldehyde solutions of 1 percent or more. Other employees may also require protective clothing or equipment to prevent dermatitis.]

Respiratory Protection: Use NIOSH-approved full facepiece negative pressure respirators equipped with approved cartridges or canisters within the use limitations of these devices. (Present restrictions on cartridges and canisters do not permit them to be used for a full workshift.) In all other situations, use positive pressure respirators such as the positive-pressure air purifying respirator or the self-contained breathing apparatus (SCBA). If you use a negative pressure respirator, your employer must provide you with fit testing of the respirator at least once a year.

Protective Gloves: Wear protective (impervious) gloves provided by your employer, at no cost, to prevent contact with formalin. Your employer should select these gloves based on the results of permeation testing and in accordance with the ACGIH Guidelines for Selection of Chemical Protective Clothing.

Eye Protection: If you might be splashed in the eyes with formalin, it is essential that you wear goggles or some other type of complete protection for the eye. You may also need a face shield if your face is likely to be splashed with formalin, but you must not substitute face shields for eye protection. (This section pertains to formaldehyde solutions of 1 percent or more.)

Other Protective Equipment: You must wear protective (impervious) clothing and equipment provided by your employer at no cost to prevent repeated or prolonged contact with formaldehyde liquids. If you are required to change into whole-body chemical protective clothing, your employer must provide a change room for your privacy and for storage of your normal clothing.

If you are splashed with formaldehyde, use the emergency showers and eyewash fountains provided by your employer immediately to prevent serious injury. Report the incident to your supervisor and obtain necessary medical support.

Entry Into an IDLH Atmosphere

Enter areas where the formaldehyde concentration might be 100 ppm or more only with complete body protection including a self-contained breathing apparatus with a full facepiece operated in a positive pressure mode or a supplied air respirator with full facepiece and operated in a positive pressure mode. This equipment is essential to protect your life and health under such extreme conditions.

Engineering Controls

Ventilation is the most widely applied engineering control method for reducing the concentration of airborne substances in the breathing zones of workers. There are two distinct types of ventilation.

Local Exhaust: Local exhaust ventilation is designed to capture airborne contaminants as near to the point of generation as possible. To protect you, the direction of contaminant flow must always be toward the local exhaust system inlet and away from you.

General (Mechanical): General dilution ventilation involves continuous introduction of fresh air into the workroom to mix with the contaminated air and lower your breathing zone concentration of formaldehyde. Effectiveness depends on the number of air changes per hour. Where devices emitting formaldehyde are spread out over a large area, general dilution ventilation may be the only practical method of control.

Work Practices: Work practices and administrative procedures are an important part of a control system. If you are asked to perform a task in a certain manner to limit your exposure to formaldehyde, it is extremely important that you follow these procedures.

Medical Surveillance
Medical surveillance helps to protect employees' health. You are encouraged strongly to participate in the medical surveillance program.

Your employer must make a medical surveillance program available at no expense to you and at a reasonable time and place if you are exposed to formaldehyde at concentrations above 0.5 ppm as an 8-hour average or 2 ppm over any 15-minute period. You will be offered medical surveillance at the time of your initial assignment and once a year afterward as long as your exposure is at least 0.5 ppm (TWA) or 2 ppm (STEL). Even if your exposure is below these levels, you should inform your employer if you have signs and symptoms that you suspect, through your training, are related to your formaldehyde exposure because you may need medical surveillance to determine if your health is being impaired by your exposure.

The surveillance plan includes:
(a) A medical disease questionnaire.
(b) A physical examination if the physician determines this is necessary.

If you are required to wear a respirator, your employer must offer you a physical examination and a pulmonary function test every year.

The physician must collect all information needed to determine if you are at increased risk from your exposure to formaldehyde. At the physician's discretion, the medical examination may include other tests, such as a chest x-ray, to make this determination.

After a medical examination the physician will provide your employer with a written opinion which includes any special protective measures recommended and any restrictions on your exposure. The physician must inform you of any medical conditions you have which would be aggravated by exposure to formaldehyde.

All records from your medical examinations, including disease surveys, must be retained at your employer's expense.

Emergencies
If you are exposed to formaldehyde in an emergency and develop signs or symptoms associated with acute toxicity from formaldehyde exposure, your employer must provide you with a medical examination as soon as possible. This medical examination will include all steps necessary to stabilize your health. You may be kept in the hospital for observation if your symptoms are severe to ensure that any delayed effects are recognized and treated.

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990; 71 FR 16673, April 3, 2006; 78 FR 9313, Feb. 8, 2013]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048 Appendix B
Title: Sampling strategy and analytical methods for formaldehyde

To protect the health of employees, exposure measurements must be unbiased and representative of employee exposure. The proper measurement of employee exposure requires more than a token commitment on the part of the employer. OSHA's mandatory requirements establish a baseline; under the best of circumstances all questions regarding employee exposure will be answered. Many employers, however, will wish to conduct more extensive monitoring before undertaking expensive commitments, such as engineering controls, to assure that the modifications are truly necessary. The following sampling strategy, which was developed at NIOSH by Nelson A. Leidel, Kenneth A. Busch, and Jeremiah R. Lynch and described in NIOSH publication No. 77-173 (Occupational Exposure Sampling Strategy Manual) will assist the employer in developing a strategy for determining the exposure of his or her employees.

There is no one correct way to determine employee exposure. Obviously, measuring the exposure of every employee exposed to formaldehyde will provide the most information on any given day. Where few employees are exposed, this may be a practical solution. For most employers, however, use of the following strategy will give just as much information at less cost.

Exposure data collected on a single day will not automatically guarantee the employer that his or her workplace is always in compliance with the Formaldehyde Standard. This does not imply, however, that it is impossible for an employer to be sure that his or her worksite is in compliance with the Standard. Indeed, a properly designed sampling strategy showing that all employees are exposed below the PELs, at least with a 95 percent certainty, is compelling evidence that the exposure limits are being achieved provided that measurements are conducted using valid sampling strategy and approved analytical methods.

There are two PELs, the TWA concentration and the STEL. Most employers will find that one of these two limits is more critical in the control of their operations, and OSHA expects that the employer will concentrate monitoring efforts on the critical component. If the more difficult exposure is controlled, this information, along with calculations to support the assumptions, should be adequate to show that the other exposure limit is also being achieved.

Sampling Strategy
Determination of the Need for Exposure Measurements
The employer must determine whether employees may be exposed to concentrations in excess of the action level. This determination becomes the first step in an employee exposure monitoring program that minimizes employer sampling burdens while providing adequate employee protection. If employees may be exposed above the action level, the employer must measure exposure. Otherwise, an objective determination that employee exposure is low provides adequate evidence that exposure potential has been examined.

The employer should examine all available relevant information, eg. insurance company and trade association data and information from suppliers or exposure data collected from similar operations. The employer may also use previously-conducted sampling including area monitoring. The employer must make a determination relevant to each operation although this need not be on a separate piece of paper. If the employer can demonstrate conclusively that no employee is exposed above the action level or the STEL through the use of objective data, the employer need proceed no further on employee exposure monitoring until such time that conditions have changed and the determination is no longer valid.

If the employer cannot determine that employee exposure is less than the action level and the STEL, employee exposure monitoring will have to be conducted.

Workplace Material Survey
The primary purpose of a survey of raw material is to determine if formaldehyde is being used in the work environment and if so, the conditions under which formaldehyde is being used.

The first step is to tabulate all situations where formaldehyde is used in a manner such that it may be released into the workplace atmosphere or contaminate the skin. This information should be available through analysis of company records and information on the MSDSs available through provisions of this Standard and the Hazard Communication Standard.

If there is an indication from materials handling records and accompanying MSDSs that formaldehyde is being used in the following types of processes or work operations, there may be a potential for releasing formaldehyde into the workplace atmosphere:

(1) Any operation that involves grinding, sanding, sawing, cutting, crushing, screening, sieving, or any other manipulation of material that generates formaldehyde-bearing dust

(2) Any processes where there have been employee complaints or symptoms indicative of exposure to formaldehyde

(3) Any liquid or spray process involving formaldehyde

(4) Any process that uses formaldehyde in preserved tissue

(5) Any process that involves the heating of a formaldehyde-bearing resin. Processes and work operations that use formaldehyde in these manners will probably require further investigation at the worksite to determine the extent of employee monitoring that should be conducted.

Workplace Observations
To this point, the only intention has been to provide an indication as to the existence of potentially exposed employees. With this information, a visit to the workplace is needed to observe work operations, to identify potential health hazards, and to determine whether any employees may be exposed to hazardous concentrations of formaldehyde.

In many circumstances, sources of formaldehyde can be identified through the sense of smell. However, this method of detection should be used with caution because of olfactory fatigue.

Employee location in relation to source of formaldehyde is important in determining if an employee may be significantly exposed to formaldehyde. In most instances, the closer a worker is to the source, the higher the probability that a significant exposure will occur.

Other characteristics should be considered. Certain high temperature operations give rise to higher evaporation rates. Locations of open doors and windows provide natural ventilation that tend to dilute formaldehyde emissions. General room ventilation also provides a measure of control.

Calculation of Potential Exposure Concentrations
By knowing the ventilation rate in a workplace and the quantity of formaldehyde generated, the employer may be able to determine by calculation if the PELs might be exceeded. To account for poor mixing of formaldehyde into the entire room, locations of fans and proximity of employees to the work operation, the employer must include a safety factor. If an employee is relatively close to a source, particularly if he or she is located downwind, a safety factor of 100 may be necessary. For other situations, a factor of 10 may be acceptable. If the employer can demonstrate through such calculations that employee exposure does not exceed the action level or the STEL, the employer may use this information as objective data to demonstrate compliance with the Standard.

Sampling Strategy
Once the employer determines that there is a possibility of substantial employee exposure to formaldehyde, the employer is obligated to measure employee exposure.

The next step is selection of a maximum risk employee. When there are different processes where employees may be exposed to formaldehyde, a maximum risk employee should be selected for each work operation.

Selection of the maximum risk employee requires professional judgment. The best procedure for selecting the maximum risk employee is to observe employees and select the person closest to the source of formaldehyde. Employee mobility may affect this selection; eg. if the closest employee is mobile in his tasks, he may not be the maximum risk employee. Air movement patterns and differences in work habits will also affect selection of the maximum risk employee.

When many employees perform essentially the same task, a maximum risk employee cannot be selected. In this circumstance, it is necessary to resort to random sampling of the group of workers. The objective is to select a subgroup of adequate size so that there is a high probability that the random sample will contain at least one worker with high exposure if one exists. The number of persons in the group influences the number that need to be sampled to ensure that at least one individual from the highest 10 percent exposure group is contained in the sample. For example, to have 90 percent confidence in the results, if the group size is 10, nine should be sampled; for 50, only 18 need to be sampled.

If measurement shows exposure to formaldehyde at or above the action level or the STEL, the employer needs to identify all other employees who may be exposed at or above the action level or STEL and measure or otherwise accurately characterize the exposure of these employees.

Whether representative monitoring or random sampling are conducted, the purpose remains the same-to determine if the exposure of any employee is above the action level. If the exposure of the most exposed employee is less than the action level and the STEL, regardless of how the employee is identified, then it is reasonable to assume that measurements of exposure of the other employees in that operation would be below the action level and the STEL.

Exposure Measurements
There is no "best" measurement strategy for all situations. Some elements to consider in developing a strategy are:

(1) Availability and cost of sampling equipment

(2) Availability and cost of analytic facilities

(3) Availability and cost of personnel to take samples

(4) Location of employees and work operations

(5) Intraday and interday variations in the process

(6) Precision and accuracy of sampling and analytic methods, and

(7) Number of samples needed.

Samples taken for determining compliance with the STEL differ from those that measure the TWA concentration in important ways. STEL samples are best taken in a nonrandom fashion using all available knowledge relating to the area, the individual, and the process to obtain samples during periods of maximum expected concentrations. At least three measurements on a shift are generally needed to spot gross errors or mistakes; however, only the highest value represents the STEL.

If an operation remains constant throughout the workshift, a much greater number of samples would need to be taken over the 32 discrete nonoverlapping periods in an 8-hour workshift to verify compliance with a STEL. If employee exposure is truly uniform throughout the workshift, however, an employer in compliance with the 1 ppm TWA would be in compliance with the 2 ppm STEL, and this determination can probably be made using objective data.

Need to Repeat the Monitoring Strategy

Interday and intraday fluctuations in employee exposure are mostly influenced by the physical processes that generate formaldehyde and the work habits of the employee. Hence, in-plant process variations influence the employer's determination of whether or not additional controls need to be imposed. Measurements that employee exposure is low on a day that is not representative of worst conditions may not provide sufficient information to determine whether or not additional engineering controls should be installed to achieve the PELs.

The person responsible for conducting sampling must be aware of systematic changes which will negate the validity of the sampling results. Systematic changes in formaldehyde exposure concentration for an employee can occur due to:

(1) The employee changing patterns of movement in the workplace

(2) Closing of plant doors and windows

(3) Changes in ventilation from season to season

(4) Decreases in ventilation efficiency or abrupt failure of engineering control equipment

(5) Changes in the production process or work habits of the employee. Any of these changes, if they may result in additional exposure that reaches the next level of action (i.e. 0.5 or 1.0 ppm as an 8-hr average or 2 ppm over 15 minutes) require the employer to perform additional monitoring to reassess employee exposure.

A number of methods are suitable for measuring employee exposure to formaldehyde or for characterizing emissions within the worksite. The preamble to this Standard describes some methods that have been widely used or subjected to validation testing. A detailed analytical procedure derived from the OSHA Method 52 for acrolein and formaldehyde is presented below for informational purposes.

Inclusion of OSHA's method in this appendix in no way implies that it is the only acceptable way to measure employee exposure to formaldehyde. Other methods that are free from significant interferences and that can determine formaldehyde at the permissible exposure limits within + or - 25 percent of the "true" value at the 95 percent confidence level are also acceptable. Where applicable, the method should also be capable of measuring formaldehyde at the action level to + or - 35 percent of the "true" value with a 95 percent confidence level. OSHA encourages employers to choose methods that will be best for their individual needs. The employer must exercise caution, however, in choosing an appropriate method since some techniques suffer from interferences that are likely to be present in workplaces of certain industry sectors where formaldehyde is used.

OSHA's Analytical Laboratory Method

Method No: 52
Matrix: Air
Target Concentration: 1 ppm (1.2 mg/m(3))
Procedures: Air samples are collected by drawing known volumes of air through sampling tubes containing XAD-2 adsorbent which have been coated with 2-(hydroxymethyl) piperidine. The samples are desorbed with toluene and then analyzed by gas chromatography using a nitrogen selective detector.

Recommended Sampling Rate and Air Volumes: 0.1 L/min and 24 L
Reliable Quantitation Limit:16 ppb (20 ug/m(3))
Standard Error of Estimate at the Target Concentration: 7.3 percent
Status of the Method: A sampling and analytical method that has been subjected to the established evaluation procedures of the Organic Methods Evaluation Branch.

Date: March 1985

1. General Discussion

1.1 Background: The current OSHA method for collecting acrolein vapor recommends the use of activated 13X molecular sieves. The samples must be stored in an ice bath during and after sampling and also they must be analyzed within 48 hours of collection. The current OSHA method for collecting formaldehyde vapor recommends the use of bubblers containing 10 percent methanol in water as the trapping solution.

This work was undertaken to resolve the sample stability problems associated with acrolein and also to eliminate the need to use bubblers to sample formaldehyde. A goal of this work was to develop and/or to evaluate a common sampling and analytical procedure for acrolein and formaldehyde.

NIOSH has developed independent methodologies for acrolein and formaldehyde which recommend the use of reagent-coated adsorbent tubes to collect the aldehydes as stable derivatives. The formaldehyde sampling tubes contain Chromosorb 102 adsorbent coated with N-benzylethanolamine (BEA) which reacts with formaldehyde vapor to form a stable oxazolidine compound. The acrolein sampling tubes contain XAD-2 adsorbent coated with 2-(hydroxymethyl)piperidine (2-HMP) which reacts with acrolein vapor to form a different, stable oxazolidine derivative. Acrolein does not appear to react with BEA to give a suitable reaction product. Therefore, the formaldehyde procedure cannot provide a common method for both aldehydes. However, formaldehyde does react with 2-HMP to form a very suitable reaction product. It is the quantitative reaction of acrolein and formaldehyde with 2-HMP that provides the basis for this evaluation.

This sampling and analytical procedure is very similar to the method recommended by NIOSH for acrolein. Some changes in the NIOSH methodology were necessary to permit the simultaneous determination of both aldehydes and also to accommodate OSHA laboratory equipment and analytical techniques.

1.2 Limit-defining parameters: The analyte air concentrations reported in this method are based on the recommended air volume for each analyte collected separately and a desorption volume of 1 mL. The amounts are presented as acrolein and/or formaldehyde, even though the derivatives are the actual species analyzed.

1.2.1 Detection limits of the analytical procedure: The detection limit of the analytical procedure was 386 pg per injection for formaldehyde. This was the amount of analyte which gave a peak whose height was about five times the height of the peak given by the residual formaldehyde derivative in a typical blank front section of the recommended sampling tube.

1.2.2 Detection limits of the overall procedure: The detection limits of the overall procedure were 482 ng per sample (16 ppb or 20 ug/m(3) for formaldehyde). This was the amount of analyte spiked on the sampling device which allowed recoveries approximately equal to the detection limit of the analytical procedure.

1.2.3 Reliable quantitation limits: The reliable quantitation limit was 482 ng per sample (16 ppb or 20 ug/m(3)) for formaldehyde. These were the smallest amounts of analyte which could be quantitated within the limits of a recovery of at least 75 percent and a precision ((+ or -)(1.96 SD) of + or - 25 percent or better.

The reliable quantitation limit and detection limits reported in the method are based upon optimization of the instrument for the smallest possible amount of analyte. When the target concentration of an exceptionally higher than these limits, they may not be attainable at the routine operating parameters.

1.2.4 Sensitivity: The sensitivity of the analytical procedure over concentration ranges representing 0.4 to 2 times the target concentration, based on the recommended air volumes, was 7,589 area units per ug/mL for formaldehyde. This value was determined from the slope of the calibration curve. The sensitivity may vary with the particular instrument used in the analysis.

1.2.5 Recovery: The recovery of formaldehyde from samples used in an 18-day storage test remained above 92 percent when the samples were stored at ambient temperature. These values were determined from regression lines which were calculated from the storage data. The recovery of the analyte from the collection device must be at least 75 percent following storage.

1.2.6 Precision (analytical method only): The pooled coefficient of variation obtained from replicate determinations of analytical standards over the range of 0.4 to 2 times the target concentration was 0.0052 for formaldehyde (Section 4.3).

1.2.7 Precision (overall procedure): The precision at the 95 percent confidence level for the ambient temperature storage tests was (+ or -) 14.3 percent for formaldehyde. These values each include an additional (+ or -) 5 percent for sampling error. The overall procedure must provide results at the target concentrations that are (+ or -) 25 percent at the 95 percent confidence level.

1.2.8 Reproducibility: Samples collected from controlled test atmospheres and a draft copy of this procedure were given to a chemist unassociated with this evaluation. The formaldehyde samples were analyzed following 15 days storage. The average recovery was 96.3 percent and the standard deviation was 1.7 percent.

1.3 Advantages:

1.3.1 The sampling and analytical procedures permit the simultaneous determination of acrolein and formaldehyde.

1.3.2 Samples are stable following storage at ambient temperature for at least 18 days.

1.4 Disadvantages: None.

2. Sampling Procedure

2.1 Apparatus:

2.1.1 Samples are collected by use of a personal sampling pump that can be calibrated to within (+ or -) 5 percent of the recommended 0.1 L/min sampling rate with the sampling tube in line.

2.1.2 Samples are collected with laboratory prepared sampling tubes. The sampling tube is constructed of silane treated glass and is about 8-cm long. The ID is 4 mm and the OD is 6 mm. One end of the tube is tapered so that a glass wool end plug will hold the contents of the tube in place during sampling. The other end of the sampling tube is open to its full 4-mm ID to facilitate packing of the tube. Both ends of the tube are fire-polished for safety. The tube is packed with a 75-mg backup section, located nearest the tapered end and a 150-mg sampling section of pretreated XAD-2 adsorbent which has been coated with 2-HMP. The two sections of coated adsorbent are separated and retained with small plugs of silanized glass wool. Following packing, the sampling tubes are sealed with two 7/32 inch OD plastic end caps. Instructions for the pretreatment and the coating of XAD-2 adsorbent are presented in Section 4 of this method.

