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Note: *Certain links in this chapter are only available to FDA employees via the FDA Intranet site and cannot be accessed by individuals outside the FDA internal network. Requests for information can be made through the Freedom of Information Act (FOIA) process described in IOM Section 8.1.3.*

10.1 - Purpose

The purpose of this chapter is to give you the basic knowledge and skills to anticipate, recognize, evaluate, and apply control strategies to eliminate or minimize hazardous conditions and unsafe practices encountered during field investigations and inspections.

A *hazard* is defined as any source of, or the potential for, injury, damage, harm, adverse health effects, or death. Hazards include any substance, material, activity, or process that has the potential to cause harm or injury.

Workplace hazards are classified into various categories. Hazard categories addressed in this chapter include traumatic injury, biological/chemical/ergonomic/physical agents, and radiation.

Due to the unlimited variability of potential safety situations, it is not feasible to describe in the Investigations Operations Manual (IOM) what to do in each and every instance. The decision of what to do in each individual circumstance rests with you and your program/division management.

Personal Safety will not be discussed in detail in this chapter. The Personal Safety section below will currently continue to reference IOM Chap 5.3.1.1 until further notice.

10.2 - Unacceptable Risk

Most environments in which OII conducts investigations or inspections contain identifiable risks. This chapter discusses many hazards found in regulated industries and describes approaches to protect OII employees by reducing risks to acceptable levels. However, special consideration must be given when unacceptable risks are present. This section is intended as a framework to help investigators and their supervisors decide whether it is too unsafe to continue an investigation. It is critical to focus on plausible risks to investigators' wellbeing, and not to base these decisions entirely on regulations or definitions.

First and foremost, if you suspect that conditions in your work environment may harm you, take immediate and reasonable steps to avoid those conditions. If the decision may impact completion of your assignment, let your supervisor know right away.

While it is not possible to cover every possible situation in a single guidance document, some situations that should always be considered as unacceptable risks include:

- If you doubt your ability to perform an activity safely, e.g., walking on a layer of ice.
- If you feel there is a reasonable chance of a non-trivial injury or illness, for example, close proximity to unguarded machinery, or exposure to an infectious disease.
- If you suspect that you might be exposed to a hazardous chemical above an established occupational exposure limit such as an OSHA Permissible Exposure Limit (PEL).

"Reasonable" steps will depend on the situation. While it would certainly be reasonable to avoid using an unstable flight of stairs, it probably would not be reasonable to end the investigation and leave the premises because of them. Encountering pervasive hazards throughout a firm, or a single hazard with life-threatening implications (e.g., plausible risk of a serious chemical release or an explosion), would

likely make leaving the premises a reasonable step. If in doubt, move to a safe location and contact your supervisor for guidance.

Take a similar approach to situations or conditions that make it difficult to complete your assignment but might not present a plausible risk of injury. Some investigations may occur in environments that are hard to tolerate due to physical discomfort, irritating materials, or similar conditions. If you follow the advice in this chapter for dealing with factors like temperature extremes or eye irritants, and still have difficulty tolerating the environment, move to a better location and contact your supervisor. OII's Office of Safety is available for consultation. Investigators and their supervisors can reach out to their supporting Industrial Hygienists or the Office of Safety Leadership team.

10.2.1 - C.O.V.E.R. (Control, Observe, Vary, Exit, Report)

A tool that you can use to maintain safety awareness generally, and in instances where a safety or health hazard puts you at unreasonable risk of death or serious injury or illness, is to remember the mnemonic C.O.V.E.R.: Control, Observe, Vary, Exit, and Report.

10.2.1.1 - Control

First, psychologically and physically CONTROL your environment as much as possible.

- Maintain awareness of your surroundings as you perform inspectional activities. Always remain cognizant or conscious, of what is going on around you.
- Exhibit and maintain a professional attitude, driven by the reason that you are there, with a specific mission or task to accomplish.
- Carry yourself in a confident and professional manner--one that commands respect and cooperation.

10.2.1.2 - Observe

Carefully OBSERVE the environment and those within it during inspectional activities.

- Assess the exterior and interior environmental factors to identify potential hazards and/or dangers, and to locate escape routes and exit points.
- Consider behaviors of firm employees, such as threats, aggressiveness, awkward behaviors, and movements, etc.
- Look closely for weapons, anything that someone could potentially use as a weapon, or other physical hazards that may present safety concerns.