2.1.3 Sampling tubes, similar to those recommended in this method, are marketed by Supelco, Inc. These tubes were not available when this work was initiated; therefore, they were not evaluated.

2.2 Reagents: None required.

2.3 Technique:

2.3.1 Properly label the sampling tube before sampling and then remove the plastic end caps.

2.3.2 Attach the sampling tube to the pump using a section of flexible plastic tubing such that the large, front section of the sampling tube is exposed directly to the atmosphere. Do not place any tubing ahead of the sampling tube. The sampling tube should be attached in the worker's breathing zone in a vertical manner such that it does not impede work performance.

2.3.3 After sampling for the appropriate time, remove the sampling tube from the pump and then seal the tube with plastic end caps.

2.3.4 Include at least one blank for each sampling set. The blank should be handled in the same manner as the samples with the exception that air is not drawn through it.

2.3.5 List any potential interferences on the sample data sheet.

2.4 Breakthrough:

2.4.1 Breakthrough was defined as the relative amount of analyte found on a backup sample in relation to the total amount of analyte collected on the sampling train.

2.4.2 For formaldehyde collected from test atmospheres containing 6 times the PEL, the average 5 percent breakthrough air volume was 41 L. The sampling rate was 0.1 L/min and the average mass of formaldehyde collected was 250 ug.

2.5 Desorption Efficiency: No desorption efficiency corrections are necessary to compute air sample results because analytical standards are prepared using coated adsorbent. Desorption efficiencies were determined, however, to investigate the recoveries of the analytes from the sampling device. The average recovery over the range of 0.4 to 2 times the target concentration, based on the recommended air volumes, was 96.2 percent for formaldehyde. Desorption efficiencies were essentially constant over the ranges studied.

2.6 Recommended Air Volume and Sampling Rate:

2.6.1. The recommended air volume for formaldehyde is 24 L.

2.6.2. The recommended sampling rate is 0.1 L/min.

2.7 Interferences:

2.7.1 Any collected substance that is capable of reacting 2-HMP and thereby depleting the derivatizing agent is a potential interference. Chemicals which contain a carbonyl group, such as acetone, may be capable or reacting with 2-HMP.

2.7.2 There are no other known interferences to the sampling method.

2.8 Safety Precautions:

2.8.1 Attach the sampling equipment to the worker in such a manner that it well not interfere with work performance or safety.

2.8.2 Follow all safety practices that apply to the work area being sampled.

3. Analytical Procedure

3.1 Apparatus:

3.1.1 A gas chromatograph (GC), equipped with a nitrogen selective detector. A Hewlett-Packard Model 5840A GC fitted with a nitrogen-phosphorus flame ionization detector (NPD) was used for this evaluation. Injections were performed using a Hewlett-Packard Model 7671A automatic sampler.

3.1.2 A GC column capable of resolving the analytes from any interference. A 6 ft x 1/4 in OD (2mm ID) glass GC column containing 10 percent UCON 50-HB-5100 + 2 percent KOH on 80/100 mesh Chromosorb W-AW was used for the evaluation. Injections were performed on-column.

3.1.3 Vials, glass 2-mL with Teflon-lined caps.

3.1.4 Volumetric flasks, pipets, and syringes for preparing standards, making dilutions, and performing injections.

3.2 Reagents:

3.2.1 Toluene and dimethylformamide. Burdick and Jackson solvents were used in this evaluation.

3.2.2 Helium, hydrogen, and air, GC grade.

3.2.3 Formaldehyde, 37 percent, by weight, in water. Aldrich Chemical, ACS Reagent Grade formaldehyde was used in this evaluation.

3.2.4 Amberlite XAD-2 adsorbent coated with 2-(hydroxymethyl-piperidine (2-HMP), 10 percent by weight (Section 4).

3.2.5 Desorbing solution with internal standard. This solution was prepared by adding 20 uL of dimethylformamide to 100 mL of toluene.

3.3 Standard preparation:

3.3.1 Formaldehyde: Prepare stock standards by diluting known volumes of 37 percent formaldehyde solution with methanol. A procedure to determine the formaldehyde content of these standards is presented in Section 4. A standard containing 7.7 mg/mL formaldehyde was prepared by diluting 1 mL of the 37 percent reagent to 50 mL with methanol.

3.3.2 It is recommended that analytical standards be prepared about 16 hours before the air samples are to be analyzed in order to ensure the complete reaction of the analytes with 2-HMP. However, rate studies have shown the reaction to be greater than 95 percent complete after 4 hours. Therefore, one or two standards can be analyzed after this reduced time if sample results are outside the concentration range of the prepared standards.

3.3.3 Place 150-mg portions of coated XAD-2 adsorbent, from the same lot number as used to collect the air samples, into each of several glass 2-mL vials. Seal each vial with a Teflon-lined cap.

3.3.4 Prepare fresh analytical standards each day by injecting appropriate amounts of the diluted analyte directly onto 150-mg portions of coated adsorbent. It is permissible to inject both acrolein and formaldehyde on the same adsorbent portion. Allow the standards to stand at room temperature. A standard, approximately the target levels, was prepared by injecting 11 uL of the acrolein and 12 uL of the formaldehyde stock standards onto a single coated XAD-2 adsorbent portion.

3.3.5 Prepare a sufficient number of standards to generate the calibration curves. Analytical standard concentrations should bracket sample concentrations. Thus, if samples are not in the concentration range of the prepared standards, additional standards must be prepared to determine detector response.

3.3.7 Desorb the standards in the same manner as the samples following the 16-hour reaction time.

3.4 Sample preparation:

3.4.1 Transfer the 150-mg section of the sampling tube to a 2-mL vial. Place the 75-mg section in a separate vial. If the glass wool plugs contain a significant number of adsorbent beads, place them with the appropriate sampling tube section. Discard the glass wool plugs if they do not contain a significant number of adsorbent beads.

3.4.2 Add 1 mL of desorbing solution to each vial.

3.4.3 Seal the vials with Teflon-lined caps and then allow them to desorb for one hour. Shake the vials by hand with vigorous force several times during the desorption time.

3.4.4 Save the used sampling tubes to be cleaned and recycled.

3.5 Analysis:

3.5.1 GC Conditions

Column Temperature:

Bi-level temperature program—First level: 100 to 140 deg. C at 4 deg. C/min following completion of the first level.

Second level: 140 to 180 deg. C at 20 deg. C/min following completion of the first level.

Isothermal period: Hold column at 180 deg. C until the recorder pen returns to baseline (usually about 25 min after injection).

Injector temperature: 180 deg. C

Helium flow rate: 30 mL/min (detector response will be reduced if nitrogen is substituted for helium carrier gas).

Injection volume: 0.8 uL

GC column: Six-ft x 1/4 -in OD (2 mm ID) glass GC column containing 10 percent

UCON 50-HB-5100+2 percent KOH on 80/100 Chromosorb W-AW.

NPD conditions:

Hydrogen flow rate: 3 mL/min

Air flow rate: 50 mL/min

Detector temperature: 275 deg. C

3.5.2 Chromatogram: For an example of a typical chromatogram, see Figure 4.11 in OSHA Method 52.

3.5.3 Use a suitable method, such as electronic integration, to measure detector response.

3.5.4 Use an internal standard method to prepare the calibration curve with several standard solutions of different concentrations. Prepare the calibration curve daily. Program the integrator to report results in ug/mL.

3.5.5 Bracket sample concentrations with standards.

3.6 Interferences (Analytical)

3.6.1 Any compound with the same general retention time as the analytes and which also gives a detector response is a potential interference. Possible interferences should be reported to the laboratory with submitted samples by the industrial hygienist.

3.6.2 GC parameters (temperature, column, etc.) may be changed to circumvent interferences.

3.6.3 A useful means of structure designation is GC/MS. It is recommended this procedure be used to confirm samples whenever possible.

3.6.4 The coated adsorbent usually contains a very small amount of residual formaldehyde derivative (Section 4.8).

3.7 Calculations:

3.7.1 Results are obtained by use of calibration curves. Calibration curves are prepared by plotting detector response against concentration for each standard. The best line through the data points is determined by curve fitting.

3.7.2 The concentration, in ug/mL, for a particular sample is determined by comparing its detector response to the calibration curve. If either of the analytes is found on the backup section, it is added to the amount found on the front section. Blank corrections should be performed before adding the results together.

3.7.3 The acrolein and/or formaldehyde air concentration can be expressed using the following equation: mg/m(3) = (A)(B)/C where A = ug/mL from 3.7.2, B = desorption volume, and C = L of air sampled.

No desorption efficiency corrections are required.

3.7.4 The following equation can be used to convert results in mg/m(3) to ppm.

ppm = (mg/m(3))(24.45)/MW where mg/m(3) = result from 3.7.3, 24.45 = molar volume of an ideal gas at 760 mm Hg and 25 deg. C, MW = molecular weight (30.0).

4. Backup Data

4.1 Backup data on detection limits, reliable quantitation limits, sensitivity and precision of the analytical method, breakthrough, desorption efficiency, storage, reproducibility, and generation of test atmospheres are available in OSHA Method 52, developed by the Organics Methods Evaluation Branch, OSHA Analytical Laboratory, Salt Lake City, Utah.

4.2 Procedure to Coat XAD-2 Adsorbent with 2-HMP:

4.2.1 Apparatus: Soxhlet extraction apparatus, rotary evaporation apparatus, vacuum dessicator, 1-L vacuum flask, 1-L round-bottomed evaporative flask, 1-L Erlenmeyer flask, 250-mL Buchner funnel with a coarse fritted disc, etc.

4.2.2 Reagents:

4.2.2.1 Methanol, isooctane, and toluene.

4.2.2.2 2-(Hydroxymethyl)piperidine.

4.2.2.3 Amberlite XAD-2 non-ionic polymeric adsorbent, 20 to 60 mesh, Aldrich Chemical XAD-2 was used in this evaluation.

4.2.3 Procedure: Weigh 125 g of crude XAD-2 adsorbent into a 1-L Erlenmeyer flask. Add about 200 mL of water to the flask and then swirl the mixture to wash the adsorbent. Discard any adsorbent that floats to the top of the water and then filter the mixture using a fritted Buchner funnel. Air dry the adsorbent for 2 minutes. Transfer the adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent back to the Erlenmeyer flask and then add about 200 mL of methanol to the flask. Swirl and then filter the mixture as before. Transfer the washed adsorbent to a 1-L round-bottomed evaporative flask, add 13 g of 2-HMP and then 200 mL of methanol, swirl the mixture and then allow it to stand for one hour. Remove the methanol at about 40 deg. C and reduced pressure using a rotary evaporation apparatus. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator at room temperature overnight. Transfer the coated adsorbent to a Soxhlet extractor and then extract the material with toluene for about 24 hours. Discard the contaminated toluene, add methanol in its place and then continue the Soxhlet extraction for an additional 4 hours. Transfer the adsorbent to a weighted 1-L round-bottom evaporative flask and remove the methanol using the rotary evaporation apparatus. Determine the weight of the adsorbent and then add an amount of 2-HMP, which is 10 percent by weight of the adsorbent. Add 200 mL of methanol and then swirl the mixture. Allow the mixture to stand for one hour. Remove the methanol by rotary evaporation. Transfer the coated adsorbent to a suitable container and store it in a vacuum desiccator until all traces of solvents are gone. Typically, this will take 2-3 days. The coated adsorbent should be protected from contamination. XAD-2 adsorbent treated in this manner will probably not contain residual acrolein derivative. However, this adsorbent will often contain residual formaldehyde derivative levels of about 0.1 ug per 150 mg of adsorbent. If the blank values for a batch of coated adsorbent are too high, then the batch should be returned to the Soxhlet extractor, extracted with toluene again and then recoated. This process can be repeated until the desired blank levels are attained.

The coated adsorbent is now ready to be packed into sampling tubes. The sampling tubes should be stored in a sealed container to prevent contamination. Sampling tubes should be stored in the dark at room temperature. The sampling tubes should be segregated by coated adsorbent lot number. A sufficient amount of each lot number of coated adsorbent should be retained to prepare analytical standards for use with air samples from that lot number.

4.3 A Procedure to Determine Formaldehyde by Acid Titration: Standardize the 0.1 N HCl solution using sodium carbonate and methyl orange indicator.

Place 50 mL of 0.1 M sodium sulfite and three drops of thymophthalein indicator into a 250-mL Erlenmeyer flask. Titrate the contents of the flask to a colorless endpoint with 0.1 N HCl (usually one or two drops is sufficient). Transfer 10 mL of the formaldehyde/methanol solution (prepared in 3.3.1) into the same flask and titrate the mixture with 0.1 N HCl, again, to a colorless endpoint. The formaldehyde concentration of the standard may be calculated by the following equation:

$$\text{Formaldehyde, mg/mL} = \frac{\text{acid titer x acid normality x 30.0}}{\text{mL of sample}}$$

This method is based on the quantitative liberation of sodium hydroxide when formaldehyde reacts with sodium sulfite to form the formaldehyde-bisulfite addition product. The volume of sample may be varied depending on the formaldehyde content but the solution to be titrated must contain excess sodium sulfite. Formaldehyde solutions containing substantial amounts of acid or base must be neutralized before analysis.

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048 Appendix C
Title: Medical surveillance— Formaldehyde

I. Health Hazards

The occupational health hazards of formaldehyde are primarily due to its toxic effects after inhalation, after direct contact with the skin or eyes by formaldehyde in liquid or vapor form, and after ingestion.

II. Toxicology

A. Acute Effects of Exposure

1. Inhalation (breathing): Formaldehyde is highly irritating to the upper airways. The concentration of formaldehyde that is immediately dangerous to life and health is 100 ppm. Concentrations above 50 ppm can cause severe pulmonary reactions within minutes. These include pulmonary edema, pneumonia, and bronchial irritation which can result in death. Concentrations above 5 ppm readily cause lower airway irritation characterized by cough, chest tightness and wheezing. There is some controversy regarding whether formaldehyde gas is a pulmonary sensitizer which can cause occupational asthma in a previously normal individual. Formaldehyde can produce symptoms of bronchial asthma in humans. The mechanism may be either sensitization of the individual by exposure to formaldehyde or direct irritation by formaldehyde in persons with pre-existing asthma. Upper airway irritation is the most common respiratory effect reported by workers and can occur over a wide range of concentrations, most frequently above 1 ppm. However, airway irritation has occurred in some workers with exposures to formaldehyde as low as 0.1 ppm. Symptoms of upper airway irritation include dry or sore throat, itching and burning sensations of the nose, and nasal congestion. Tolerance to this level of exposure may develop within 1-2 hours. This tolerance can permit workers remaining in an environment of gradually increasing formaldehyde concentrations to be unaware of their increasingly hazardous exposure.

2. Eye contact: Concentrations of formaldehyde between 0.05 ppm and 0.5 ppm produce a sensation of irritation in the eyes with burning, itching, redness, and tearing. Increased rate of blinking and eye closure generally protects the eye from damage at these low levels, but these protective mechanisms may interfere with some workers' work abilities. Tolerance can occur in workers continuously exposed to concentrations of formaldehyde in this range. Accidental splash injuries of human eyes to aqueous solutions of formaldehyde (formalin) have resulted in a wide range of ocular injuries including corneal opacities and blindness. The severity of the reactions have been directly dependent on the concentration of formaldehyde in solution and the amount of time lapsed before emergency and medical intervention.

3. Skin contact: Exposure to formaldehyde solutions can cause irritation of the skin and allergic contact dermatitis. These skin diseases and disorders can occur at levels well below those encountered by many formaldehyde workers. Symptoms include erythema, edema, and vesiculation or hives. Exposure to liquid formalin or formaldehyde vapor can provoke skin reactions in sensitized individuals even when airborne concentrations of formaldehyde are well below 1 ppm.

4. Ingestion: Ingestion of as little as 30 ml of a 37 percent solution of formaldehyde (formalin) can result in death. Gastrointestinal toxicity after ingestion is most severe in the stomach and results in symptoms which can include nausea, vomiting, and severe abdominal pain. Diverse damage to other organ systems including the liver, kidney, spleen, pancreas, brain, and central nervous systems can occur from the acute response to ingestion of formaldehyde.

B. Chronic Effects of Exposure

Long term exposure to formaldehyde has been shown to be associated with an increased risk of cancer of the nose and accessory sinuses, nasopharyngeal and oropharyngeal cancer, and lung cancer in humans. Animal experiments provide conclusive evidence of a causal relationship between nasal cancer in rats and formaldehyde exposure. Concordant evidence of carcinogenicity includes DNA binding, genotoxicity in short-term tests, and cytotoxic changes in the cells of the target organ suggesting both preneoplastic changes and a dose-rate effect. Formaldehyde is a complete carcinogen and appears to exert an effect on at least two stages of the carcinogenic process.

III. Surveillance considerations

A. History

1. Medical and occupational history: Along with its acute irritative effects, formaldehyde can cause allergic sensitization and cancer. One of the goals of the work history should be to elicit information on any prior or additional exposure to formaldehyde in either the occupational or the non-occupational setting.

2. Respiratory history: As noted above, formaldehyde has recognized properties as an airway irritant and has been reported by some authors as a cause of occupational asthma. In addition, formaldehyde has been associated with cancer of the entire respiratory system of humans. For these reasons, it is appropriate to include a comprehensive review of the respiratory system in the medical history. Components of this history might include questions regarding dyspnea on exertion, shortness of breath, chronic airway complaints, hyperreactive airway disease, rhinitis, bronchitis, bronchiolitis, asthma, emphysema, respiratory allergic reaction, or other preexisting pulmonary disease.

In addition, generalized airway hypersensitivity can result from exposures to a single sensitizing agent. The examiner should, therefore, elicit any prior history of exposure to pulmonary irritants, and any short- or long-term effects of that exposure.

Smoking is known to decrease mucociliary clearance of materials deposited during respiration in the nose and upper airways. This may increase a worker's exposure to inhaled materials such as formaldehyde vapor. In addition, smoking is a potential confounding factor in the investigation of any chronic respiratory disease, including cancer. For these reasons, a complete smoking history should be obtained.

3. Skin Disorders: Because of the dermal irritant and sensitizing effects of formaldehyde, a history of skin disorders should be obtained. Such a history might include the existence of skin irritation, previously documented skin sensitivity, and other dermatologic disorders. Previous exposure to formaldehyde and other dermal sensitizers should be recorded.

4. History of atopic or allergic diseases: Since formaldehyde can cause allergic sensitization of the skin and airways, it might be useful to identify individuals with prior allergen sensitization. A history of atopic disease and allergies to formaldehyde or any other substances should also be obtained. It is not definitely known at this time whether atopic diseases and allergies to formaldehyde or any other substances should also be obtained. Also it is not definitely known at this time whether atopic individuals have a greater propensity to develop formaldehyde sensitivity than the general population, but identification of these individuals may be useful for ongoing surveillance.

5. Use of disease questionnaires: Comparison of the results from previous years with present results provides the best method for detecting a general deterioration in health when toxic signs and symptoms are measured subjectively. In this way recall bias does not affect the results of the analysis. Consequently, OSHA has determined that the findings of the medical and work histories should be kept in a standardized form for comparison of the year-to-year results.

B. Physical Examination

1. Mucosa of eyes and airways: Because of the irritant effects of formaldehyde, the examining physician should be alert to evidence of this irritation. A speculum examination of the nasal mucosa may be helpful in assessing possible irritation and cytotoxic changes, as may be indirect inspection of the posterior pharynx by mirror.

2. Pulmonary system: A conventional respiratory examination, including inspection of the thorax and auscultation and percussion of the lung fields should be performed as part of the periodic medical examination. Although routine pulmonary function testing is only required by the Standard once every year for persons who are exposed over the TWA concentration limit, these tests have an obvious value in investigating possible respiratory dysfunction and should be used wherever deemed appropriate by the physician. In cases of alleged formaldehyde-induced airway disease, other possible causes of pulmonary disfunction (including exposures to other substances) should be ruled out. A chest radiograph may be useful in these circumstances. In cases of suspected airway hypersensitivity or allergy, it may be appropriate to use bronchial challenge testing with formaldehyde or methacholine to determine the nature of the disorder. Such testing should be performed by or under the supervision of a physician experienced in the procedures involved.

3. Skin: The physician should be alert to evidence of dermal irritation of sensitization, including reddening and inflammation, urticaria, blistering, scaling, formation of skin fissures, or other symptoms. Since the integrity of the skin barrier is compromised by other dermal diseases, the presence of such disease should be noted. Skin sensitivity testing carries with it some risk of inducing sensitivity, and therefore, skin testing for formaldehyde sensitivity should not be used as a routine screening test. Sensitivity testing may be indicated in the investigation of a suspected existing sensitivity. Guidelines for such testing have been prepared by the North American Contact Dermatitis Group.