10.2.1.3 - Vary

VARY your tactics, techniques, or approaches based on what you know, observe, and experience. Review the firm's establishment inspection file and pay special attention to anything that causes you to be concerned about your safety (including such examples as a questionable geographic location, or noted questionable/suspicious firm behaviors, animals, etc.). Note existing personal safety flags in the firm file. Adjust your approach as warranted.

10.2.1.4 - Exit

Have an EXIT strategy in mind before you enter the establishment. Locate escape routes and exit points ideally before, or as you enter, the establishment.

10.2.1.5 - Report

REPORT the status and progress of your interviews, inspections, and other contacts.

- Tell your supervisor about any problems, threats, and safety concerns immediately.
- Generate a Personal Safety Alert (PSA) when warranted.

10.3 - Personal Safety

Personal safety entails protecting the physical and mental safety, health, and welfare of FDA employees. It also involves active engagement on your part and a general recognition and avoidance of possible harmful situations, or persons, in your surroundings. Basically, personal safety allows you to conduct or support field activities in a safe and effective manner. OII managers should ensure that their employees have the resources and training they need to conduct their work safely, ***and*** that their employees keep abreast of and follow safety procedures.

First and foremost, if during inspectional activities, you determine there is the possibility of a threat to your personal safety or if you are assaulted (either physically, or put in fear by threats of physical/verbal violence), you should:

- Immediately disengage.
- Exit the premises.
- Get to safety.
- Contact the police as necessary.
- Get medical attention if needed.
- Call your supervisor.

OII considers the safety of all staff who meet with regulated industry to be of utmost importance. Personal safety concerns can be further defined as those risk factors and circumstances that you should be aware of which constitute a possible threat or compromise to your safety while conducting an inspection. These include, but are not limited to:

- Situations in which another party initiates an assault (including both physical and verbal assaults) upon you or your colleagues; displays force (including the show or use of weapons, aggressive animals, or other similar tactics); or otherwise communicates resistance towards you or the work you are engaged in.
- Firms with a known or suspected history of potential violence, either agency-documented (via an inspection report, memo, PSA/flag, or other resource) or suspected (via reports from media, other federal agencies, law enforcement, neighbors, etc.).
- Situations of heightened security or vulnerability due to political, social, and economic factors or unrest, etc.
- Work assignments that involve Office of Criminal Investigations (OCI) and/or other federal agencies, as they tend to constitute more complex, potentially multi-jurisdictional activities.
- Firms associated with suspected illegal/criminal activities, tampering incidents, or any other suspicious activities, occurring both on-- and off-site.
- Work assignments that warrant visits to any private or remotely located residences.
- PSA-flagged firms or firms associated with prior personal safety plans.
- Work sites located in questionable or potentially unsafe surroundings (remote areas and/or high crime areas, etc.).
- Situations in which specific personal protective safety equipment is warranted.

- Situations in which a particular inspection may be medically contraindicated for some FDA personnel.

When these and similar conditions are noted prior to inspectional activities, you should discuss the situation with your supervisor. When these conditions are encountered without prior knowledge during inspectional activities, follow IOM sections 10.2 and 10.3 of this chapter to immediately mitigate any hazards and then notify your management as soon as you are able.

If the inspectional activity is deemed a personal safety risk, your supervisor can assist in assembling a team to create a Personal Safety Plan (PSP) prior to performing the assigned work**. The PSP should be cleared and approved prior to the start of any inspectional activities.** See IOM Chapter 5 for Personal Safety Plan information.

If a PSP is established, your supervisor will contact the local police/law enforcement to notify them of the situation and the potential hazards, as well as to brief them on the approval or resolution of the PSP. Your supervisor can also request assistance from the Federal Protective Service (1-877-437-7411) or contact OCI headquarters for additional assistance (301-294-4030). While OCI does not normally provide physical security in such cases, they will assist in threat evaluation based on specific facts provided and available criminal databases. OCI can also make contacts, on your behalf, with local police and federal agencies, based on their previous established liaisons (United States Marshals, Federal Bureau of Investigation (FBI), etc.).