C. Additional Examinations or Tests

The physician may deem it necessary to perform other medical examinations or tests as indicated. The Standard provides a mechanism whereby these additional investigations are covered under the Standard for occupational exposure to formaldehyde.

D. Emergencies

The examination of workers exposed in an emergency should be directed at the organ systems most likely to be affected. Much of the content of the examination will be similar to the periodic examination unless the patient has received a severe acute exposure requiring immediate attention to prevent serious consequences. If a severe overexposure requiring medical intervention or hospitalization has occurred, the physician must be alert to the possibility of delayed symptoms. Followup nonroutine examinations may be necessary to assure the patient's well-being.

E. Employer Obligations

The employer is required to provide the physician with the following information: A copy of this Standard and appendices A, C, D, and E; a description of the affected employee's duties as they relate to his or her exposure concentration; an estimate of the employee's exposure including duration (e.g. 15 hr/wk, three 8-hour shifts, full-time); a description of any personal protective equipment, including respirators, used by the employee; and the results of any previous medical determinations for the affected employee related to formaldehyde exposure to the extent that this information is within the employer's control.

F. Physician's Obligations

The Standard requires the employer to obtain a written statement from the physician. This statement must contain the physician's opinion as to whether the employee has any medical condition which would place him or her at increased risk of impaired health from exposure to formaldehyde or use of respirators, as appropriate. The physician must also state his opinion regarding any restrictions that should be placed on the employee's exposure to formaldehyde or upon the use of protective clothing or equipment such as respirators. If the employee wears a respirator as a result of his or her exposure to formaldehyde, the physician's opinion must also contain a statement regarding the suitability of the employee to wear the type of respirator assigned. Finally, the physician must inform the employer that the employee has been told the results of the medical examination and of any medical conditions which require further explanation or treatment. This written opinion is not to contain any information on specific findings or diagnoses unrelated to occupational exposure to formaldehyde.

The purpose in requiring the examining physician to supply the employer with a written opinion is to provide the employer with a medical basis to assist the employer in placing employees initially, in assuring that their health is not being impaired by formaldehyde, and to assess the employee's ability to use any required protective equipment.

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048 Appendix D
Title: Nonmandatory medical disease questionnaire

A. Identification

Plant Name _____

Date _____

Employee Name _____

Job Title _____

Birthdate: _____

Age: _____

Sex: _____

Height: _____

Weight: _____

B. Medical History

1. Have you ever been in the hospital as a patient? Yes ____ No ____

If yes, what kind of problem were you having?

_____

2. Have you ever had any kind of operation? Yes ____ No ____

If yes, what kind? _____

3. Do you take any kind of medicine regularly? Yes ____ No ____

If yes, what kind? _____

4. Are you allergic to any drugs, foods, or chemicals? Yes ____ No ____

If yes, what kind of allergy is it? _____

What causes the allergy? _____

5. Have you ever been told that you have asthma, hayfever, or sinusitis?

Yes ____ No ____

6. Have you ever been told that you have emphysema, bronchitis, or any other respiratory problems? Yes ____ No ____

7. Have you ever been told you had hepatitis? Yes ____ No ____

8. Have you ever been told that you had cirrhosis? Yes ____ No ____

9. Have you ever been told that you had cancer? Yes ____ No ____

10. Have you ever had arthritis or joint pain? Yes ____ No ____

11. Have you ever been told that you had high blood pressure?

Yes ____ No ____

12. Have you ever had a heart attack or heart trouble?

Yes ____ No ____

B-1. Medical History Update

1. Have you been in the hospital as a patient any time within the past year? Yes ____ No ____

If so, for what condition? _____

2. Have you been under the care of a physician during the past year?

Yes ____ No ____

If so, for what condition? _____

3. Is there any change in your breathing since last year?

Yes ____ No ____

Better? _____

Worse? _____

No change? _____

If change, do you know why? _____

4. Is your general health different this year from last year?

Yes ____ No ____

If different, in what way? _____

5. Have you in the past year or are you now taking any medication on a regular basis? Yes ____ No ____

Name Rx _____

Condition being treated _____

C. Occupational History

1. How long have you worked for your present employer?

_____

2. What jobs have you held with this employer? Include job title and length of time in each job.

_____

3. In each of these jobs, how many hours a day were you exposed to chemicals? _____

4. What chemicals have you worked with most of the time?

_____

5. Have you ever noticed any type of skin rash you feel was related to your work? Yes ____ No ____

6. Have you ever noticed that any kind of chemical makes you cough?
Yes ____ No ____

Wheeze? Yes ____ No ____

Become short of breath or cause your chest to become tight?

Yes ____ No ____

7. Are you exposed to any dust or chemicals at home?
Yes ____ No ____

If yes, explain: _____

8. In other jobs, have you ever had exposure to:

Wood dust? Yes ____ No ____

Nickel of chromium? Yes ____ No ____

Silica (foundry, sand blasting)? Yes ____ No ____

Arsenic or asbestos? Yes ____ No ____

Organic solvents? Yes ____ No ____

Urethane foams? Yes ____ No ____

C-1. Occupational History Update

1. Are you working on the same job this year as you were last year?

Yes ____ No ____

If not, how has your job changed? _____

2. What chemicals are you exposed to on your job?

_____

3. How many hours a day are you exposed to chemicals?

_____

4. Have you noticed any skin rash within the past year you feel was related to your work? Yes ____ No ____

If so, explain circumstances: _____

5. Have you noticed that any chemical makes you cough, be short of breath, or wheeze? Yes ____ No ____

If so, can you identify it? _____

D. Miscellaneous

1. Do you smoke? Yes ____ No ____

If so, how much and for how long? _____

Pipe ____ Cigars ____ Cigarettes ____

2. Do you drink alcohol in any form? Yes ____ No ____

If so, how much, how long, and how often?

_____

3. Do you wear glasses or contact lenses? Yes ____ No ____

4. Do you get any physical exercise other than that required to do your job? Yes ____ No ____

If so, explain: _____

5. Do you have any hobbies or "side jobs" that require you to use chemicals, such as furniture stripping, sand blasting, insulation or manufacture of urethane foam, furniture, etc? Yes ____ No ____

If so, please describe, giving type of business or hobby, chemicals used and length of exposures._____

E. Symptoms Questionnaire

1. Do you ever have any shortness of breath? Yes ____ No ____

If yes, do you have to rest after climbing several flights of stairs? Yes ____ No ____

If yes, if you walk on the level with people your own age, do you walk slower than they do? Yes ____ No ____

If yes, if you walk slower than a normal pace, do you have to limit the distance that you walk? Yes ____ No ____

If yes, do you have to stop and rest while bathing or dressing? Yes ____ No ____

2. Do you cough as much as three months out of the year? Yes ____ No ____

If yes, have you had this cough for more than two years? Yes ____ No ____

If yes, do you ever cough anything up from chest? Yes ____ No ____

3. Do you ever have a feeling of smothering, unable to take a deep breath, or tightness in your chest? Yes ____ No ____

If yes, do you notice that this on any particular day of the week? Yes ____ No ____

If yes, what day or the week? Yes ____ No ____

If yes, do you notice that this occurs at any particular place? Yes ____ No ____

If yes, do you notice that this is worse after you have returned to work after being off for several days? Yes ____ No ____

4. Have you ever noticed any wheezing in your chest? Yes ____ No ____

If yes, is this only with colds or other infections? Yes ____ No ____

Is this caused by exposure to any kind of dust or other material? Yes ____ No ____

If yes, what kind? _____

5. Have you noticed any burning, tearing, or redness of your eyes when you are at work? Yes ____ No ____

If so, explain circumstances: _____

6. Have you noticed any sore or burning throat or itchy or burning nose when you are at work? Yes ____ No ____

If so, explain circumstances: _____

7. Have you noticed any stuffiness or dryness of your nose? Yes ____ No ____

8. Do you ever have swelling of the eyelids or face? Yes ____ No ____

9. Have you ever been jaundiced? Yes ____ No ____

If yes, was this accompanied by any pain? Yes ____ No ____

10. Have you ever had a tendency to bruise easily or bleed excessively? Yes ____ No ____

11. Do you have frequent headaches that are not relieved by aspirin or tylenol? Yes ____ No ____

If yes, do they occur at any particular time of the day or week? Yes ____ No ____

If yes, when do they occur? _____

12. Do you have frequent episodes of nervousness or irritability? Yes ____ No ____

13. Do you tend to have trouble concentrating or remembering? Yes ____ No ____

14. Do you ever feel dizzy, light-headed, excessively drowsy or like you have been drugged? Yes ____ No ____

15. Does your vision ever become blurred? Yes ____ No ____

16. Do you have numbness or tingling of the hands or feet or other parts of your body? Yes ____ No ____

17. Have you ever had chronic weakness or fatigue? Yes ____ No ____

18. Have you ever had any swelling of your feet or ankles to the point where you could not wear your shoes? Yes ____ No ____

19. Are you bothered by heartburn or indigestion? Yes ____ No ____

20. Do you ever have itching, dryness, or peeling and scaling of the hands Yes ____ No ____

21. Do you ever have a burning sensation in the hands, or reddening of the skin? Yes ____ No ____

22. Do you ever have cracking or bleeding of the skin on your hands? Yes ____ No ____

23. Are you under a physician's care? Yes ____ No ____

If yes, for what are you being treated?_____

24. Do you have any physical complaints today? Yes ____ No ____

If yes, explain?_____

25. Do you have other health conditions not covered by these questions? Yes ____ No ____

If yes, explain:_____

[52 FR 46291, Dec. 4, 1987; 53 FR 6629, March 2, 1988; 53 FR 45082, Nov. 8, 1988; 53 FR 47188, Nov. 22, 1988; 53 FR 50199, Dec. 13, 1988; 54 FR 24334, June 7, 1989; 54 FR 29546, July 13, 1989; 54 FR 31765, Aug. 1, 1989; 54 FR 35639, Aug. 29, 1989; 55 FR 24070, June 13, 1990; 84 FR 21518, May 14, 2019]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: Z
Subpart Title: Toxic and Hazardous Substances
Standard Number: 1910.1048 Appendix E
Title: Qualitative and quantitative fit testing procedures

[Removed]

[63 FR 1152, Jan. 8, 1998]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: I
Subpart Title: Personal Protective Equipment
Standard Number: 1910.134 Appendix A
Title: Fit Testing Procedures (Mandatory)

Part I. OSHA-Accepted Fit Test Protocols

A. Fit Testing Procedures—General Requirements

The employer shall conduct fit testing using the following procedures. The requirements in this appendix apply to all OSHA-accepted fit test methods, both QLFT and QNFT.

1. The test subject shall be allowed to pick the most acceptable respirator from a sufficient number of respirator models and sizes so that the respirator is acceptable to, and correctly fits, the user.

2. Prior to the selection process, the test subject shall be shown how to put on a respirator, how it should be positioned on the face, how to set strap tension and how to determine an acceptable fit. A mirror shall be available to assist the subject in evaluating the fit and positioning of the respirator. This instruction may not constitute the subject's formal training on respirator use, because it is only a review.

3. The test subject shall be informed that he/she is being asked to select the respirator that provides the most acceptable fit. Each respirator represents a different size and shape, and if fitted and used properly, will provide adequate protection.

4. The test subject shall be instructed to hold each chosen facepiece up to the face and eliminate those that obviously do not give an acceptable fit.

5. The more acceptable facepieces are noted in case the one selected proves unacceptable; the most comfortable mask is donned and worn at least five minutes to assess comfort. Assistance in assessing comfort can be given by discussing the points in the following item A.6. If the test subject is not familiar with using a particular respirator, the test subject shall be directed to don the mask several times and to adjust the straps each time to become adept at setting proper tension on the straps.

6. Assessment of comfort shall include a review of the following points with the test subject and allowing the test subject adequate time to determine the comfort of the respirator:

(a) Position of the mask on the nose

(b) Room for eye protection

(c) Room to talk

(d) Position of mask on face and cheeks

7. The following criteria shall be used to help determine the adequacy of the respirator fit:

(a) Chin properly placed;

(b) Adequate strap tension, not overly tightened;

(c) Fit across nose bridge;

(d) Respirator of proper size to span distance from nose to chin;

(e) Tendency of respirator to slip;

(f) Self-observation in mirror to evaluate fit and respirator position.

8. The test subject shall conduct a user seal check, either the negative and positive pressure seal checks described in Appendix B-1 of this section or those recommended by the respirator manufacturer which provide equivalent protection to the procedures in Appendix B-1. Before conducting the negative and positive pressure checks, the subject shall be told to seat the mask on the face by moving the head from side-to-side and up and down slowly while taking in a few slow deep breaths. Another facepiece shall be selected and retested if the test subject fails the user seal check tests.

9. The test shall not be conducted if there is any hair growth between the skin and the facepiece sealing surface, such as stubble beard growth, beard, mustache or sideburns which cross the respirator sealing surface. Any type of apparel which interferes with a satisfactory fit shall be altered or removed.

10. If a test subject exhibits difficulty in breathing during the tests, she or he shall be referred to a physician or other licensed health care professional, as appropriate, to determine whether the test subject can wear a respirator while performing her or his duties.

11. If the employee finds the fit of the respirator unacceptable, the test subject shall be given the opportunity to select a different respirator and to be retested.

12. Exercise regimen. Prior to the commencement of the fit test, the test subject shall be given a description of the fit test and the test subject's responsibilities during the test procedure. The description of the process shall include a description of the test exercises that the subject will be performing. The respirator to be tested shall be worn for at least 5 minutes before the start of the fit test.

13. The fit test shall be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.

14. Test Exercises.

(a) Employers must perform the following test exercises for all fit testing methods prescribed in this appendix, except for the two modified ambient aerosol CNC quantitative fit testing protocols, the CNP quantitative fit testing protocol, and the CNP REDON quantitative fit testing protocol. For the modified ambient aerosol CNC quantitative fit testing protocols, employers shall ensure that the test subjects (i.e., employees) perform the exercise procedure specified in Part I.C.4(b) of this appendix for full-facepiece and half-mask elastomeric respirators, or the exercise procedure specified in Part I.C.5(b) for filtering facepiece respirators. Employers shall ensure that the test subjects (i.e., employees) perform the exercise procedure specified in Part I.C.6(b) of this appendix for the CNP quantitative fit testing protocol, or the exercise procedure described in Part I.C.7(b) of this appendix for the CNP REDON quantitative fit testing protocol. For the remaining fit testing methods, employers shall ensure that the test exercises are performed in the appropriate test environment in the following manner:

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply, taking caution so as not to hyperventilate.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his/her head from side to side between the extreme positions on each side. The head shall be held at each extreme momentarily so the subject can inhale at each side.

(4) Moving head up and down. Standing in place, the subject shall slowly move his/her head up and down. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling).

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song.

Rainbow Passage
When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look, but no one ever finds it. When a man looks for something beyond reach, his friends say he is looking for the pot of gold at the end of the rainbow.

(6) Grimace. The test subject shall grimace by smiling or frowning. (This applies only to QNFT testing; it is not performed for QLFT)

(7) Bending over. The test subject shall bend at the waist as if he/she were to touch his/her toes. Jogging in place shall be substituted for this exercise in those test environments such as shroud type QNFT or QLFT units that do not permit bending over at the waist.

(8) Normal breathing. Same as exercise (1).

(b) Each test exercise shall be performed for one minute except for the grimace exercise which shall be performed for 15 seconds. The test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried. The respirator shall not be adjusted once the fit test exercises begin. Any adjustment voids the test, and the fit test must be repeated.

B. Qualitative Fit Test (QLFT) Protocols

1. General
(a) The employer shall ensure that persons administering QLFT are able to prepare test solutions, calibrate equipment and perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QLFT equipment is kept clean and well maintained so as to operate within the parameters for which it was designed.

2. Isoamyl Acetate Protocol
Note: This protocol is not appropriate to use for the fit testing of particulate respirators. If used to fit test particulate respirators, the respirator must be equipped with an organic vapor filter.

(a) Odor Threshold Screening

Odor threshold screening, performed without wearing a respirator, is intended to determine if the individual tested can detect the odor of isoamyl acetate at low levels.

(1) Three 1 liter glass jars with metal lids are required.

(2) Odor-free water (e.g., distilled or spring water) at approximately 25 deg. C (77 deg. F) shall be used for the solutions.

(3) The isoamyl acetate (IAA) (also known at isopentyl acetate) stock solution is prepared by adding 1 ml of pure IAA to 800 ml of odor-free water in a 1 liter jar, closing the lid and shaking for 30 seconds. A new solution shall be prepared at least weekly.

(4) The screening test shall be conducted in a room separate from the room used for actual fit testing. The two rooms shall be well-ventilated to prevent the odor of IAA from becoming evident in the general room air where testing takes place.

(5) The odor test solution is prepared in a second jar by placing 0.4 ml of the stock solution into 500 ml of odor-free water using a clean dropper or pipette. The solution shall be shaken for 30 seconds and allowed to stand for two to three minutes so that the IAA concentration above the liquid may reach equilibrium. This solution shall be used for only one day.

(6) A test blank shall be prepared in a third jar by adding 500 cc of odor-free water.

(7) The odor test and test blank jar lids shall be labeled (e.g., 1 and 2) for jar identification. Labels shall be placed on the lids so that they can be peeled off periodically and switched to maintain the integrity of the test.

(8) The following instruction shall be typed on a card and placed on the table in front of the two test jars (i.e., 1 and 2): "The purpose of this test is to determine if you can smell banana oil at a low concentration. The two bottles in front of you contain water. One of these bottles also contains a small amount of banana oil. Be sure the covers are on tight, then shake each bottle for two seconds. Unscrew the lid of each bottle, one at a time, and sniff at the mouth of the bottle. Indicate to the test conductor which bottle contains banana oil."

(9) The mixtures used in the IAA odor detection test shall be prepared in an area separate from where the test is performed, in order to prevent olfactory fatigue in the subject.

(10) If the test subject is unable to correctly identify the jar containing the odor test solution, the IAA qualitative fit test shall not be performed.

(11) If the test subject correctly identifies the jar containing the odor test solution, the test subject may proceed to respirator selection and fit testing.

(b) Isoamyl Acetate Fit Test

(1) The fit test chamber shall be a clear 55-gallon drum liner suspended inverted over a 2-foot diameter frame so that the top of the chamber is about 6 inches above the test subject's head. If no drum liner is available, a similar chamber shall be constructed using plastic sheeting. The inside top center of the chamber shall have a small hook attached.

(2) Each respirator used for the fitting and fit testing shall be equipped with organic vapor cartridges or offer protection against organic vapors.

(3) After selecting, donning, and properly adjusting a respirator, the test subject shall wear it to the fit testing room. This room shall be separate from the room used for odor threshold screening and respirator selection, and shall be well-ventilated, as by an exhaust fan or lab hood, to prevent general room contamination.

(4) A copy of the test exercises and any prepared text from which the subject is to read shall be taped to the inside of the test chamber.

(5) Upon entering the test chamber, the test subject shall be given a 6-inch by 5-inch piece of paper towel, or other porous, absorbent, single-ply material, folded in half and wetted with 0.75 ml of pure IAA. The test subject shall hang the wet towel on the hook at the top of the chamber. An IAA test swab or ampule may be substituted for the IAA wetted paper towel provided it has been demonstrated that the alternative IAA source will generate an IAA test atmosphere with a concentration equivalent to that generated by the paper towel method.

(6) Allow two minutes for the IAA test concentration to stabilize before starting the fit test exercises. This would be an appropriate time to talk with the test subject; to explain the fit test, the importance of his/her cooperation, and the purpose for the test exercises; or to demonstrate some of the exercises.

(7) If at any time during the test, the subject detects the banana-like odor of IAA, the test is failed. The subject shall quickly exit from the test chamber and leave the test area to avoid olfactory fatigue.

(8) If the test is failed, the subject shall return to the selection room and remove the respirator. The test subject shall repeat the odor sensitivity test, select and put on another respirator, return to the test area and again begin the fit test procedure described in (b) (1) through (7) above. The process continues until a respirator that fits well has been found. Should the odor sensitivity test be failed, the subject shall wait at least 5 minutes before retesting. Odor sensitivity will usually have returned by this time.

(9) If the subject passes the test, the efficiency of the test procedure shall be demonstrated by having the subject break the respirator face seal and take a breath before exiting the chamber.

(10) When the test subject leaves the chamber, the subject shall remove the saturated towel and return it to the person conducting the test, so that there is no significant IAA concentration buildup in the chamber during subsequent tests. The used towels shall be kept in a self-sealing plastic bag to keep the test area from being contaminated.

3. Saccharin Solution Aerosol Protocol

The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste threshold screening. The saccharin taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of saccharin.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches in diameter by 14 inches tall with at least the front portion clear and that allows free movements of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a 3/4-inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his/her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a sweet taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the threshold check solution into the enclosure. The nozzle is directed away from the nose and mouth of the person. This nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The threshold check solution is prepared by dissolving 0.83 gram of sodium saccharin USP in 100 ml of warm water. It can be prepared by putting 1 ml of the fit test solution (see (b)(5) below) in 100 ml of distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand.

(7) Ten squeezes are repeated rapidly and then the test subject is asked whether the saccharin can be tasted. If the test subject reports tasting the sweet taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the saccharin is tasted. If the test subject reports tasting the sweet taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the saccharin is not tasted after 30 squeezes (step 10), the test subject is unable to taste saccharin and may not perform the saccharin fit test.

Note to paragraph 3. (a): If the test subject eats or drinks something sweet before the screening test, he/she may be unable to taste the weak saccharin solution.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Saccharin solution aerosol fit test procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure described in 3. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected in section I. A. of this appendix. The respirator shall be properly adjusted and equipped with a particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 83 grams of sodium saccharin to 100 ml of warm water.

(6) As before, the test subject shall breathe through the slightly open mouth with tongue extended, and report if he/she tastes the sweet taste of saccharin.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of saccharin fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test. A minimum of 10 squeezes is required.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the original number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of saccharin is detected. If the test subject does not report tasting the saccharin, the test is passed.

(11) If the taste of saccharin is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

(12) Since the nebulizer has a tendency to clog during use, the test operator must make periodic checks of the nebulizer to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid.

4. Bitrex™ (Denatonium Benzoate) Solution Aerosol Qualitative Fit Test Protocol

The Bitrex™ (Denatonium benzoate) solution aerosol QLFT protocol uses the published saccharin test protocol because that protocol is widely accepted. Bitrex is routinely used as a taste aversion agent in household liquids which children should not be drinking and is endorsed by the American Medical Association, the National Safety Council, and the American Association of Poison Control Centers. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) Taste Threshold Screening.

The Bitrex taste threshold screening, performed without wearing a respirator, is intended to determine whether the individual being tested can detect the taste of Bitrex.

(1) During threshold screening as well as during fit testing, subjects shall wear an enclosure about the head and shoulders that is approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall. The front portion of the enclosure shall be clear from the respirator and allow free movement of the head when a respirator is worn. An enclosure substantially similar to the 3M hood assembly, parts # FT 14 and # FT 15 combined, is adequate.

(2) The test enclosure shall have a 3/4 inch (1.9 cm) hole in front of the test subject's nose and mouth area to accommodate the nebulizer nozzle.

(3) The test subject shall don the test enclosure. Throughout the threshold screening test, the test subject shall breathe through his or her slightly open mouth with tongue extended. The subject is instructed to report when he/she detects a bitter taste.

(4) Using a DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent, the test conductor shall spray the Threshold Check Solution into the enclosure. This Nebulizer shall be clearly marked to distinguish it from the fit test solution nebulizer.

(5) The Threshold Check Solution is prepared by adding 13.5 milligrams of Bitrex to 100 ml of 5 percent salt (NaCl) solution in distilled water.

(6) To produce the aerosol, the nebulizer bulb is firmly squeezed so that the bulb collapses completely, and is then released and allowed to fully expand.

(7) An initial ten squeezes are repeated rapidly and then the test subject is asked whether the Bitrex can be tasted. If the test subject reports tasting the bitter taste during the ten squeezes, the screening test is completed. The taste threshold is noted as ten regardless of the number of squeezes actually completed.

(8) If the first response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the second ten squeezes, the screening test is completed. The taste threshold is noted as twenty regardless of the number of squeezes actually completed.

(9) If the second response is negative, ten more squeezes are repeated rapidly and the test subject is again asked whether the Bitrex is tasted. If the test subject reports tasting the bitter taste during the third set of ten squeezes, the screening test is completed. The taste threshold is noted as thirty regardless of the number of squeezes actually completed.

(10) The test conductor will take note of the number of squeezes required to solicit a taste response.

(11) If the Bitrex is not tasted after 30 squeezes (step 10), the test subject is unable to taste Bitrex and may not perform the Bitrex fit test.

(12) If a taste response is elicited, the test subject shall be asked to take note of the taste for reference in the fit test.

(13) Correct use of the nebulizer means that approximately 1 ml of liquid is used at a time in the nebulizer body.

(14) The nebulizer shall be thoroughly rinsed in water, shaken to dry, and refilled at least each morning and afternoon or at least every four hours.

(b) Bitrex Solution Aerosol Fit Test Procedure.

(1) The test subject may not eat, drink (except plain water), smoke, or chew gum for 15 minutes before the test.

(2) The fit test uses the same enclosure as that described in 4. (a) above.

(3) The test subject shall don the enclosure while wearing the respirator selected according to section I. A. of this appendix. The respirator shall be properly adjusted and equipped with any type particulate filter(s).

(4) A second DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure. This nebulizer shall be clearly marked to distinguish it from the screening test solution nebulizer.

(5) The fit test solution is prepared by adding 337.5 mg of Bitrex to 200 ml of a 5 percent salt (NaCl) solution in warm water.

(6) As before, the test subject shall breathe through his or her slightly open mouth with tongue extended, and be instructed to report if he/she tastes the bitter taste of Bitrex.

(7) The nebulizer is inserted into the hole in the front of the enclosure and an initial concentration of the fit test solution is sprayed into the enclosure using the same number of squeezes (either 10, 20 or 30 squeezes) based on the number of squeezes required to elicit a taste response as noted during the screening test.

(8) After generating the aerosol, the test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(9) Every 30 seconds the aerosol concentration shall be replenished using one half the number of squeezes used initially (e.g., 5, 10 or 15).

(10) The test subject shall indicate to the test conductor if at any time during the fit test the taste of Bitrex is detected. If the test subject does not report tasting the Bitrex, the test is passed.

(11) If the taste of Bitrex is detected, the fit is deemed unsatisfactory and the test is failed. A different respirator shall be tried and the entire test procedure is repeated (taste threshold screening and fit testing).

5. Irritant Smoke (Stannic Chloride) Protocol

This qualitative fit test uses a person's response to the irritating chemicals released in the "smoke" produced by a stannic chloride ventilation smoke tube to detect leakage into the respirator.

(a) General Requirements and Precautions

(1) The respirator to be tested shall be equipped with high efficiency particulate air (HEPA) or P100 series filter(s).

(2) Only stannic chloride smoke tubes shall be used for this protocol.

(3) No form of test enclosure or hood for the test subject shall be used.

(4) The smoke can be irritating to the eyes, lungs, and nasal passages. The test conductor shall take precautions to minimize the test subject's exposure to irritant smoke. Sensitivity varies, and certain individuals may respond to a greater degree to irritant smoke. Care shall be taken when performing the sensitivity screening checks that determine whether the test subject can detect irritant smoke to use only the minimum amount of smoke necessary to elicit a response from the test subject.

(5) The fit test shall be performed in an area with adequate ventilation to prevent exposure of the person conducting the fit test or the build-up of irritant smoke in the general atmosphere.

(b) Sensitivity Screening Check

The person to be tested must demonstrate his or her ability to detect a weak concentration of the irritant smoke.

(1) The test operator shall break both ends of a ventilation smoke tube containing stannic chloride, and attach one end of the smoke tube to a low flow air pump set to deliver 200 milliliters per minute, or an aspirator squeeze bulb. The test operator shall cover the other end of the smoke tube with a short piece of tubing to prevent potential injury from the jagged end of the smoke tube.

(2) The test operator shall advise the test subject that the smoke can be irritating to the eyes, lungs, and nasal passages and instruct the subject to keep his/her eyes closed while the test is performed.

(3) The test subject shall be allowed to smell a weak concentration of the irritant smoke before the respirator is donned to become familiar with its irritating properties and to determine if he/she can detect the irritating properties of the smoke. The test operator shall carefully direct a small amount of the irritant smoke in the test subject's direction to determine that he/she can detect it.

(c) Irritant Smoke Fit Test Procedure

(1) The person being fit tested shall don the respirator without assistance, and perform the required user seal check(s).

(2) The test subject shall be instructed to keep his/her eyes closed.

(3) The test operator shall direct the stream of irritant smoke from the smoke tube toward the faceseal area of the test subject, using the low flow pump or the squeeze bulb. The test operator shall begin at least 12 inches from the facepiece and move the smoke stream around the whole perimeter of the mask. The operator shall gradually make two more passes around the perimeter of the mask, moving to within six inches of the respirator.

(4) If the person being tested has not had an involuntary response and/or detected the irritant smoke, proceed with the test exercises.

(5) The exercises identified in section I.A. 14. of this appendix shall be performed by the test subject while the respirator seal is being continually challenged by the smoke, directed around the perimeter of the respirator at a distance of six inches.

(6) If the person being fit tested reports detecting the irritant smoke at any time, the test is failed. The person being retested must repeat the entire sensitivity check and fit test procedure.

(7) Each test subject passing the irritant smoke test without evidence of a response (involuntary cough, irritation) shall be given a second sensitivity screening check, with the smoke from the same smoke tube used during the fit test, once the respirator has been removed, to determine whether he/she still reacts to the smoke. Failure to evoke a response shall void the fit test.

(8) If a response is produced during this second sensitivity check, then the fit test is passed.

C. Quantitative Fit Test (QNFT) Protocols

The following quantitative fit testing procedures have been demonstrated to be acceptable: Quantitative fit testing using a non-hazardous test aerosol (such as corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS], or sodium chloride) generated in a test chamber, and employing instrumentation to quantify the fit of the respirator; Quantitative fit testing using ambient aerosol as the test agent and appropriate instrumentation (condensation nuclei counter) to quantify the respirator fit; Quantitative fit testing using controlled negative pressure and appropriate instrumentation to measure the volumetric leak rate of a facepiece to quantify the respirator fit.

1. General

(a) The employer shall ensure that persons administering QNFT are able to calibrate equipment and perform tests properly, recognize invalid tests, calculate fit factors properly and ensure that test equipment is in proper working order.

(b) The employer shall ensure that QNFT equipment is kept clean, and is maintained and calibrated according to the manufacturer's instructions so as to operate at the parameters for which it was designed.

2. Generated Aerosol Quantitative Fit Testing Protocol

(a) Apparatus.

(1) Instrumentation. Aerosol generation, dilution, and measurement systems using particulates (corn oil, polyethylene glycol 400 [PEG 400], di-2-ethyl hexyl sebacate [DEHS] or sodium chloride) as test aerosols shall be used for quantitative fit testing.

(2) Test chamber. The test chamber shall be large enough to permit all test subjects to perform freely all required exercises without disturbing the test agent concentration or the measurement apparatus. The test chamber shall be equipped and constructed so that the test agent is effectively isolated from the ambient air, yet uniform in concentration throughout the chamber.

(3) When testing air-purifying respirators, the normal filter or cartridge element shall be replaced with a high efficiency particulate air (HEPA) or P100 series filter supplied by the same manufacturer.

(4) The sampling instrument shall be selected so that a computer record or strip chart record may be made of the test showing the rise and fall of the test agent concentration with each inspiration and expiration at fit factors of at least 2,000. Integrators or computers that integrate the amount of test agent penetration leakage into the respirator for each exercise may be used provided a record of the readings is made.

(5) The combination of substitute air-purifying elements, test agent and test agent concentration shall be such that the test subject is not exposed in excess of an established exposure limit for the test agent at any time during the testing process, based upon the length of the exposure and the exposure limit duration.

(6) The sampling port on the test specimen respirator shall be placed and constructed so that no leakage occurs around the port (e.g., where the respirator is probed), a free air flow is allowed into the sampling line at all times, and there is no interference with the fit or performance of the respirator. The in-mask sampling device (probe) shall be designed and used so that the air sample is drawn from the breathing zone of the test subject, midway between the nose and mouth and with the probe extending into the facepiece cavity at least 1/4 inch.

(7) The test setup shall permit the person administering the test to observe the test subject inside the chamber during the test.

(8) The equipment generating the test atmosphere shall maintain the concentration of test agent constant to within a 10 percent variation for the duration of the test.

(9) The time lag (interval between an event and the recording of the event on the strip chart or computer or integrator) shall be kept to a minimum. There shall be a clear association between the occurrence of an event and its being recorded.

(10) The sampling line tubing for the test chamber atmosphere and for the respirator sampling port shall be of equal diameter and of the same material. The length of the two lines shall be equal.

(11) The exhaust flow from the test chamber shall pass through an appropriate filter (i.e., high efficiency particulate filter) before release.

(12) When sodium chloride aerosol is used, the relative humidity inside the test chamber shall not exceed 50 percent.

(13) The limitations of instrument detection shall be taken into account when determining the fit factor.

(14) Test respirators shall be maintained in proper working order and be inspected regularly for deficiencies such as cracks or missing valves and gaskets.

(b) Procedural Requirements.

(1) When performing the initial user seal check using a positive or negative pressure check, the sampling line shall be crimped closed in order to avoid air pressure leakage during either of these pressure checks.

(2) The use of an abbreviated screening QLFT test is optional. Such a test may be utilized in order to quickly identify poor fitting respirators that passed the positive and/or negative pressure test and reduce the amount of QNFT time. The use of the CNC QNFT instrument in the count mode is another optional method to obtain a quick estimate of fit and eliminate poor fitting respirators before going on to perform a full QNFT.

(3) A reasonably stable test agent concentration shall be measured in the test chamber prior to testing. For canopy or shower curtain types of test units, the determination of the test agent's stability may be established after the test subject has entered the test environment.

(4) Immediately after the subject enters the test chamber, the test agent concentration inside the respirator shall be measured to ensure that the peak penetration does not exceed 5 percent for a half mask or 1 percent for a full facepiece respirator.

(5) A stable test agent concentration shall be obtained prior to the actual start of testing.

(6) Respirator restraining straps shall not be over-tightened for testing. The straps shall be adjusted by the wearer without assistance from other persons to give a reasonably comfortable fit typical of normal use. The respirator shall not be adjusted once the fit test exercises begin.

(7) The test shall be terminated whenever any single peak penetration exceeds 5 percent for half masks and 1 percent for full facepiece respirators. The test subject shall be refitted and retested.

(8) Calculation of fit factors.

(i) The fit factor shall be determined for the quantitative fit test by taking the ratio of the average chamber concentration to the concentration measured inside the respirator for each test exercise except the grimace exercise.

(ii) The average test chamber concentration shall be calculated as the arithmetic average of the concentration measured before and after each test (i.e., 7 exercises) or the arithmetic average of the concentration measured before and after each exercise or the true average measured continuously during the respirator sample.

(iii) The concentration of the challenge agent inside the respirator shall be determined by one of the following methods:

(A) Average peak penetration method means the method of determining test agent penetration into the respirator utilizing a strip chart recorder, integrator, or computer. The agent penetration is determined by an average of the peak heights on the graph or by computer integration, for each exercise except the grimace exercise. Integrators or computers that calculate the actual test agent penetration into the respirator for each exercise will also be considered to meet the requirements of the average peak penetration method.

(B) Maximum peak penetration method means the method of determining test agent penetration in the respirator as determined by strip chart recordings of the test. The highest peak penetration for a given exercise is taken to be representative of average penetration into the respirator for that exercise.

(C) Integration by calculation of the area under the individual peak for each exercise except the grimace exercise. This includes computerized integration.

(D) The calculation of the overall fit factor using individual exercise fit factors involves first converting the exercise fit factors to penetration values, determining the average, and then converting that result back to a fit factor. This procedure is described in the following equation:

$$\text{Overall Fit Factor} = \frac{\text{Number of exercises}}{1/ff_1 + 1/ff_2 + 1/ff_3 + 1/ff_4 + 1/ff_5 + 1/ff_6 + 1/ff_7 + 1/ff_8}$$

Where ff1, ff2, ff3, etc. are the fit factors for exercises 1, 2, 3, etc.

(9) The test subject shall not be permitted to wear a half mask or quarter facepiece respirator unless a minimum fit factor of 100 is obtained, or a full facepiece respirator unless a minimum fit factor of 500 is obtained.

(10) Filters used for quantitative fit testing shall be replaced whenever increased breathing resistance is encountered, or when the test agent has altered the integrity of the filter media.

3. Ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol.

The ambient aerosol condensation nuclei counter (CNC) quantitative fit testing (PortaCount®) protocol quantitatively fit tests respirators with the use of a probe. The probed respirator is only used for quantitative fit tests. A probed respirator has a special sampling device, installed on the respirator, that allows the probe to sample the air from inside the mask. A probed respirator is required for each make, style, model, and size that the employer uses and can be obtained from the respirator manufacturer or distributor. The primary CNC instrument manufacturer, TSI Incorporated, also provides probe attachments (TSI mask sampling adapters) that permit fit testing in an employee's own respirator. A minimum fit factor pass level of at least 100 is necessary for a half-mask respirator (elastomeric or filtering facepiece) and a minimum fit factor pass level of at least 500 is required for a full-facepiece elastomeric respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) PortaCount® Fit Test Requirements.

(1) Check the respirator to make sure the sampling probe and line are properly attached to the facepiece and that the respirator is fitted with a particulate filter capable of preventing significant penetration by the ambient particles used for the fit test (e.g., NIOSH 42 CFR 84 series 100, series 99, or series 95 particulate filter) per manufacturer's instruction.

(2) Instruct the person to be tested to don the respirator for five minutes before the fit test starts. This purges the ambient particles trapped inside the respirator and permits the wearer to make certain the respirator is comfortable. This individual shall already have been trained on how to wear the respirator properly.

(3) Check the following conditions for the adequacy of the respirator fit: Chin properly placed; Adequate strap tension, not overly tightened; Fit across nose bridge; Respirator of proper size to span distance from nose to chin; Tendency of the respirator to slip; Self-observation in a mirror to evaluate fit and respirator position.

(4) Have the person wearing the respirator do a user seal check. If leakage is detected, determine the cause. If leakage is from a poorly fitting facepiece, try another size of the same model respirator, or another model of respirator.

(5) Follow the manufacturer's instructions for operating the PortaCount® and proceed with the test.

(6) The test subject shall be instructed to perform the exercises in section I. A. 14. of this appendix.

(7) After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of respirator shall be tried.

(b) PortaCount® Test Instrument.

(1) The PortaCount® will automatically stop and calculate the overall fit factor for the entire set of exercises. The overall fit factor is what counts. The Pass or Fail message will indicate whether or not the test was successful. If the test was a Pass, the fit test is over.

(2) Since the pass or fail criterion of the PortaCount® is user programmable, the test operator shall ensure that the pass or fail criterion meet the requirements for minimum respirator performance in this Appendix.

(3) A record of the test needs to be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style, and size of respirator used; and date tested.

4. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for full-facepiece and halfmask elastomeric respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–1 of this appendix.

Table A-1: Modified Ambient Aerosal CNC Quantitative Fit Testing Protocol for Full Facepiece and Half-Mask Elastomeric Respirators

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2]	A 20 second ambient sample, followed by a 30 second mask sample.
Jogging-in-Place	The test subject shall jog in place comfortably for 30 seconds	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2]	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2]	A 30 second mask sample followed by a 9 second ambient sample.

[1] Exercises are listed in the order in which they are to be administered.

[2] It is optional for test subjects to take additional breaths at other times during the exercise.

5. Modified ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol for filtering facepiece respirators.

(a) When administering this protocol to test subjects, employers shall comply with the requirements specified in Part I.C.3 of this appendix (ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol), except they shall use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in section I.C.3(a)(6) of this appendix.

(b) Employers shall ensure that each test subject being fit tested using this protocol follows the exercise and duration procedures, including the order of administration, described in Table A–2 of this appendix.

Table A-2: Modified Ambient Aerosal CNC Quantitative Fit Testing Protocol for Filtering Facepiece Respirators

Exercises[1]	Exercise procedure	Measurement procedure
Bending Over	The test subject shall bend at the waist, as if going to touch his/her toes for 50 seconds and inhale 2 times at the bottom[2]	A 20 second ambient sample, followed by a 30 second mask sample.
Talking	The test subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor for 30 seconds. He/she will either read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song	A 30 second mask sample.
Head Side-to-Side	The test subject shall stand in place, slowly turning his/her head from side to side for 30 seconds and inhale 2 times at each extreme[2]	A 30 second mask sample.
Head Up-and-Down	The test subject shall stand in place, slowly moving his/her head up and down for 39 seconds and inhale 2 times at each extreme[2]	A 30 second mask sample followed by a 9 second ambient sample.