Tips to maximize your personal safety:

- Prepare for your inspectional activities with safety in mind and attempt to anticipate any issues.
- Formulate an exit/backup plan.
- Don’t make yourself vulnerable by being distracted, disorganized, or inattentive/negligent.
- Move with confidence, focus, intention, purpose, and assertiveness.
- Pay attention to your surroundings and the people around you.
- Trust yourself and your instincts and avoid anything, anyone, or any situation that does not feel safe.
- Immediately report suspicious activity to your supervisor.

10.3.1 - Uniform Use

Uniform use, particularly by FDA Imports and PHS, has been a long-standing issue regarding personal safety. There are times when uniforms can potentially contribute to the perception of FDA as a threat and may create more volatile situations, especially during activities with certain commodities (for example, tobacco, produce, raw milk) or types of inspections (for example, license revocations, outbreaks, injunctions).

Uniformed, and therefore identified, regulatory personnel could possibly become targets while performing their duties. If you determine that there might be a personal safety hazard to wear your uniform in certain locations, situations or during specific activities, consult with your management immediately. Be sure to provide facts and details to support your concern(s).

Refer to IOM 5.3.1.1 - Personal Safety for additional personal safety concerns and information.

10.3.2 - Personal Safety Alerts (PSA)

During your review of eNSpect/Field Management Services (FMS), you should determine if any personal safety concerns exist. Prior to the start of your inspection, previously noted concerns will be flagged in

the Firm field within eNSpect/FMS. Online Search and Retrieval System (OSAR) also prompts you to check the firm's files for a PSA Memo, which, if in existence, provides an explanation of why a firm was flagged. PSA Memos are filed on the left-hand side of the establishment file jacket and printed in eye-catching color so to be easily recognized. If the PSA indicates a firm has any documented associations with, or history of, personal safety threats, you should discuss these details with your supervisor and evaluate whether a PSP is warranted, prior to the start of the inspection.

Refer to this chapter and IOM Chapter 5 if you encounter any personal safety issues—including, a threat to your personal safety, a need for specific Personal Protective Equipment (PPE), or circumstances posing medical contraindication risks (for example, staff with penicillin allergy potentially exposed to penicillin). First and foremost, take immediate steps to mitigate any hazards or threats. Once you are safe, including being potentially moved to another location, and after discussion with management, you should check the PSA flag field box associated with the firm in eNSpect/FMS to alert other investigators of the experienced threats to safety.

In eNSpect, the person creating an assignment can add PSA information on the Firm page by checking the flag box and utilizing the additional text box. This field is editable any time after the assignment has been created. This PSA tab will be selected when a firm, or inspection site, is affiliated with a potential hazard, including any of the following:

- A history of physical, verbal, or other types of threats or assaults; or other forms of physical resistance.
- A need for specific PPE, including respirators.
- The presence of medical risks, including those affecting specific investigator populations, such as women of child-bearing years who may be exposed to drugs known to be potentially hazardous to them; or individuals with allergies to peanuts, penicillin, or other products who may incidentally encounter those products or ingredients on site as part of their work.

When a personal safety concern is encountered, a PSA should be documented in the Endorsement text and in a Memo to the File. The Memo should be titled "Memo to File - Personal Safety Alert" and includes factual information to support the alert. Such details will also serve as critical background information for colleagues and future investigators who will also be consulting eNSpect for safety issues. As with other evidence, ensure the memo is factual when documenting PSA details, as it could later be used for legal purposes/proceedings and may result in a court case.

In addition, the Memo should:

- Be filed in the official establishment file jacket, with copies sent to all resident posts and import program divisions who may interact with the relevant firm.
- Be filed on the opposite side of the folder from all other documents and printed on eye-catching colored paper to be noticeably visible to the next investigator.
- Be retained and maintained at the program division office.
- Be sent to OIICSOSafety@fda.hhs.gov.

The supervisor and/or other program division management will be responsible for evaluating the need for any corrective actions to be taken by the firm, or individual, to remove or stop the potentially dangerous situation, circumstance, or condition. Follow-up inspections at the facility should continue to document the status of the ongoing safety situation, including its cessation. If the safety situation ceases

or is resolved (by new management, dismissal of an employee, or removal of penicillin in a facility, etc.), the PSA should then be end dated as per IOM 10.3.1.1.3 from eNSpect/FMS with required explanation.