[1] Exercises are listed in the order in which they are to be administered.

[2] It is optional for test subjects to take additional breaths at other times during the exercise.

6. Controlled negative pressure (CNP) quantitative fit testing protocol.

The CNP protocol provides an alternative to aerosol fit test methods. The CNP fit test method technology is based on exhausting air from a temporarily sealed respirator facepiece to generate and then maintain a constant negative pressure inside the facepiece. The rate of air exhaust is controlled so that a constant negative pressure is maintained in the respirator during the fit test. The level of pressure is selected to replicate the mean inspiratory pressure that causes leakage into the respirator under normal use conditions. With pressure held constant, air flow out of the respirator is equal to air flow into the respirator. Therefore, measurement of the exhaust stream that is required to hold the pressure in the temporarily sealed respirator constant yields a direct measure of leakage air flow into the respirator. The CNP fit test method measures leak rates through the facepiece as a method for determining the facepiece fit for negative pressure respirators. The CNP instrument manufacturer Occupational Health Dynamics of Birmingham, Alabama also provides attachments (sampling manifolds) that replace the filter cartridges to permit fit testing in an employee's own respirator. To perform the test, the test subject closes his or her mouth and holds his/her breath, after which an air pump removes air from the respirator facepiece at a pre-selected constant pressure. The facepiece fit is expressed as the leak rate through the facepiece, expressed as milliliters per minute. The quality and validity of the CNP fit tests are determined by the degree to which the in-mask pressure tracks the test pressure during the system measurement time of approximately five seconds. Instantaneous feedback in the form of a real-time pressure trace of the in-mask pressure is provided and used to determine test validity and quality. A minimum fit factor pass level of 100 is necessary for a half-mask respirator and a minimum fit factor of at least 500 is required for a full facepiece respirator. The entire screening and testing procedure shall be explained to the test subject prior to the conduct of the screening test.

(a) CNP Fit Test Requirements.

(1) The instrument shall have a non-adjustable test pressure of 15.0 mm water pressure.

(2) The CNP system defaults selected for test pressure shall be set at—15 mm of water (-0.58 inches of water) and the modeled inspiratory flow rate shall be 53.8 liters per minute for performing fit tests.

(**Note**: CNP systems have built-in capability to conduct fit testing that is specific to unique work rate, mask, and gender situations that might apply in a specific workplace. Use of system default values, which were selected to represent respirator wear with medium cartridge resistance at a low-moderate work rate, will allow inter-test comparison of the respirator fit.)

(3) The individual who conducts the CNP fit testing shall be thoroughly trained to perform the test.

(4) The respirator filter or cartridge needs to be replaced with the CNP test manifold. The inhalation valve downstream from the manifold either needs to be temporarily removed or propped open.

(5) The employer must train the test subject to hold his or her breath for at least 10 seconds.

(6) The test subject must don the test respirator without any assistance from the test administrator who is conducting the CNP fit test. The respirator must not be adjusted once the fit-test exercises begin. Any adjustment voids the test, and the test subject must repeat the fit test.

(7) The QNFT protocol shall be followed according to section I. C. 1. of this appendix with an exception for the CNP test exercises.

(b) CNP Test Exercises.

(1) Normal breathing. In a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject needs to hold head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(2) Deep breathing. In a normal standing position, the subject shall breathe slowly and deeply for 1 minute, being careful not to hyperventilate. After the deep breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during test measurement.

(3) Turning head side to side. Standing in place, the subject shall slowly turn his or her head from side to side between the extreme positions on each side for 1 minute. The head shall be held at each extreme momentarily so the subject can inhale at each side. After the turning head side to side exercise, the subject needs to hold head full left and hold his or her breath for 10 seconds during test measurement. Next, the subject needs to hold head full right and hold his or her breath for 10 seconds during test measurement.

(4) Moving head up and down. Standing in place, the subject shall slowly move his or her head up and down for 1 minute. The subject shall be instructed to inhale in the up position (i.e., when looking toward the ceiling). After the moving head up and down exercise, the subject shall hold his or her head full up and hold his or her breath for 10 seconds during test measurement. Next, the subject shall hold his or her head full down and hold his or her breath for 10 seconds during test measurement.

(5) Talking. The subject shall talk out loud slowly and loud enough so as to be heard clearly by the test conductor. The subject can read from a prepared text such as the Rainbow Passage, count backward from 100, or recite a memorized poem or song for 1 minute. After the talking exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(6) Grimace. The test subject shall grimace by smiling or frowning for 15 seconds.

(7) Bending Over. The test subject shall bend at the waist as if he or she were to touch his or her toes for 1 minute. Jogging in place shall be substituted for this exercise in those test environments such as shroud-type QNFT units that prohibit bending at the waist. After the bending over exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement.

(8) Normal Breathing. The test subject shall remove and re-don the respirator within a one-minute period. Then, in a normal standing position, without talking, the subject shall breathe normally for 1 minute. After the normal breathing exercise, the subject shall hold his or her head straight ahead and hold his or her breath for 10 seconds during the test measurement. After the test exercises, the test subject shall be questioned by the test conductor regarding the comfort of the respirator upon completion of the protocol. If it has become unacceptable, another model of a respirator shall be tried.

(c) CNP Test Instrument.

(1) The test instrument must have an effective audio-warning device, or a visual-warning device in the form of a screen tracing, that indicates when the test subject fails to hold his or her breath during the test. The test must be terminated and restarted from the beginning when the test subject fails to hold his or her breath during the test. The test subject then may be refitted and retested.

(2) A record of the test shall be kept on file, assuming the fit test was successful. The record must contain the test subject's name; overall fit factor; make, model, style and size of respirator used; and date tested.

7. Controlled negative pressure (CNP) REDON quantitative fit testing protocol.

(a) When administering this protocol to test subjects, employers must comply with the requirements specified in paragraphs (a) and (c) of part I.C.6 of this appendix ("Controlled negative pressure (CNP) quantitative fit testing protocol",) as well as use the test exercises described below in paragraph (b) of this protocol instead of the test exercises specified in paragraph (b) of part I.C.6 of this appendix.

(b) Employers must ensure that each test subject being fit tested using this protocol follows the exercise and measurement procedures, including the order of administration, described below in Table A-3 of this appendix.

Table A-3: CNP REDON Quantitative Fit Testing Protocol

Exercises[1]	Exercise procedure	Measurement procedure
Facing Forward	Stand and breathe normally, without talking, for 30 seconds.	Face forward, while holding breath for 10 seconds.
Bending Over	Bend at the waist, as if going to touch his or her toes, for 30 seconds.	Face parallel to the floor, while holding breath for 10 seconds.
Head Shaking	For about three seconds, shake head back and forth vigorously several times while shouting.	Face forward, while holding breath for 10 seconds.
REDON 1	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask.	Face forward, while holding breath for 10 seconds.
REDON 2	Remove the respirator mask, loosen all facepiece straps, and then redon the respirator mask again.	Face forward, while holding breath for 10 seconds.

[1] *Exercises are listed in the order in which they are to be administered.*

(c) After completing the test exercises, the test administrator must question each test subject regarding the comfort of the respirator. When a test subject states that the respirator is unacceptable, the employer must ensure that the test administrator repeats the protocol using another respirator model.

(d) Employers must determine the overall fit factor for each test subject by calculating the harmonic mean of the fit testing exercises as follows:

$$\text{Overall Fit Factor} = \frac{N}{[1/FF_1 + 1/FF_2 + \ldots 1/FF_N]}$$

Where:
N = The number of exercises;
FF_1 = The fit factor for the first exercise;
FF_2 = The fit factor for the second exercise; and
FF_N = The fit factor for the nth exercise.

Part II. New Fit Test Protocols

A. Any person may submit to OSHA an application for approval of a new fit test protocol. If the application meets the following criteria, OSHA will initiate a rulemaking proceeding under section 6(b)(7) of the OSH Act to determine whether to list the new protocol as an approved protocol in this Appendix A.

B. The application must include a detailed description of the proposed new fit test protocol. This application must be supported by either:

1. A test report prepared by an independent government research laboratory (e.g., Lawrence Livermore National Laboratory, Los Alamos National Laboratory, the National Institute for Standards and Technology) stating that the laboratory has tested the protocol and had found it to be accurate and reliable; or

2. An article that has been published in a peer-reviewed industrial hygiene journal describing the protocol and explaining how test data support the protocol's accuracy and reliability.

C. If OSHA determines that additional information is required before the Agency commences a rulemaking proceeding under this section, OSHA will so notify the applicant and afford the applicant the opportunity to submit the supplemental information. Initiation of a rulemaking proceeding will be deferred until OSHA has received and evaluated the supplemental information.

[63 FR 1270, 1276, Jan. 8, 1998; 63 FR 20098, 20099, April 23, 1998; 69 FR 46993, Aug. 4, 2004; 84 FR 50755, Sept. 26, 2019]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: I
Subpart Title: Personal Protective Equipment
Standard Number: 1910.134 Appendix B-1
Title: User Seal Check Procedures (Mandatory)

The individual who uses a tight-fitting respirator is to perform a user seal check to ensure that an adequate seal is achieved each time the respirator is put on. Either the positive and negative pressure checks listed in this appendix, or the respirator manufacturer's recommended user seal check method shall be used. User seal checks are not substitutes for qualitative or quantitative fit tests.

I. Facepiece Positive and/or Negative Pressure Checks

A. Positive pressure check. Close off the exhalation valve and exhale gently into the facepiece. The face fit is considered satisfactory if a slight positive pressure can be built up inside the facepiece without any evidence of outward leakage of air at the seal. For most respirators this method of leak testing requires the wearer to first remove the exhalation valve cover before closing off the exhalation valve and then carefully replacing it after the test.

B. Negative pressure check. Close off the inlet opening of the canister or cartridge(s) by covering with the palm of the hand(s) or by replacing the filter seal(s), inhale gently so that the facepiece collapses slightly, and hold the breath for ten seconds. The design of the inlet opening of some cartridges cannot be effectively covered with the palm of the hand.

The test can be performed by covering the inlet opening of the cartridge with a thin latex or nitrile glove. If the facepiece remains in its slightly collapsed condition and no inward leakage of air is detected, the tightness of the respirator is considered satisfactory.

II. Manufacturer's Recommended User Seal Check Procedures

The respirator manufacturer's recommended procedures for performing a user seal check may be used instead of the positive and/or negative pressure check procedures provided that the employer demonstrates that the manufacturer's procedures are equally effective.

[63 FR 1152, 1270, 1282, Jan. 8, 1998]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: I
Subpart Title: Personal Protective Equipment
Standard Number: 1910.134 Appendix B-2
Title: Respirator Cleaning Procedures (Mandatory)

These procedures are provided for employer use when cleaning respirators. They are general in nature, and the employer as an alternative may use the cleaning recommendations provided by the manufacturer of the respirators used by their employees, provided such procedures are as effective as those listed here in Appendix B- 2. Equivalent effectiveness simply means that the procedures used must accomplish the objectives set forth in Appendix B-2, i.e., must ensure that the respirator is properly cleaned and disinfected in a manner that prevents damage to the respirator and does not cause harm to the user.

I. Procedures for Cleaning Respirators

A. Remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure- demand valve assemblies, hoses, or any components recommended by the manufacturer. Discard or repair any defective parts.

B. Wash components in warm (43 deg. C [110 deg. F] maximum) water with a mild detergent or with a cleaner recommended by the manufacturer. A stiff bristle (not wire) brush may be used to facilitate the removal of dirt.

C. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain.

D. When the cleaner used does not contain a disinfecting agent, respirator components should be immersed for two minutes in one of the following:

1. Hypochlorite solution (50 ppm of chlorine) made by adding approximately one milliliter of laundry bleach to one liter of water at 43 deg. C (110 deg. F); or,

2. Aqueous solution of iodine (50 ppm iodine) made by adding approximately 0.8 milliliters of tincture of iodine (6-8 grams ammonium and/or potassium iodide/100 cc of 45 percent alcohol) to one liter of water at 43 deg. C (110 deg. F); or,

3. Other commercially available cleansers of equivalent disinfectant quality when used as directed, if their use is recommended or approved by the respirator manufacturer.

E. Rinse components thoroughly in clean, warm (43 deg. C [110 deg. F] maximum), preferably running water. Drain. The importance of thorough rinsing cannot be overemphasized. Detergents or disinfectants that dry on facepieces may result in dermatitis. In addition, some disinfectants may cause deterioration of rubber or corrosion of metal parts if not completely removed.

F. Components should be hand-dried with a clean lint-free cloth or air-dried.

G. Reassemble facepiece, replacing filters, cartridges, and canisters where necessary.

H. Test the respirator to ensure that all components work properly.

[63 FR 1152, 1270, 1282, Jan. 8, 1998]

Part Number: 1910
Part Title: Occupational Safety and Health Standards
Subpart: I
Subpart Title: Personal Protective Equipment
Standard Number: 1910.134 Appendix C
Title: OSHA Respirator Medical Evaluation Questionnaire (Mandatory)

To the employer: Answers to questions in Section 1, and to question 9 in Section 2 of Part A, do not require a medical examination.

To the employee:

Your employer must allow you to answer this questionnaire during normal working hours, or at a time and place that is convenient to you. To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it.

Part A. Section 1. (Mandatory) The following information must be provided by every employee who has been selected to use any type of respirator (please print).

1. Today's date: _____

2. Your name: _____

3. Your age (to nearest year): _____

4. Sex (circle one): Male/Female

5. Your height: _____ ft. _____ in.

6. Your weight: _____ lbs.

7. Your job title: _____

8. A phone number where you can be reached by the health care professional who reviews this questionnaire (include the Area Code):

_____

9. The best time to phone you at this number: _____

10. Has your employer told you how to contact the health care professional who will review this questionnaire (circle one): Yes/No

11. Check the type of respirator you will use (you can check more than one category):

a. _____ N, R, or P disposable respirator (filter-mask, non-cartridge type only).

b. _____ Other type (for example, half- or full-facepiece type, powered-air purifying, supplied-air, self-contained breathing apparatus).

12. Have you worn a respirator (circle one): Yes/No

If "yes," what type(s): _____

Part A. Section 2. (Mandatory) Questions 1 through 9 below must be answered by every employee who has been selected to use any type of respirator (please circle "yes" or "no").

1. Do you currently smoke tobacco, or have you smoked tobacco in the last month: Yes/No

2. Have you ever had any of the following conditions?

a. Seizures: Yes/No

b. Diabetes (sugar disease): Yes/No

c. Allergic reactions that interfere with your breathing: Yes/No

d. Claustrophobia (fear of closed-in places): Yes/No

e. Trouble smelling odors: Yes/No

3. Have you ever had any of the following pulmonary or lung problems?

a. Asbestosis: Yes/No

b. Asthma: Yes/No

c. Chronic bronchitis: Yes/No

d. Emphysema: Yes/No

e. Pneumonia: Yes/No

f. Tuberculosis: Yes/No

g. Silicosis: Yes/No

h. Pneumothorax (collapsed lung): Yes/No

i. Lung cancer: Yes/No

j. Broken ribs: Yes/No

k. Any chest injuries or surgeries: Yes/No

l. Any other lung problem that you've been told about: Yes/No

4. Do you currently have any of the following symptoms of pulmonary or lung illness?

a. Shortness of breath: Yes/No

b. Shortness of breath when walking fast on level ground or walking up a slight hill or incline: Yes/No

c. Shortness of breath when walking with other people at an ordinary pace on level ground: Yes/No

d. Have to stop for breath when walking at your own pace on level ground: Yes/No

e. Shortness of breath when washing or dressing yourself: Yes/No

f. Shortness of breath that interferes with your job: Yes/No

g. Coughing that produces phlegm (thick sputum): Yes/No

h. Coughing that wakes you early in the morning: Yes/No

i. Coughing that occurs mostly when you are lying down: Yes/No

j. Coughing up blood in the last month: Yes/No

k. Wheezing: Yes/No

l. Wheezing that interferes with your job: Yes/No

m. Chest pain when you breathe deeply: Yes/No

n. Any other symptoms that you think may be related to lung problems: Yes/No

5. Have you ever had any of the following cardiovascular or heart problems?

a. Heart attack: Yes/No

b. Stroke: Yes/No

c. Angina: Yes/No

d. Heart failure: Yes/No

e. Swelling in your legs or feet (not caused by walking): Yes/No

f. Heart arrhythmia (heart beating irregularly): Yes/No

g. High blood pressure: Yes/No

h. Any other heart problem that you've been told about: Yes/No

6. Have you ever had any of the following cardiovascular or heart symptoms?

a. Frequent pain or tightness in your chest: Yes/No

b. Pain or tightness in your chest during physical activity: Yes/No

c. Pain or tightness in your chest that interferes with your job: Yes/No

d. In the past two years, have you noticed your heart skipping or missing a beat: Yes/No

e. Heartburn or indigestion that is not related to eating: Yes/No

f. Any other symptoms that you think may be related to heart or circulation problems: Yes/No

7. Do you currently take medication for any of the following problems?

a. Breathing or lung problems: Yes/No

b. Heart trouble: Yes/No

c. Blood pressure: Yes/No

d. Seizures: Yes/No

8. If you've used a respirator, have you ever had any of the following problems? (If you've never used a respirator, check the following space and go to question 9:)

a. Eye irritation: Yes/No

b. Skin allergies or rashes: Yes/No

c. Anxiety: Yes/No

d. General weakness or fatigue: Yes/No

e. Any other problem that interferes with your use of a respirator: Yes/No

9. Would you like to talk to the health care professional who will review this questionnaire about your answers to this questionnaire: Yes/No

Questions 10 to 15 below must be answered by every employee who has been selected to use either a full-facepiece respirator or a self-contained breathing apparatus (SCBA). For employees who have been selected to use other types of respirators, answering these questions is voluntary.

10. Have you ever lost vision in either eye (temporarily or permanently): Yes/No

11. Do you currently have any of the following vision problems?

a. Wear contact lenses: Yes/No

b. Wear glasses: Yes/No

c. Color blind: Yes/No

d. Any other eye or vision problem: Yes/No

12. Have you ever had an injury to your ears, including a broken ear drum: Yes/No

13. Do you currently have any of the following hearing problems?

a. Difficulty hearing: Yes/No

b. Wear a hearing aid: Yes/No

c. Any other hearing or ear problem: Yes/No

14. Have you ever had a back injury: Yes/No

15. Do you currently have any of the following musculoskeletal problems?

a. Weakness in any of your arms, hands, legs, or feet: Yes/No

b. Back pain: Yes/No

c. Difficulty fully moving your arms and legs: Yes/No

d. Pain or stiffness when you lean forward or backward at the waist: Yes/No

e. Difficulty fully moving your head up or down: Yes/No

f. Difficulty fully moving your head side to side: Yes/No

g. Difficulty bending at your knees: Yes/No

h. Difficulty squatting to the ground: Yes/No

i. Climbing a flight of stairs or a ladder carrying more than 25 lbs: Yes/No

j. Any other muscle or skeletal problem that interferes with using a respirator: Yes/No

Part B. Any of the following questions, and other questions not listed, may be added to the questionnaire at the discretion of the health care professional who will review the questionnaire.

1. In your present job, are you working at high altitudes (over 5,000 feet) or in a place that has lower than normal amounts of oxygen: Yes/No

If "yes," do you have feelings of dizziness, shortness of breath, pounding in your chest, or other symptoms when you're working under these conditions: Yes/No

2. At work or at home, have you ever been exposed to hazardous solvents, hazardous airborne chemicals (e.g., gases, fumes, or dust), or have you come into skin contact with hazardous chemicals: Yes/No

If "yes," name the chemicals if you know them: _____

3. Have you ever worked with any of the materials, or under any of the conditions, listed below:

a. Asbestos: Yes/No

b. Silica (e.g., in sandblasting): Yes/No

c. Tungsten/cobalt (e.g., grinding or welding this material): Yes/No

d. Beryllium: Yes/No

e. Aluminum: Yes/No

f. Coal (for example, mining): Yes/No

g. Iron: Yes/No

h. Tin: Yes/No

i. Dusty environments: Yes/No

j. Any other hazardous exposures: Yes/No

If "yes," describe these exposures: _____

4. List any second jobs or side businesses you have: _____

5. List your previous occupations: _____

6. List your current and previous hobbies: _____

7. Have you been in the military services? Yes/No

If "yes," were you exposed to biological or chemical agents (either in training or combat): Yes/No

8. Have you ever worked on a HAZMAT team? Yes/No

9. Other than medications for breathing and lung problems, heart trouble, blood pressure, and seizures mentioned earlier in this questionnaire, are you taking any other medications for any reason (including over-the-counter medications): Yes/No

If "yes, " name the medications if you know them: _____

10. Will you be using any of the following items with your respirator(s)?

a. HEPA Filters: Yes/No

b. Canisters (for example, gas masks): Yes/No

c. Cartridges: Yes/No

11. How often are you expected to use the respirator(s) (circle "yes" or "no" for all answers that apply to you)?:

a. Escape only (no rescue): Yes/No

b. Emergency rescue only: Yes/No

c. Less than 5 hours per week: Yes/No

d. Less than 2 hours per day: Yes/No

e. 2 to 4 hours per day: Yes/No

f. Over 4 hours per day: Yes/No

12. During the period you are using the respirator(s), is your work effort:

a. Light (less than 200 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of a light work effort are sitting while writing, typing, drafting, or performing light assembly work; or standing while operating a drill press (1-3 lbs.) or controlling machines.

b. Moderate (200 to 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of moderate work effort are sitting while nailing or filing; driving a truck or bus in urban traffic; standing while drilling, nailing, performing assembly work, or transferring a moderate load (about 35 lbs.) at trunk level; walking on a level surface about 2 mph or down a 5-degree grade about 3 mph; or pushing a wheelbarrow with a heavy load (about 100 lbs.) on a level surface. c. Heavy (above 350 kcal per hour): Yes/No

If "yes," how long does this period last during the average shift:_____hrs._____mins.

Examples of heavy work are lifting a heavy load (about 50 lbs.) from the floor to your waist or shoulder; working on a loading dock; shoveling; standing while bricklaying or chipping castings; walking up an 8-degree grade about 2 mph; climbing stairs with a heavy load (about 50 lbs.).

13. Will you be wearing protective clothing and/or equipment (other than the respirator) when you're using your respirator: Yes/No

If "yes," describe this protective clothing and/or equipment: _____

_____

14. Will you be working under hot conditions (temperature exceeding 77 deg. F): Yes/No

15. Will you be working under humid conditions: Yes/No

16. Describe the work you'll be doing while you're using your respirator(s):_____

17. Describe any special or hazardous conditions you might encounter when you're using your respirator(s) (for example, confined spaces, life-threatening gases): _____

18. Provide the following information, if you know it, for each toxic substance that you'll be exposed to when you're using your respirator(s):

Name of the first toxic substance: _____

Estimated maximum exposure level per shift:_____

Duration of exposure per shift: _____

Name of the second toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

Name of the third toxic substance: _____

Estimated maximum exposure level per shift: _____

Duration of exposure per shift: _____

The name of any other toxic substances that you'll be exposed to while using your respirator:

_____

19. Describe any special responsibilities you'll have while using your respirator(s) that may affect the safety and well-being of others (for example, rescue, security):

_____

[63 FR 1152, 1270, 1282, Jan. 8, 1998; 63 FR 20098, 20099, April 23, 1998; 76 FR 33606, 33607, June 8, 2011; 77 FR 46949, Aug. 7, 2012]

Part Number: 1910
Part Title: Occupational Safety and Health Standard
Subpart: I
Subpart Title: Personal Protective Equipment
Standard Number: 1910.134 Appendix D
Title: (Mandatory) Information for Employees Using Respirators When Not Required Under Standard

Respirators are an effective method of protection against designated hazards when properly selected and worn. Respirator use is encouraged, even when exposures are below the exposure limit, to provide an additional level of comfort and protection for workers. However, if a respirator is used improperly or not kept clean, the respirator itself can become a hazard to the worker. Sometimes, workers may wear respirators to avoid exposures to hazards, even if the amount of hazardous substance does not exceed the limits set by OSHA Standards. If your employer provides respirators for your voluntary use, or if you provide your own respirator, you need to take certain precautions to be sure that the respirator itself does not present a hazard.

You should do the following:

1. Read and heed all instructions provided by the manufacturer on use, maintenance, cleaning and care, and warnings regarding the respirators limitations.

2. Choose respirators certified for use to protect against the contaminant of concern. NIOSH, the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services, certifies respirators. A label or statement of certification should appear on the respirator or respirator packaging. It will tell you what the respirator is designed for and how much it will protect you.

3. Do not wear your respirator into atmospheres containing contaminants for which your respirator is not designed to protect against. For example, a respirator designed to filter dust particles will not protect you against gases, vapors, or very small solid particles of fumes or smoke.

4. Keep track of your respirator so that you do not mistakenly use someone else's respirator.

[63 FR 1152, 1270, 1284, Jan. 8, 1998; 63 FR 20098, 20099, April 23, 1998]

Fact Sheets Introduction

Bloodborne Pathogens Defined

A bloodborne pathogen is a microorganism present in human blood and other potentially infectious material (OPIM) that cause disease in humans who are exposed to blood containing the pathogen. The Bloodborne Pathogen Standard specifically identifies Hepatitis B virus (HBV) and Human Immunodeficiency Virus (HIV), but pathogenic microorganisms can also cause diseases such as Hepatitis C, COVID-19, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob Disease, adult t-cell leukemia/lymphoma (caused by HTLV-I), HTLV-I-associated myelopathy, diseases associated with HTLV-II, and viral hemorrhagic fever.

OSHA has determined these hazards can be minimized or eliminated by using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, Hepatitis B vaccination, signs and labels, and other provisions.

Hepatitis

Hepatitis is a disease characterized by inflammation of the liver, usually producing swelling and, in many cases, permanent damage to the liver. A number of different agents can cause Hepatitis, including infectious diseases, chemical poisons, drugs, and alcohol. Viral hepatitis refers to a set of at least six viruses that are known to cause hepatitis: Hepatitis A (HAV), Hepatitis B (HBV), Hepatitis C (HCV), Hepatitis D (HDV), Hepatitis E (HEV), and Hepatitis G (HGV). Recent scientific evidence also suggests the existence of other, as of yet unidentified, strains. The most common types of viral hepatitis are HAV, HBV, and HCV. Both HBV and HCV can lead to serious, permanent liver damage, and, in many cases, death. Unlike the other types of viral hepatitis, HCV is very difficult for the immune system to overcome.

Viral Hepatitis is the leading cause of liver cancer and the most common reason for liver transplantation. About 80,000 new Hepatitis infections occur each year. In 2018, the CDC estimates that 2.4 million Americans will be living with chronic Hepatitis and not know they are infected.

How Viral Infections Occur

A viral infection is caused by the spread of viruses in the body. These viruses can live in the air, on surfaces, and within the body in body fluids. The skin as a natural barrier is one of the body's most important defense systems, followed by mucous membranes. Unfortunately, viruses can easily pass into the body through cuts, scrapes, and punctures in the skin or mucous membranes.

Once in the body, viruses will live in body fluids. The immune system defends the body against them. However, if the viruses are strong and the body weak or lacking resistance, the defense systems can fail, and the viruses can multiply causing disease and/or infection.

Hepatitis B (HBV)

Hepatitis B virus (HBV) is a potentially life threatening bloodborne pathogen. The infection is transmitted through exposure to blood and other infectious body fluids and tissues. Anyone with occupational exposure to blood, such as funeral home employees are at risk of contracting the infection.

Of the common forms of viral hepatitis, Hepatitis B appears to be the most serious because of the many ways it can be acquired and its potential for complications. Hepatitis B, formerly called serum hepatitis, is caused by the Hepatitis B virus, which causes an infection in or inflammation of the liver and is more prevalent and infectious than HIV.

Transmission

Hepatitis B is a very common yet strong virus that resists the usual practices of hygiene. Its strength increases the chances of infection. Hepatitis B virus is transmitted through infected blood and other body fluids such as urine, tears, semen, vaginal secretions, open sores, as well as in unfixed organs, such as viscera. Because it is difficult to kill, Hepatitis B can live for more than a week in dried blood or saliva, on clothing or other surfaces.

Hepatitis B is predominately spread by sexual contact. Other risk groups include health care workers, embalmers, prison inmates and personnel, IV drug users, and recipients of blood transfusions prior to 1975. In families, it appears that the virus can be casually spread from adult to child.

HBV can survive outside the body for at least 7 days and still cause infection. Any blood spills, including dried blood, can still be infectious. A cleaning solution of one to ten dilution of one-part bleach to ten parts water may be used to disinfect the area.

While most patients recover, the disease can be very serious and even fatal.

Symptoms

Many people with chronic Hepatitis B may be asymptomatic, meaning they never feel sick or have symptoms. These individuals generally are not aware of having the disease, yet they can infect others and further spread the disease.

Others may have a mild flu-like illness with symptoms including fatigue, headache, mild fever, sore throat, muscle and joint aches, nausea, vomiting, loss of appetite, vague abdominal pain, and occasional diarrhea. More severe signs and symptoms would be jaundice—a yellow cast to the skin and/or eyes accompanied by dark urine, light colored stools and skin irritation.

It may take anywhere from 30 to 180 days after exposure for these symptoms to become apparent. Long-term consequences of Hepatitis B may include chronic active hepatitis (1.4 million U.S. carriers), cirrhosis, and liver cancer and in the case of less than 1 percent of infected patients, early death.

In 2017, the CDC estimated 22,200 people in the United States were newly infected with HBV. Rates are highest among adults, particularly males aged 25–44 years old.

Complications of Hepatitis B

Funeral home employees that become infected can become extremely ill—sick enough to be out of work for weeks, even months. Full recovery has been known to take up to six months in healthy adults.

Although the unpredictability of the disease can lead to further complications, most patients recover. Five to ten percent of those individuals who do become infected become "chronic carriers" capable of spreading the disease to others for an indefinite period of time. Carriers also have a risk greater than the general population of contracting liver cancer. In the United States, approximately 4,000 people die annually from Hepatitis B-related infection.

You Are in a High-Risk Group

Funeral directors, embalmers, and all funeral home staff that are exposed to human remains, the preparation room, removal vehicles, and equipment used with human remains are at an increased risk of contracting Hepatitis B. Funeral home staff members may contract the infection both directly and indirectly.

Direct methods include needlesticks and/or spaters of body fluids. If you are the victim of an injury by a needlestick contaminated with Hepatitis-B-infected blood, you have a 20 to 30 percent chance of becoming infected.

Indirect methods of becoming infected include handling sheets contaminated with blood or urine of the deceased patient with Hepatitis B or handling surfaces on which contaminated objects have been placed, and then touching your eyes, mouth, nose or an open cut.

There is no specific treatment for acute Hepatitis B infection—no medicine will cure it. The patient is kept comfortable at home or in a hospital. Annually, more than 10,000 people are hospitalized for Hepatitis B. Although there is no treatment or cure, there is a way to prevent Hepatitis B.

Prevention
Employers must provide engineering controls; workers must use proper work practices and personal protective equipment to prevent exposure to potentially infectious materials.

The following prevention methods will help keep you, your colleagues and your families safe from Hepatitis B.

1. Get the vaccination.
2. Follow universal precautions.
3. Use personal protective equipment.
4. Follow proper work practices.
5. Wash your hands and other skin surfaces thoroughly after contact with remains.
6. Properly dispose of sharps and medical waste.
7. Clean up all blood and body fluid spills immediately and thoroughly.
8. Properly clean your personal protective equipment and work areas.

Funeral Home Employees Need Vaccination Protection
While there is no medical means available to cure Hepatitis B, there are vaccines available that provides active immunity against Hepatitis B for susceptible persons who are at increased risk of contracting the disease.

OSHA has stated that the most effective method of infection control against this disease is the Hepatitis B vaccine. Therefore, the OSHA Standard covering bloodborne pathogens requires employers to offer the three-injection vaccination series free to all employees who are exposed to blood or other potentially infectious materials as part of their job functions. Funeral home employees are specifically named in the requirement.

The vaccination must be offered within ten days of initial assignment to a job where exposure to blood or other potentially infectious materials can be "reasonably anticipated." The requirement for vaccinations of employees already on the job took effect July 6, 1992.

The Safety of the Vaccine
The Hepatitis B vaccine is a non-infectious, yeast-based vaccine that has been manufactured by genetic engineering and is given in three injections in the arm. It is prepared from recombinant yeast cultures, rather than from human blood, blood products or plasma. There is absolutely no risk of contamination from other bloodborne pathogens nor is there any chance of developing HBV from the vaccination.

The second injection is given one month after the first, and the third injection six months after the initial dose. More than 90 percent of those vaccinated will develop immunity to the Hepatitis B virus. To ensure immunity individuals must receive all three injections. It is unclear how long the immunity lasts, so booster shots may be required at some point in the future. Presently, the U.S. Public Health Service does not require such boosters.

The vaccine causes no harm to those who are already immune or to those who may be HBV carriers. Employees may opt to have their blood tested for antibodies to determine the need for the vaccination. Employers, however, cannot make such screening a condition for receiving the vaccine, nor are they permitted to prescreen employees.

There are very few people, those with a hypersensitivity to yeast or vaccine components who should not be vaccinated for HBV. Employees should consult with their health care professional when the vaccination is being considered in order to determine whether inoculation is necessary or recommended based on the individual's health status.

Side Effects of Vaccine
There are some side effects to the Hepatitis B vaccination, but they are usually mild and last only for a short time. The most common effects are soreness, redness and swelling at the place on the arm where the injection was given. These reactions generally subside within two days of vaccination.

After the injection, some people have felt tired, dizzy or may have had a headache, slight fever or, an upset stomach. Due to the fact that there are different brands of vaccine available, you should consult your doctor for the specific benefits and potential side effects of the actual vaccination you are to receive.

Declining the Vaccination
Workers who decide to decline vaccination must complete a declination form. Employers must keep the form on file so that they know the vaccination status of everyone who is exposed to blood or other potentially infectious materials. At any time after an employee initially declines to receive the vaccine, he or she may later opt to take it.

Exposure Prior to Vaccination
If an employee experiences an exposure incident, such as a needlestick or mucous membrane splash incident, he or she is entitled to receive a confidential medical evaluation from a licensed health care professional with appropriate follow-up. To the extent possible by law, the employer is to determine the status of the source individual for HBV as well as human immunodeficiency virus (HIV) infectivity. The worker's blood will also be screened if he or she agrees.

The healthcare professional is to follow the guidelines of the U.S. Public Health Service in providing treatment. This would include Hepatitis B vaccination. The health care professional must give a written opinion on whether or not vaccination is recommended and whether the employee received it. Only this information is reported to the employer. Employee medical records must remain confidential. HIV or HBV status must NOT be reported to the employer.

Summary of Vaccine Benefits
The potential savings with immunization far exceed the cost that could be incurred with infection. More importantly, for the individual employee there is the possibility of lost income, the potential health consequences of HBV infection and the risk of transmission to family members.

The employer equally benefits because there is reduced risk of employee to employee transmission requiring the need to replace employees who have the Hepatitis B infection.

You are in one of the occupational groups very much at risk for Hepatitis B infection. Protect yourself with the vaccination.

Hepatitis C (HCV)—A Deadly Concern

Prior to the 1989 identification of the Hepatitis C virus, large number of hepatitis victims had begun to appear, apparently with a viral cause for their illness. Upon examination, these patients tested negative for both Hepatitis A and B. When the Hepatitis C test was developed in 1990, HCV was found to be responsible for the majority of these cases and has proven to present a frightening challenge.

HCV infection is typically mild in its early stages and is rarely recognized until it has caused significant damage to the liver. The cycle of disease from infection to significant liver damage can take 20 years or more.

As a result, 75-85 percent of HCV infections become chronic and leads to liver disease, cirrhosis and liver failure. Liver failure due to HCV is the leading cause of liver transplants in the United States.

HCV infection occurs among all age groups, with the highest incidence in the 20-39 age groups, predominately males. African Americans and whites have a similar incidence rate, with Hispanics having a higher rate.

Approximately 2.4 million people in the United States are infected with HCV. With the CDC estimating 44,700 new HCV infections annually, each year approximately 17,250 deaths occur from HCV in the United States. This makes HCV one of the greatest public health threats to be faced. Often more people are infected with HCV than HIV, and it is expected that the death rate from HCV will surpass that from AIDS.

Transmission

Hepatitis C is believed to be transmitted only by blood. However, unlike many other bloodborne viruses virtually any source of blood or blood product seems to be capable of carrying the virus, even if the source is indirect. This makes HCV far more transmissible than most other bloodborne viruses—including HIV.

Almost any direct or indirect exposure to infected blood can transmit the virus. This includes injection drug use and poorly sterilized instruments, blood spills, unbandaged cuts or injuries, and as well as less obvious sources of blood, such as shared razors, toothbrushes, or body secretions.

Sexual activity with multiple partners has been clearly identified as a mode of transmission, but the exact risk in unknown. Because of the lack of sufficient information, persons in long-term, monogamous relationship are not advised to change sexual practices. Day-to-day contact with another household member who has HCV has been strongly implicated. Maternal-infant transmission has also been documented as a method of transmission.

Effective blood screening for the HCV virus was developed and implemented by 1992, this lowered the rates of post-transfusion hepatitis and reduced the risk down to 1 in 2 million. However, anyone who had a blood transfusion prior to that time is at risk for having been infected.

The most significant risk behavior for HCV infection is drug use, particularly injecting drug use, and it is responsible for about 60 percent of all identified cases. As with HIV, the sharing of contaminated needles and other drug paraphernalia increases the chance of infection dramatically.

In more than 85 percent of all cases, whether they progress to chronic liver disease or not, the infected individual carries the virus for life. This means that they also remain contagious for a lifetime and able to transmit the virus to others. And, because of the long progression of the illness, even patients who will eventually die as a result of HCV carry the virus for decades before it takes their lives. Much like HIV and AIDS, HCV lasts a lifetime and kills slowly giving the virus plenty of time to spread.

Symptoms and Progression of HCV

The symptoms of HCV are very mild, nonspecific and intermittent in the early stages of infection and can be virtually undetectable. In individuals who experience symptoms, the onset of indicators may develop 4–12 weeks after exposure. Symptoms include fatigue, mild fever, muscle and joint aches, nausea, vomiting, loss of appetite, vague abdominal pain. Many cases go undiagnosed because the symptoms suggest a flu-like illness which comes and goes, or these symptoms are so mild the patient is unaware of anything unusual. A minority of patients notice dark urine and light-colored stools, followed by jaundice.

When the disease progresses and damages the liver badly enough, the symptoms progress into cirrhosis and liver failure, jaundice, abdominal swelling, and itching of the skin.

Diagnosis and Treatment

Several blood tests are used to detect HCV infection. These include screening tests for antibody to HCV and qualitative tests to detect the presence or absence of the virus. HCV infection can be detected by as early as 2–10 weeks after infection.

HCV-positive persons should have additional liver function tests performed to detect the severity of liver disease, and possible treatment.

The treatment of choice for HCV is a combination therapy with interferon and ribavirin, which is FDA—approved for individuals over the age of three. It is a 48–week course of treatment and provides rapid improvement.

Protection

Currently, there is no vaccine for HCV, and because of the virus' frequent mutation, it may be a long time before one becomes available. However, because of HCV's slow progressive infection, infected patients have long life expectancies, and with proper treatment, many of them can recover completely.

Liver transplantation may be lifesaving in end-stage liver disease but is costly and involves continuing health care following the procedure. This treatment option is further complicated by a shortage of liver donors. For HCV—positive patients undergoing transplantation, re-infection is almost universal.

There are a number of drug treatments becoming available for HCV. Infected individuals should consult with their physician to see about the availability and effectiveness of these treatments, as well as the possibility of participating in experimental drug trials.

To protect yourself and others from Hepatitis C:

1. Use caution and wear gloves when touching or cleaning up blood on personal items.
2. Clean up spilled blood with a strong disinfectant and keep skin injuries bandaged.
3. Do not share razors, toothbrushes, pierced earrings, or other personal items with anyone.
4. Use condoms if you have multiple sex partners or when having sex with an infected person.
5. Do not share chewing gum or pre-chew food for a baby.
6. Make certain any needles or other sharp implements for drugs, ear piercing, manicuring, or tattooing are properly sterilized.
7. Remember that blood products are in many cases not tested for HCV outside of the United States and Europe.