To view PSA details in eNSpect:

1. Select “New Assignment”, then.
2. Select “Firm”.
3. Enter the applicable FDA Establishment Identifier (FEI) and click “Look Up.” If a PSA exists and is active, it will be indicated to the right of the firm’s name.
4. Select the “Details” button to display PSA details, and
5. select “View/Update” to display the reason, or basis, for the PSA.

Additionally, an internal Online Reporting Analysis Decision Support System (ORADSS) report, FIR055 Personal Safety Alert for a Firm by Home District (located in ORADSS under the Firms report folder), provides comprehensive, sortable information on PSAs (any relevant threats, PPE specifications, etc.) associated with PSA-flagged firms, including information on alert type, reason for the alert, and other remarks. This report should be used prior to field activities to prepare for personal safety situations. The report is searchable by FEI, district, state, country, and/or program area.

Refer to IOM Section 5.2 and 5.3.1.1 for more information about the PSA.

10.3.2.1 - Steps to creating a PSA

Detailed instructions with examples on how to create and edit PSAs can be found in the current eNSpect user manual at eNSpect Help References. When first accessing a firm page, the active PSA will appear as ‘No’ by default when no FEI is present. Once the FEI is added, you will see an option to add or edit the PSA. After operation creation, PSAs are editable.

10.3.3 - Personal Safety Training

10.3.3.1 - MP118 *Interviewing Skills and Personal Safety Reports*

Geared towards new FDA investigators and analysts, this instructor-led course provides participants the ability to successfully plan an on-site regulatory inspection while maintaining personal safety.

10.3.3.2 - MP8001S: ORA Personal Safety and Inspections Refresher 8 Part Training Series

This course chronicles the history of how OII became involved in providing meaningful, interactive training to keep our Investigators and Analysts safer during inspections. This multi video series course describes the difficulties faced by Investigators and analysts during inspections and identifies tools that can be used to gain additional knowledge about firms prior to inspection that could help keep staff safer. How to create a Personal Safety plan is defined during this video series and necessary elements required in the plan are explained in detail. Also provided are basic evasive tactics to use if necessary to escape from a physical altercation. Though open to all FDA, the target audience is OII employees who conduct inspections, those who supervise inspectional employees, Compliance Officers, DDs and HQ staff involved in approval process of Personal Safety Plans or scheduling of OII inspections. This training applies to all commodities and program areas.

10.4 - Employer/Employee Safety Responsibilities

Safety in all OII work environments is foundational to our public health mission. The OSH Act requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section

5(a)(1) of the OSH Act, employers shall provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.

Safety is the responsibility of FDA employees, supervisors, and management. The agency will not allow employees or supervisors to disregard established or otherwise reasonable safety precautions and thereby place themselves, and/or their fellow employees, and/or the agency's facilities, at risk.

The FDA strives to provide a safe, healthy, and injury-free work environment for employees and promote a positive safety culture in which all employees value safety and behave in ways that prioritize their own safety, as well as the safety of their colleagues, and others around them.

You have a responsibility for your own safety and an obligation to observe established health and safety rules and precautions as a measure of protection for yourself and others. You will not engage in willful misconduct that causes or will likely cause the FDA to be in violation of any rule, regulation, order, permit, or license issued by a regulatory authority.

You are required to become familiar with and observe health- and safety-related policies, procedures, and guidelines. If provided with safety equipment, PPE, or any other devices and procedures necessary for your protection, you will use such equipment and procedures as directed. Respirator use should include consultation with your supervisor, in conjunction with the Office of Chief Scientist (OCS)/Office of Science and Regulatory Operations Safety Staff (ROSS).

While performing assigned work, be alert to the presence of potentially unsafe or unhealthy conditions. When such conditions are observed, it is your right and responsibility to report them. Determine if these conditions warrant disclosure to OSHA (See IOM 10.7.3.1). In the case of imminent danger situations, after first ensuring your own safety, alert your management immediately. In such situations, you should C.O.V.E.R. when you have a reasonable belief that, under the circumstances, the task or area poses an imminent danger. (See IOM 10.2.1).

10.4.1 - Safety Incident Reporting

Workplace incident reporting helps keep our workplaces safe for everyone. You must report all work-related incidents, injuries, near misses, and property damage through the portal for Occupational Safety and Health (pOSH+). (A near miss is defined as an event in which no property is damaged, and no personal injury or exposure sustained, but where—given a slight shift in time or position—damage, injury, and/or exposure could have easily occurred. An example: A workplace shelf collapses and narrowly misses striking an employee.) The process of reporting any workplace incidents in the pOSH+ ensures incident investigation, mitigation, and corrective actions are completed with the intent to prevent future occurrences.