8. If you feel that you or another family member is at risk for being infected with HCV or any other form of hepatitis, get tested. A simple blood test can put your mind at ease and protect the health of your family.

Other Known Hepatitis Viruses

In addition to Hepatitis B and C, there are other known hepatitis viruses to be aware of.

Hepatitis A (Foodborne)

Hepatitis A is usually transmitted by drinking water or eating food that has been contaminated with fecal matter containing the virus. Feces from an infected person have a high concentration of the virus. The virus can survive in fecal matter on a person's hand or other surfaces for three to four hours at normal room temperatures. Intimate contact, and certain sexual activities can transmit the virus.

Eating utensils are a frequent source of infection, along with fruits, vegetables, shellfish, ice and water. The risk of contracting HAV generally depends on the hygienic and sanitary conditions in a given area.

As is common with the other forms of viral hepatitis, the infected person may not have any symptoms. When they do occur, symptoms resembling the flu normally appear during the first four weeks of infection. These include fatigue, nausea, vomiting, pain in the liver area, dark urine or light-colored stools and fever. Many adults develop jaundice. Most people recover from HAV within six months without any serious health problems.

There is a Hepatitis A vaccine that is highly effective, with no serious side effects. It is administered in two shots, six months apart. The vaccine also come in a combination form, containing both Hepatitis A and B. Treatment is aimed at maintaining comfort and adequate nutritional balance, including the replacement of fluids.

In 2018 the Centers for Disease Control and Prevention (CDC) estimated that 24,900 people in the United States are infected each year by HAV, a low rate compared to underdeveloped countries.

Hepatitis D Virus (Bloodborne)

Infection with Hepatitis D occurs only in patients already infected with Hepatitis B (HBV). HDV is spread mainly by contaminated needles and blood. IV drug users have a high incidence. The simultaneous infection with HBV and HDV produces more severe illness and higher rates of long-term liver failure than HBV alone. The disease is usually effectively prevented via the HBV vaccine.

Hepatitis E Virus (Foodborne)

Hepatitis E, whose symptoms and methods of transmission resemble HAV, is caused by a virus commonly found in underdeveloped countries. Testing for HEV is being developed but is not yet available commercially. The symptoms of HEV are like those of HAV, although the period of illness may be as long as several months. HEV is rarely, if ever, responsible for causes of chronic hepatitis.

Hepatitis E is uncommon in the United States, it is usually contracted after traveling to a developing country where Hepatitis E is an epidemic.

HIV—Human Immunodeficiency Virus

The Human Immunodeficiency Virus (HIV) destroys the body's natural defenses against a wide range of illnesses and, in most cases, leads to death. An individual infected with HIV may carry the virus for years before starting to look or feel sick. Even though that person may not appear to be sick, he or she is still infectious and can transmit the virus to others. It is HIV that causes Acquired Immunodeficiency Syndrome (AIDS).

HIV infection and AIDS can now be viewed as a family disease, not limited to homosexuals or illicit drug users. An infected individual can transmit the disease sexually to his or her spouse and an infected woman can transmit the disease to her fetus or newborn.

In the United States, the number of HIV carriers is one million or more, with about 38,000 new infections among adults and adolescents annually. Because of the large number of individuals already infected, the AIDS epidemic will continue for the foreseeable future. HIV infection can be prevented by people who know how the virus is transmitted, how it is not, and how to protect themselves. The general population as well as health care personnel needs to become informed and involved if this epidemic is to be curtailed and those already affected given appropriate care.

Transmission

HIV is spread by sexual contact with an infected person, by sharing needles and/or syringes (primarily for drug injection) with someone who is infected, or, less commonly (and now very rarely in countries where blood is screened for HIV antibodies), through transfusions of infected blood clotting factors. Babies born to HIV-infected women may become infected before, during birth, or through breastfeeding.

In the health care setting, workers have been infected with HIV after being stuck with needles containing HIV-infected blood or, less frequently, after infected blood gets into a worker's open cut or mucous membrane.

Symptoms

Many individuals are infectious and contagious, yet do not look or feel sick. (Symptoms of HIV and AIDS are like any other virus at first, flu and fever, which eventually subside.) Other symptoms can include a white coating on the tongue, swollen lymph glands, chronic diarrhea, shortness of breath, and mental confusion. The more severe and noticeable symptoms are severe weight loss and purple bruises and/or lesions on the skin.

Complications of HIV

AIDS is the most severe manifestation of HIV. It is a secondary immunodeficiency syndrome characterized by opportunistic infections, malignancies, neurologic dysfunctions, and a variety of other syndromes. A person infected with HIV is diagnosed with AIDS when he or she has one or more opportunistic infections, such as pneumonia or tuberculosis, and has a dangerously low number of CD4+ T cells (less than 200 cells per cubic millimeter of blood).The possibility remains that almost all HIV infected persons will develop AIDS. There have been NO complete recoveries from AIDS.

You Are in a High-Risk Group

Funeral home personnel who have contact with blood or body fluid are at an increased risk of contracting HIV.

HIV exposure may occur if you have direct contact with infected blood or other body fluids such as semen, saliva, and vaginal fluids in any one of the following ways; a needlestick injury with an infected needle or sharp, injection of infected blood during IV injection or illicit drug use, transfusion of contaminated blood, heterosexual or male homosexual

contact with infected individuals, or by having an incident where infected blood or body fluid is splashed into the mouth, eyes, or nose, or onto skin that is cut, scratched, or unprotected.

No HIV or AIDS Vaccine Is Available

Currently there is no vaccine against HIV or AIDS infection, nor is one likely to be available for years. Prevention depends on knowing the routes of infection and taking appropriate steps to avoid exposure.

HIV antibody testing can be utilized as a useful diagnostic procedure for individuals at risk. The most common HIV tests use blood to detect HIV infection. Tests using saliva or urine are also available. Some tests take a few days for results, but rapid test can give results in about 20 minutes. Rapid HIV antibody tests are now available in the U.S. and are interpreted visually. Like the conventional HIV enzyme immunoassays (EIAs), rapid HIV tests are screening tests that require confirmation if reactive. Antibody testing should only be carried out voluntarily after informed consent is obtained and accompanied by counseling and education about the significance of the results, risk behaviors, and prevention.

Treatment

In the early 1980s when the HIV/AIDS epidemic began, people with AIDS were not likely to live longer than a few years. Today, there are multiple antiretroviral drugs approved by the USFDA to treat HIV infection. These treatments do not cure, rather, they suppress the virus, even to undetectable levels, but they do not completely eliminate HIV from the body. By suppressing the amount of virus in the body, people infected with HIV can now lead longer and healthier lives. However, they can still transmit the virus and must continuously take antiretroviral drugs in order to maintain their health quality.

Follow Universal Precautions.

Universal Precautions are an approach to infection control. All human blood and body fluids should be treated as if known to be infectious for HIV and Hepatitis B.

Funeral home personnel should wear gloves, at a minimum, whenever handling remains. Body fluids and viscera should be handled in the same manner as those from remains with Hepatitis B. Accidental needlesticks of health care employees are remarkably common and special emphasis must be placed on teaching all individuals how to avoid these potentially dangerous accidents.

HIV is readily inactivated by heat and commonly used disinfecting agents, including peroxide, alcohol, phenol, and hypochlorite. Although individuals with AIDS are ordinarily not infectious, their body fluids and blood are and should be handled with extreme care.

While the risk of HIV transmission appears to be much lower than that of Hepatitis B transmission, the potential consequences are much worse. There is NO cure and NO treatment for this disease. The potential consequence of an accidental exposure incident in the embalming room is death.

Novel Coronavirus Disease 2019 (COVID-19)— Not a Bloodborne Pathogen (Airborne)

Is a respiratory disease caused by the SARS-CoV-2 virus. Because of the shape of the virus, it was named Corona from the Latin word meaning "crown." At the time of publication there remains much to be learned about this threat.

Transmission

On March 11, 2020, COVID-19, was declared a pandemic by the World Health Organization (WHO). On March 13, 2020, a national emergency was declared in the United States concerning the COVID-19 Outbreak.

The virus is a contagious respiratory illness spread person-to-person through respiratory droplets. It may be possible for individuals to become infected by touching a surface or object that has been contaminated with the SARS-CoV-2 virus and then touching their eyes, mouth, or nose.

The virus that causes COVID-19 is spreading very easily and sustainably between people. Information from the ongoing COVID-19 pandemic suggest that this virus is spreading more efficiently than influenza, but not as efficiently as measles, which is highly contagious.

Symptoms

Flu-like symptoms may include fever, chills, coughing, shortness of breath or difficulty in breathing, fatigue, muscle or body aches, headache. Loss of taste or smell, sore throat, congestion, nausea, vomiting and diarrhea. Symptoms may appear in as few as two days, or up to 14 days following exposure. Asymptomatic cases have experienced no symptoms at all.

Prevention

Steps to protect yourself include:

- Using face masks
- Social distancing
- Good hygiene and infection control practices
- Covering your nose and mouth when you cough or sneeze (respiratory etiquette.)
- Washing your hands frequently with soap and water for at least 20 seconds.
- Keeping commonly touched surfaces (i.e., telephones, computers, doorknobs, light switches, embalming tables, countertops, instruments, etc.) clean with a solution that contains 70 percent ethanol, 5 percent Lysol, or 10 percent bleach.
- Remaining at home if ill or experiencing a fever.

High Risk Groups

OSHA has divided COVID-19 job tasks into four risk exposure levels:

- **Very High**, Are those with high potential for exposure to known or suspected sources of COVID-19 during specific medical, postmortem or laboratory procedures.
  - Workers in this category include:
    - All of funeral home Category I staff
    - **Morgue workers performing autopsies, which generally involve aerosol-generating procedures**, on the bodies of people who are known to have, or suspected of having, COVID-19 at the time of their death.
  - Aspiration is an **aerosol-generating procedure**
- **High**, Are those with high potential for exposure to known or suspected sources of COVID-19.
  - Workers in this category include:
    - All funeral home Category I and II staff
    - **Mortuary workers involved in preparing (e.g., for burial or cremation) the bodies of people who are known to have, or suspected of having, COVID-19 at the time of their death.**
- Medium, and
- Low risk

The Funeral Profession

Since the funeral profession is one that requires close contact with families, employees, and ultimately the public, it faces special considerations in preventing the spread of any airborne respiratory disease when dealing with the public.

The CDC's Biosafety Guideline for Laboratory Workers and Guideline for Infection Control in Healthcare Settings, which the funeral industry uses as guidance for mortuary personnel, continues to suggest the following embalming best practices (universal precautions):

- Personal Protective Equipment
- Respiratory Protection
- Surgical mask (on embalmers and decedent)
- Fit tested respirator (N95)—only in the context of a respiratory protection program established within your facility in accordance with OSHA
- Shoe Covers
- Gown
- Double Gloves
- Eye Protection
- Good and constant ventilation at a minimum of 10-15 air exchanges per active table per hour.

Standard droplet and contact precautions should be observed during body transfer, drainage, and aspiration, (In order to minimize the possibility of droplet aerosolization thoracic and abdominal aspiration is strongly discouraged if possible) with funeral directors reminded to wash their hands thoroughly with soap and water on a regular basis and to use hand sanitizer when soap and water are not readily available.

The CDC has prepared "Funeral Guidance for Individuals and Families" for further review https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/funeral-guidance.html.

Additionally, the CDC's "Collection and Submission of Postmortem Specimens from Deceased Persons with Known or Suspected COVID-19" provides funeral home personal with recommendations on cleaning, disinfection and transportation, https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-postmortem-specimens.html.

Clostridioidies Difficile formerly known as Clostridium Difficile (C. difficile or C. diff)—Not a Bloodborne Pathogen

Clostridioidies difficile (often referred to as C. difficile or C. diff) is a bacterium found in the intestines that causes diarrhea, colitis, and more serious life-threatening intestinal conditions.

It has been estimated that C. diff is responsible for more than half million new cases each year in the U.S. The elderly and individuals who have experienced extended hospitalization or been in a long-term care facility, people with serious underlying injuries and/or have had a prolonged use of antibiotics have the greatest risk of acquiring the disease.

Over the past several years, increased rates of C. diff infection have been reported, thought to be a result of changes in antibiotic use, changes in infection control practices, or the emergence of an epidemic strain of a C. diff infection with increased virulence and/or antimicrobial resistance.

Symptoms

The most common symptoms of mild to moderate C. diff infection include watery diarrhea three or more times a day for two or more days, and mild abdominal pain and tenderness.

In the more severe cases, the colon becomes inflamed and the symptoms become more prominent. These include watery diarrhea 10 to 15 times a day, moderate to severe abdominal cramping and pain, fever, blood or pus in the stool, nausea, dehydration, loss of appetite and weight loss.

Transmission

C. diff is found in human feces and has the ability to form spores. People can become infected when they touch items and surfaces that are contaminated with feces and then touch their mouth. In preparation rooms, C. diff can spread via hand contact with commodes, sheets/linens, pouches, transfer stretchers, trocars and embalming tables. Funeral home staff should consider themselves at high risk for contracting C. diff.

It is important to note that C. diff bacteria produce spores that could live on surfaces for up to five months.

Treatment

Once the bacterium is properly diagnosed, there are strong antibiotics used to treat C. diff. Treatment also calls for stopping antibiotics for other purposes, whenever possible. In severe cases a person might have to have surgery to remove the infected part of the intestines. This type of surgery is required in every one to two of 100 persons infected with C. diff.

Prevention
The CDC recommends strict adherence to universal and contact precautions through use of personal protective equipment and implementation of an environmental cleaning and disinfection policy:

- Always wear gloves when contact is made with human remains, OPIM, and possibly contaminated surfaces.
- Wash hands with soap and water after removing gloves. Because alcohol does not kill C. diff spores, the use of hand rubs should only be introduced after effectively washing your hands with soap and water.
- It is recommended to perform disinfection of surfaces with (1:10 dilution) household bleach and water or the use of an EPA registered sodium hypochlorite-based disinfectant for environmental surface disinfection after cleaning.
- If you have diarrhea, avoid using the same toilet as other staff/family members unless the toilet can be cleaned with a bleach and water mixture after each use.

Creutzfeldt–Jakob Disease—Not a Bloodborne Pathogen

Creutzfeldt–Jakob Disease (CJD) is an infectious, progressive, degenerative neurological disorder with incubation periods ranging from 1 year to over 20 years, typically in the elderly. Once symptoms appear, the disease progresses rapidly—usually within one year—from dementia to death. There is no known treatment and the disease is always fatal. The causative agent, a prion, is extremely hardy, resistant to all measures of decontamination and sterilization routinely used in mortuaries today and can live for long periods in a dried state. Clearly, CJD poses one of the greatest challenges in decontamination today.

CJD has been described as: Sporadic CJD, which accounts for 85% of cases and is a result of either mutations arising in the tissue and accumulating over time or from an infectious transmission from an unknown source; familial CJD, a genetic mutation inherited from a parent; and acquired CJD (iatrogenic or infectious) where the prion is introduced from an external source, such as corneal transplants, dura mater grafts, human growth hormones or contaminated surgical instruments.

Variant CJD (vCJD) is a form of the acquired CJD where person become infected through their consumption of cattle products contaminated with Bovine Spongiform Encephalopathy (BSE). Unlike other forms, vCJD affects predominantly young adults. Of the two reported cases, the patients presumably acquired the disease while living in Great Britain.

Diagnosis
Definite diagnosis is made by a brain biopsy obtained surgically or on a postmortem examination. The infected brain tissue contains vacuoles, which give the tissue a "sponge-like" appearance on the microscopic level. For this reason, CJD and related disorders are called transmissible spongiform encephalopathies (TSE).

Transmission
The natural transmission of CJD is not understood, primarily because of difficulties determining causality after a long incubation period. The incidence rate is less than one year per million people per year. Although CJD has been found throughout the world, in the United States in recent years, fewer than 250-300 cases of CJD have been reported annually.

While skin and most bodily secretions and excretions (e.g. urine, feces, milk, saliva, and semen) are considered noninfectious, transmissions have occurred via transplanted tissue; cadaver extracted hormones used as a growth treatment for dwarfism and short stature; and using contaminated surgical instruments. Transplanted tissue including cornea, pericardial homograft and dura mater has transmitted the disease to recipients.

Transmission studies have shown that primates can be infected via the percutaneous route. Brain, spinal cord and cerebrospinal fluid from human or animals with CJD have regularly transmitted infection when inoculated into animals. Other viscera (liver, lung, kidney and spleen) transmit the infection with less predictability.

Risk Management
Careful planning in advance of embalming makes decontamination afterwards a manageable task. Universal Precautions (as advocated for all other embalming) should be followed. To appropriately decontaminate the instruments about to be utilized, a steam sterilizer should be located and prepared for use in cleaning all instruments following use. It is preferable that a "pre-vacuum" sterilizer capable of reaching 132 degrees Celsius (270 degrees Fahrenheit) and maintaining that temperature for 18 minutes be utilized, although "standard gravity" sterilization at 132 degrees C (270 degrees Fahrenheit) for 60 minutes has effectively eradicated CJD infectivity in brain tissue.

To further protect the preparation room from contamination, disposable supplies should be used whenever possible. Items requiring laundry should not be used as detergents have little effect on prions. A 1:10 dilution of household bleach can be used to spot decontaminate visible residues of tissue before cleaning with a suitable disinfectant.

Many questions remain regarding transmission and risk factors for Creutzfeldt-Jakob Disease; therefore, the precautions presented here should be considered as a simplified summary only. For further recommendations on handling CJD deaths, please see our publication "Creutzfeldt-Jakob Disease, A Practical Guide for the Embalmer."

To obtain an electronic copy of "Creutzfeldt-Jakob Disease, A Practical Guide for the Embalmer," contact The New Jersey Funeral Service Education Corporation at 732.974.9444.

For more information on CJD, visit the CJD Foundation at https://cjdfoundation.org/cjd-foundation-literature.

Influenza (Flu)—Not a Bloodborne Pathogen

What Is the Flu?
The flu refers to illnesses caused by any of the various influenza viruses.

Transmission
Influenza ("the flu") is a contagious respiratory illness caused by the influenza virus. It spreads from person-to-person and can cause mild to severe illness.

In the United States, every year 5-20 percent of the population get the flu. More than 200,000 people are hospitalized from flu complications. The CDC estimates 36,000 annually flu-associated deaths.

A flu pandemic is when a new influenza virus emerges for which there is little or no immunity in the general population. The virus can cause serious illness and spreads easily. On June 1, 2009, the World Health Organization (WHO), declared the H1N1 as a global pandemic.

Symptoms

Flu symptoms may include fever, coughing, sore throat, runny or stuffy nose, headaches, body aches, chills and fatigue. H1N1 symptoms also include vomiting and diarrhea.

Emergency warning signs include difficulty breathing or shortness of breath, pain or pressure in the chest, sudden dizziness, confusion and severe or persistent vomiting. If you experience any of these symptoms, you should seek emergency medical care.

Annual outbreaks of the seasonal flu typically occur in the spring and fall. Most healthy people recover from the flu without problems.

Prevention

Vaccination is the best protection against contracting the flu. The seasonal flu vaccine is different from the H1N1 vaccine. The Centers for Disease Control and Prevention (CDC) encourages people to get both vaccines.

Other steps to protect yourself include:

- Cover your nose and mouth with a tissue when you cough or sneeze.
- Wash your hands frequently with soap and water for at least 20 seconds.
- Keep commonly touched surfaces (i.e., telephones, computers, doorknobs, light switches, embalming tables, countertops, instruments, etc.) clean with a solution that contains 70 percent ethanol, 5 percent Lysol, or 10 percent bleach.

High Risk Groups

Certain high-risk groups of individuals are more like to have complications. This includes the elderly; children under the age of two, and individuals with have chronic medical conditions (e.g., diabetes, asthma, etc.). Complications that may occur are pneumonia, ear or sinus infection, dehydration and worsening of chronic medical conditions.

The Funeral Professional

Since the funeral profession is one that requires close contact with families, employees, and ultimately the public, it faces special considerations in preventing the spread of any form of influenza.

When making arrangements with families, try to politely avoid close contact (within six feet) and ensure that the meeting room is properly ventilated. Remember this is a social distancing precaution practiced in large group settings and should not be imposed on your families in a disrespectful manner.

The CDC's Biosafety Guideline for Laboratory Workers and Guideline for Infection Control in Healthcare Settings, which the funeral industry uses as guidance for mortuary personnel, continue to suggest the following embalming best practices (universal precautions):

- Personal Protective Equipment
- Respiratory Protection
  - Surgical mask (on embalmers and decedent)
  - Fit tested respirator (N95)—only in the context of a respiratory protection program established within your facility in accordance with OSHA
- Shoe Covers
- Gown
- Double Gloves
- Eye Protection
- Good and constant ventilation at a minimum of 10-15 air exchanges per active table per hour.

Standard droplet and contact precautions should be observed during body transfer, drainage, and aspiration, with funeral directors reminded to wash their hands thoroughly with soap and water on a regular basis and to use hand sanitizer when soap and water are not readily available.

Meningitis—Not a Bloodborne Pathogen

Acute Bacterial Meningitis is a severe infection of the bloodstream and the cerebrospinal fluid in the spinal cord and the meninges (the thin lining covering the brain and spinal cord). Bacterial meningitis can have serious consequences, such as brain damage, hearing loss, limb amputation, or learning disabilities. Today, Streptococcus pneumonia and Neisseria meningitides are the leading causes of bacterial meningitis.

Who Gets the Disease?

Anyone can get bacterial meningitis, however, as a result of effective childhood vaccines; bacterial meningitis is more commonly diagnosed among pre-teens and young adults. It may also appear in clusters of small populations such as those found in military barracks, students living in dormitories and childcare facilities.

Individuals with weakened immune systems due to certain diseases, medications, injuries, and surgical procedures may have an increased risk of meningitis as well.

Transmission

The bacteria can be spread from person to person through the exchange of respiratory and throat secretions. This can occur through coughing, kissing, and sneezing. The bacteria are not spread by casual contact or by breathing the air where a person with meningitis has been.

Symptoms

Symptoms of bacterial meningitis include a sudden onset of fever, headache and stiff neck. Other signs include nausea, vomiting, skin rash and an altered mental state. These symptoms can appear quickly or over several days. Typically, they develop within 3-7 days after exposure.

Adults may become desperately ill within 24 hours, the course being shorter for children. In older children and adults' changes in consciousness progress through irritability, confusion, drowsiness, stupor, and eventually coma. If meningitis is suspected, the person should contact a physician as soon as possible.

Diagnosis

Early diagnosis and treatment is essential. If meningitis is suspected, samples of blood or cerebrospinal fluid are collected and tested. It is important to understand the cause of meningitis because the severity of illness and the treatment will differ. If bacteria are present, they can be cultured which will help determine the precise type of bacteria that is causing the infection.

Different Diagnosis

A number of infectious and noninfectious illnesses resemble bacterial meningitis, further complicating initial diagnosis. It is important that funeral directors not confuse the diagnosis of aseptic meningitis, especially viral meningitis and encephalitis, with bacterial meningitis.

Prevention

In general, an effective method of preventing most infections is the practice of good personal hygiene, such as avoidance of, or sharing glasses/utensils and washing hands often with soap. There are safe and effective vaccines for the prevention on bacterial meningitis. Keeping up to date with recommended immunizations is the best defense.

High Risk Groups
People who have been in close contact with the infected individual, such as household members, those with an intimate relationship, health care personnel who may have performed mouth-to-mouth resuscitation, day care playmates, etc., need to be considered for preventative treatment.

Methicillin Resistant Staphylococcus Aureus (MRSA)—Not a Bloodborne Pathogen

Methicillin Resistant Staphylococcus Aureus (MRSA) is a type of staph infection resistant to many commonly prescribed antibiotics that may cause skin and other infections. There are two types of MRSA infections funeral directors need to concern themselves with; community acquired MRSA (CA-MRSA) and healthcare associated MRSA (HA-MRSA). The infections range from not serious to life threatening.

According to studies by the Centers for Disease Control and Prevention (CDC), the spread of MRSA is one of the greatest challenges to healthcare today.

High Risk Groups
HA-MRSA infection is more common in the elderly population and people with weakened immune systems. Infections generally appear in patients post-surgery, receiving dialysis, with catheters or feeding tubes and after long stays in healthcare and nursing facilities.

CA-MRSA infections are generally found in members of the population without documented healthcare risk factors or concerns. Markers may appear as commonly as pimples or boils. CA-MRSA is more prevalent among team athletes, military recruits, students and prisoners.

Funeral directors are in a high-risk group for coming into contact with MRSA. Good hygiene goes a long way toward halting the spread of infection.

Transmission
Staph is a common bacterium that can live on our body without incident. The CDC estimates over 30 percent of the U.S. population have staph bacteria in their noses and 1 percent of the population is colonized with MRSA bacteria, although most are not infected. The problem ensues when the bacteria find a way to enter our bodies. Modes of transmission are direct and indirect. HA-MRSA accounts for 58 percent of reported cases.

MRSA can be contracted by direct contact with another person's infection or by sharing personal items, such as towels or razors. It may also be transmitted by touching surface items, such as, used bandages, towels and weight-training equipment.

Symptoms
MRSA infections are usually manifested as skin infections, such as pimples or boils. The area may appear red, swollen, be painful, feel warm, be full of pus or other drainage and may be accompanied by a fever. Some common areas for infection are the legs, buttock, groin and back of the neck. If an individual experiences these symptoms, the area should be covered with a bandage and a healthcare professional contacted.

Prevention for the Funeral Professional
Funeral directors are in a high-risk group for coming in contact with MRSA. Prevention is very important since treatments for infections can be expensive and time consuming. Good hygiene goes a long way toward halting the spread of infection.

The best defense against the spread of MRSA infections for funeral service professionals is following universal precautions.

Work practices that prevent the spread of infection:

1. Practice good hygiene; keep a supply of alcohol-based hand sanitizers available.

2. Cover compromised skin on employees and the remains.

3. Follow your decontamination schedule for the preparation room.

4. Properly dispose of medical waste.

5. Always wear gloves when around human remains.

6. Clean the removal stretcher after every use.

Testing
A rapid blood test is now available that can identify the MRSA bacterium in two hours. Other screenings methods are also available.

Treatment
In the community, most MRSA infections are minor and can be treated in an outpatient setting and/or with antibiotics. More serious cases of MRSA may require hospital admission for IV antibiotics. Oral antibiotics may be needed for up to 8 weeks.

These are limited antibiotic treatments available. Vancomycin, linezolid and daptomycin, are among the drugs used for severe infection.

Tuberculosis (TB)—Not a Bloodborne Pathogen

A chronic, recurrent infection most common in the lungs, although any organ may eventually be involved and/or affected. Communicable tuberculosis refers only to the disease caused by mycobacterium tuberculosis, M. bovis or M. africanum.

Tuberculosis is commonly transmitted by coughing, sneezing, and talking (droplet nuclei). The use of reciprocating saws, such as those used during postmortem procedures, also has been known to produce enough aerosol to expose workers to the bacteria.

People with active tuberculosis expel microscopic droplets of the bacteria from their lungs or throats that can linger for hours in uncirculated air.

In 2019, there were 8,920 reported cases of TB in the United States; one of the lowest number of cases recorded since national reporting began in 1953. However, worldwide TB remains one of the leading causes of death for persons infected with HIV.

The Difference between TB Infection and Disease
There are two types of TB related conditions; latent TB infection and active TB disease.

Individuals with the latent TB infection have the TB bacteria in their body. They are not sick or have any symptoms because the TB is inactive. Most people who contract TB carry its dormant form harmlessly in the body. They are not infectious and cannot spread the TB bacteria to others. These people may develop TB disease in the future, especially if they are considered high risk. The only sign of TB infection is a positive reaction to the tuberculin skin test or special TB blood test. Medicine is often prescribed to prevent the latent TB from developing into the disease.

TB disease is when the TB bacteria becomes active, begin to multiply and the immune system cannot stop the growth. People with the disease are sick and usually have one or more TB symptoms. These individuals usually infect others and should be considered highly contagious. Permanent body damage and death can result from the disease. Medicines, which attempt to cure TB, are usually given to individuals who have the TB disease.

High Risk Groups
Persons at high risk for developing the TB disease may fall into two categories; (1) persons infected with the TB bacteria, (2) persons with a weaken immune system. Approximately 5-10 percent of individuals with latent TB infection who do not receive any treatment will develop TB disease. Persons infected with HIV have a very high risk of developing TB disease.

Although TB has been almost eliminated in some segments of the population, it is prevalent in others, e.g., persons over the age of 65 years.

Generally, the following groups of individuals are considered high risk for TB: people who share the same breathing space with someone with TB, the poor, the homeless, nursing home residents, prisoners, alcoholics, intravenous drug users, people with medical conditions, individuals who are underweight, and HIV-infected individuals.

Symptoms of TB Disease
Cough is the most common symptom associated with TB. The problem with a continual cough as a symptom is that is commonly dismissed as a "cigarette cough," bronchitis, or a nervous habit, which is the main reason most TB infections go unrecognized. As the disease progresses, the cough becomes more productive and can lead to fatigue, weakness, unexplained weight loss, chest pain, or coughing up blood. Usually an abnormal chest x-ray, and/or a skin test or blood test may indicate a TB infection.

Prophylaxis and Treatment
There are two types of tests to detect TB infection. The TB skin test (TST) and TB blood test.

The TB skin test (Mantoux tuberculin skin test) involves injecting tuberculin fluid into the skin, usually in the inner arm. The skin is then evaluated for a reaction by a trained health care works with 48 to 72 hours. The TB blood test measures how an individual's immune system reacts to the TB bacteria.

A positive TB skin or blood test only indicates that a person has been infected with the TB bacteria. It does not mean the individual has developed the TB disease. Additional tests, such as x-rays, lab tests, or sputum samples are required to determine if the TB disease is present.

There are currently 10 drugs approved by the U.S. Food and Drug Administration (FDA) for TB treatment. Regimen plans have an initial phase of two months, followed by several options for the continuation phase of either 4 or 7 months.

Although the disease can be cured, many patients stop their medicine routine once they start to feel better, causing the development of drug-resistant strains of TB. Other medications may be needed for a longer time and usually have more serious side effects.

You Should Consider Yourself a High Risk Group
Tuberculosis is quickly becoming a major concern of health care professionals. Funeral directors need to be fully aware of the rapidly changing TB strains and how they impact procedures and staff.

Because TB is an airborne disease, care should be taken not only with the deceased, but with the surviving relatives of the deceased as well. Chances are these individuals have also been infected.

Funeral directors should follow effective tuberculosis infection control, such as utilizing Universal Precautions. Engineering controls such as ventilation, air filtration, and personal protective equipment are essential for employee protection.

Ventilation of Funeral Home Preparation Rooms

Guidelines and Calculations

Division of Epidemiology, Environmental and Occupational Health

VENTILATION GUIDELINES

Ventilation requirements for funeral home preparation rooms are not specifically addressed in current existing guidelines. However, the National Mechanical Code of the Building Officials and Code Administrators (BOCA) and the Heating, Ventilation, and Air-Conditioning Handbook of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) specify ventilation criteria for autopsy rooms. These criteria for autopsy rooms can serve as useful guidelines for effectively ventilating funeral home preparation rooms.

BOCA requires a minimum of **12 air changes per hour** for autopsy rooms. The BOCA Code also requires that the **air shall be exhausted to the outdoors**, at an approved location on the exterior of the building.

ASHRAE recommends a minimum of **12 air changes per hour** be supplied to autopsy rooms, and that **at least two of the air changes per hour be outdoor air**. ASHRAE also specifies that the room be negatively pressurized in relation to adjacent areas.

The New Jersey Funeral Directors Association recommends, as an accepted industry practice, **10-15 air changes per hour** for preparation rooms.

A source of makeup air should also be provided in preparation rooms to prevent excessive negative pressurization and to improve air mixing within the room.

CALCULATIONS

AIR CHANGES PER HOUR (ACH) - To determine the number of air changes per hour occurring in an existing preparation room.

① Calculate Volume of preparation room:

length (ft) x width (ft) x height (ft) = room volume (ft^3)

② Calculate exhaust vent area in ft^2:

if rectangular: length (in) x width (in) = vent area (in^2)
if circular: 3.141 x [radius (in)]^2 = vent area (in^2)

vent area (in^2) x 0.00694* = vent area (ft^2)

(* = factor for converting in^2 to ft^2)

New Jersey Department of Health and Senior Services
Occupational Health Service
Occupational Health Surveillance Program
PO Box 360, Trenton, NJ 08625-0360
(609) 984-1863
www.state.nj.us/health/eoh/survweb/

③ Calculate Volumetric Airflow of exhausted air in Cubic Feet per Minute (CFM):

[NOTE: This will require airflow measurements using a velometer or equivalent instrument to determine average air velocity in feet per minute (ft/min) across the face area of the preparation room exhaust vent. More sophisticated measurement methods, such as duct static pressure, may also be used. Alternatively, a volumetric airflow hood can be used to directly obtain CFM.]

air velocity (ft/min) x vent area (ft^2) = CFM (ft^3/min)

④ Convert CFM to Cubic Feet per Hour (CFH):

CFM (ft^3/min) x 60 (min/hr) = CFH (ft^3/hr)

⑤ Calculate Air Changes per Hour (ACH):

CFH (ft^3/hr) ÷ room volume (ft^3) = ACH (air changes per hour)

Sample calculation for air changes per hour (ACH)

Preparation room is 30 ft. long x 20 ft. wide x 10 ft. high with an 18-inch-diameter circular exhaust fan vent having an average face velocity of 860 FPM.

ROOM VOLUME = 30 ft x 20 ft x 10 ft = 6,000 ft^3

VENT AREA = 3.141 x (9 in)^2 = 254.4 in^2 x 0.00694 = 1.77 ft^2

CFM = 860 FPM x 1.77 ft^2 = 1,522 CFM (ft^3/min)

CFH = 1,522 CFM x 60 min/hr = 91,320 CFH (ft^3/hr)

ACH = 91,320 CFH ÷ 6,000 ft^3 = 15.2 ACH

VENTILATION SYSTEM CAPACITY - To determine the ventilation system capacity in cubic feet per minute necessary to obtain a desired number of air changes per hour.

① Calculate Volume of preparation room:

length (ft) x width (ft) x height (ft) = room volume (ft^3)

② Calculate Cubic Feet per Hour (CFH) needed:

VOLUME (ft^3) x ACH (desired) = CFH (needed)

③ Convert to Cubic Feet per Minute (CFM) needed:

CFH ÷ 60 (min/hr) = CFM (needed)

Sample calculation for ventilation system capacity

Preparation room is 26 ft. long x 18 ft. wide x 9 ft. high and it is necessary to determine the number of cubic feet per minute that must be exhausted to obtain 15 air changes per hour.

4,212 ft^2 x 15 ACH = 63,180 CFH (ft^3/hr)

63,180 CFH ÷ 60 min/hr = 1,053 CFM (ft^3/min)

Calculation of the outside supplied air changes recommended by ASHRAE can be performed in the same manner as those for exhausted air.

Know Your SDS

A Supplement to Hazard Communication

All Safety Data Sheets (SDSs) contain important information detailing the chemical for which the SDS has been written. (As of June 1, 2015, chemical manufacturers, distributors, and importers are required to provide SDSs that are presented in a consistent user-friendly, 16- section format.)

Section 1 **Identification** includes product identifier; manufacturer or distributor name, address, phone number; emergency phone number; recommended use; restrictions on use.

Section 2 **Hazard(s) identification** includes all hazards regarding the chemical; required label elements.

Section 3 **Composition/information on ingredients** includes information on chemical ingredients; trade secret claims.

Section 4 **First-aid measures** includes important symptoms/ effects, acute, delayed; required treatment.

Section 5 **Fire-fighting measures** lists suitable extinguishing techniques, equipment; chemical hazards from fire.

Section 6 **Accidental release measures** lists emergency procedures; protective equipment; proper methods of containment and cleanup.

Section 7 **Handling and storage** lists precautions for safe handling and storage, including incompatibilities.

Section 8 **Exposure controls/personal protection** lists OSHA's Permissible Exposure Limits (PELs); Threshold Limit Values (TLVs); appropriate engineering controls; personal protective equipment (PPE).

Section 9 **Physical and chemical properties** lists the chemical's characteristics.

Section 10 **Stability and reactivity** lists chemical stability and possibility of hazardous reactions.

Section 11 **Toxicological information** includes routes of exposure; related symptoms, acute and chronic effects; numerical measures of toxicity.

Section 12 Ecological information*

Section 13 Disposal considerations*

Section 14 Transport information*

Section 15 Regulatory information*

Section 16 **Other information**, includes the date of preparation or last revision.

**Note: Since other Agencies regulate this information, OSHA will not be enforcing Sections 12 through 15(29 CFR 1910.1200(g)(2)).*

Employers are responsible for the maintenance of SDS.

All funeral homes are required to maintain up-to-date Chemical Identification Lists (CIL's), accompanied by the appropriate and most current version of the SDS. When new fluids are introduced or SDS are replaced by more currently issued versions, management must update the file accordingly.

The employer must maintain up-to-date documentation for each hazardous chemical in the workplace and ensure that they are available to all staff when they are in their work areas. In addition, previously used Chemical Identification Lists (CIL's) must be retained for at least 30 years.

If staff travel between work areas, CIL's and SDS may be maintained in one central location, provided that they would be immediately available in an emergency.

Fall Protection

To be compliant with OSHA's General Duty Clause, all businesses are required to have a written fall protection plan. It is the responsibility of the OSHA Compliance Officer (OCO) to implement and administer this plan. Continual awareness of fall hazards and compliance with safety rules should be considered conditions of employment.

Identification of Fall Protection Area.
The first step in establishing a safe workplace is the recognition of fall hazards on the job and to establish the procedures necessary to prevent falls. A proper fall protection plan needs to identify and address concerns associated with casket and body lifts. Most falls are to lower levels as a result of openings in lift/floor surfaces. A properly constructed plan will include continual checks and inspections as safety is an ongoing process. Employees and management share the responsibility in reporting and correcting unsafe and hazardous conditions.

Controlled Access Zone.
It is the responsibility of the OCO to create and clearly identify a controlled access zone (CAZ) where a potential hazard exists. The CAZ is to be restricted to authorized personnel only. The demarcation of a lift or shaft surface should be clearly defined and marked with a highly visible material, paint, or tape at the edge of the floor at all levels of access and the surface of the lift itself.

The CAZ should have signs and notices posted in/on the lift or in immediate proximity of the lift visible by operators regarding the limited access of the casket/body lift to the decedent, casket, stretcher or other appropriate freight. All casket/body lifts at minimum should post a sign to read:

LIFT FOR FREIGHT ONLY
NOT FOR PASSENGERS

Physical Protection Installation.
Physical Protection should be installed to create a barrier between the user of casket/body lift and potential harm. All fall protection plans are written to be site specific, the following are a list of recommendations that may help make your worksite safer:

- All lifts should be located behind locked doors. Doors should be locked with a key or combination lock. In situations where it is not physically feasible to locate a lift behind locked doors a guardrail should be installed.
- When the lift is not in use a chain or cable should be stretched across the opening marked with a highly visible material.
- Lighting should be installed that automatically illuminates lift/shaft areas when doors/gates are opened.
- Warning lines should mark the edges of floors and lifts.
- Warning lines should also denote the "drop zone."
- Switches should be installed preventing doors from opening when a lift is operating.
- Controls dedicated to operating the body/casket lift should be covered and locked when not in use.
- Lifts and elevators should be inspected on a scheduled basis.

Restrict Use of Body/Casket Lift.
The two most critical pieces in complying with a properly administered fall protection plan:

- To limit the use of body/casket lifts to individuals with the appropriate experience, skills and training to operate the equipment.
- To restrict access to all lift openings and drop zones.

Fall Protection Training/Enforcement/Investigations.
It is the responsibility for the OCO to implement site specific fall protection training. Training for employees must include:

- How to recognize and minimize fall hazards.
- Identification of areas where fall protection is needed.
  - Ramps, Steps, Stairs, Lifts, etc.
  - Nature of fall hazards specific to your worksite.
  - Procedures put in place for creating fall protection systems to prevent injury.
- Continual training.
- Describe the method for prompt, safe removal of injured workers.

Safety in any workplace is not an accident. Awareness and respect of fall hazards and compliance with safety rules should be considered conditions of employment. The OCO should work in concert with management to issue disciplinary warnings to employees, up to and including termination, for failure to follow the guidelines of the fall protection plan.

The OCO will be responsible for investigation and documentation of a fall accident. Before returning a lift into operation following any type of accident or mishap, the fall protection plan should be reviewed for necessary improvements and the lift examined/repaired by a qualified technician when malfunctioning or damaged.

New Jersey Funeral
Directors Services, Inc.

P.O. Box L, Manasquan NJ 08736-0642
800.734.3712 • Fax 732.974.8144

www.njsfda.org/osha