OII employees can use the portal to directly submit workplace incident reports to their supervisor and ROSS for further investigation. Incident reporting in pOSH+ can be done through use of a desktop icon or from any FDA mobile device. Incidents of property damage, without employee injury, may only require reporting through pOSH+. Your supervisor will automatically be notified via pOSH+ email. Your supervisor will then visit pOSH+ to review your submission before the incident is investigated by your Center/Office Occupational Safety and Health Officer (OSHO). If you visit an FDA Occupational Health Clinic as a result of an incident, the clinician will submit the report on your behalf to your Center/Office OSHO and you will not need to enter a report via pOSH+.

Additional incident reporting may also be required through the Employees' Compensation Operations and Management Portal (ECOMP). The support Industrial Hygienist (IH) for your program or division is

available to provide support and additional information for incident reporting. Users can report these four types of safety-related incidents/events:

- *Injury, Illness, or Potential Exposure*, which is defined as an occupational event resulting in bodily injury (for example, due to a slip, trip, or fall), illness, or a potential exposure (for example, of chemical, biological, or radiological origin) to an individual.
- *Property Damage*, which is defined as an unplanned, undesired event that resulted in FDA property damage *without* perceived injury or exposure.
- *Near Miss*, which is defined as an event wherein no property was damaged, and no personal injury sustained, but where—given a slight shift in time or position—damage and/or injury could have easily occurred, as defined by OSHA.
- *Event of Concern*, which is defined as a safety concern or non-compliance event.

OLS has developed a SharePoint page for implementation of pOSH+ that includes frequently asked questions, resources, and training videos to assist employees, supervisors, and safety personnel in reporting and investigating workplace incidents. Information submitted through this portal will assist the FDA in the development of recommendations and corrective actions to improve safety.

Reference the following resources for incident reporting:

- Regulatory Operations "Quick Steps" Employee's Guide to Incident Reporting (Exhibit 10-1)
- Regulatory Operations "Quick Steps" Supervisor's Guide to Incident Reporting (Exhibit 10-2)

In addition, be alert to any problems associated with defective or misused equipment, or supplies, and their possible impacts on yourself and others. Contact your supervisor and/or the headquarters contacts listed in the applicable compliance program as necessary for assessment. The home division of the manufacturer should be notified of firm product misuse, so it may be brought to the manufacturer's attention for consideration of precautionary labeling or redesign of the product. Your pOSH+ report should fully document these problems, to include the hazard and/or defect observed, and whether or not user actions could be a contributing factor. Documentation should present sufficient data, such as photos and diagrams, to supplement a narrative describing the situation, as well as the collection of samples if applicable.

10.5 - Following Firm Safety Requirements

You should always follow any applicable and appropriate safety requirements set by firm, unless otherwise instructed by your supervisor or management (for instance, employee concerns or pre-existing safety issues). A firm's safety requirements should also not hinder your ability to perform your duties. If you should experience doubt, confusion, or concerns regarding any safety requirement, seek clarification from the firm if possible. If you still have concerns, contact ROSS.

When conducting activities in facilities requiring the use of PPE, the following guidance should be provided by the firm's management:

- Information about the specific hazards present - including symptoms of exposure that may be encountered.
- Information regarding the potential levels and/or concentrations of stated hazards present.

The firm's management should be able to provide you with documentation showing how hazards were determined, what the expected exposures are, and how they relate to the OSHA Permissible Exposure Limit (PEL). Such documentation should also offer information about the PPE that will protect you

against a hazardous exposure. If you have any doubts about the hazards or doubts about the effectiveness of the equipment recommended or provided to protect against them, **do not** enter these areas. The Safety Liaison for your program or division, or the OCS ROSS, will be able to help you evaluate the information provided to you and will furnish information regarding the hazard, as well as the recommended PPE.

If you do not have the specific PPE recommended by the firm's management, request the needed equipment from your division. In some cases, the firm may be willing to provide the necessary PPE; however, if respiratory protection is required, you should comply with ORA's Respiratory Protection Program. You should *only* use respirators provided by FDA, unless your Division's IH, or the National Safety Office, has approved the use of other devices. *It is ultimately your responsibility to ensure that you do not expose yourself to any hazard.*

10.6 – Safety Risk Assessment Frameworks

Regulatory Operations Safety Staff (ROSS) uses a risk-based approach to assessing, classifying, and mitigating occupational hazards, relying on risk assessments to help determine if procedures and/or protective measures are adequate.

Using, ROSS can apply a basic procedure for risk-based criteria and make a risk assessment.

Contact ROSS for any hazard questions, concerns, or classifications guidance. Note that when consulting with OII's Safety Office for assistance with occupational hazards encountered, you may be asked to supply information that will be used to perform a risk assessment so that you can receive the most appropriate guidance on how to proceed.

10.7 - Additional Safety Information

10.7.1 - FDA Safety Programs

10.7.1.1 – Regulatory Operations Safety Staff (ROSS)

The ROSS develops safety policy, training, and information for all OII employees. Industrial hygienists work with OII programs at all levels to develop the best possible safety guidance. Site topics include dangerous goods, hazard assessments, hazard communication resources, hazardous waste management, radiation/laser safety, respiratory protection resources, safety training, safety labels, and workplace incident reporting.

10.7.1.1.1 - Industrial Hygiene (IH) Contact List

The Ross has a staff of IHs stationed at most of OII's laboratories. The IHs serve as points of contact and subject matter experts for safety issues throughout OII. Each IH covers one or more districts and provides safety support to all OII staff located within their assigned districts' geographic boundaries. Many IHs also provide focused support to one or more OII programs.

10.7.1.1.2 - Regulatory Operations Safety Staff FAQs

Frequently asked questions addressed by the Regulatory Operations Safety Staff, cover topics including, general safety, employee protection, radiation safety, opioid sampling and analysis, laboratory environmental management, shipping of dangerous goods, and shipping of hand sanitizer.

10.7.1.1.3 - ORS Safety Hazard Assessments Grab & Go's

Grab and Go documents are Hazard Assessment documents, organized by program, that provide essential safety information for OII field investigators and lab analysts. They provide one-page overviews of safety requirements for specific tasks. Investigators and analysts should review the documents relevant to their tasks to ensure awareness of safety requirements.

Each document includes:

- An overview of hazards.
- Required personal protective equipment.
- Respirator guidance.
- Training requirements.
- Other relevant topics, e.g., radiation safety or medical surveillance requirements.

10.7.1.1.4 - Office of Security and Emergency Management (OSEM)

OSEM protects FDA's personnel, facilities, and information from threats and ensures that FDA is prepared to manage emergencies and incidents, including those involving FDA-regulated products.

10.7.1.2 - Occupational Safety and Health (OSH) Program

The OSH Program strives to improve occupational safety and health through training, communication, and the implementation of initiatives that will achieve measurable results. This site offers the following resources, including, but not limited to:

- Hazard exposure self-assessment tools.
- Safety training.
- Safety and health information.
- Safety manuals.
- Preparedness resources.

10.7.2 - Emergency Response/Incident Command

You may be assigned to perform activities in which an Incident Command Structure (ICS) has been implemented. These situations may involve hazards posing a threat to human health and/or the environment. Examples of incidents that would be expected to have an active ICS structure include disease/illness outbreaks, special or national security events, chemical spills/hazardous waste sites, and natural disaster situations.

The Incident Management Team (IMT) will be responsible for tactical operations, to include performing investigations/inspections, collecting samples, and/or detaining or destroying contaminated product, and executing any other safety related functions in accordance with the Incident Action Plan (IAP) and safety plans, if appropriate.

If you are involved in a situation operating under an ICS, IMT or Incident Management Group (IMG), your reporting structure exists through that command staff; you shall follow the ICS management guidance or guidance provided by the ICS/IMT/IMG.

There is always the potential that unprotected personnel will not be permitted into hazardous zones for safety reasons. If the event has sufficient safety concerns to warrant a safety officer, safety consultations will be made in conjunction with that individual, through the ICS/IMT/IMG structure. If no safety officer is assigned, safety consultations will be conducted with your IH contacts, in conjunction with the ICS/IMT/IMG structure.

Also reference IOM 8.1.5.8 for information on FDA investigations in the aftermath of disasters.

10.7.2.1 - Office of Emergency Response (OER)

The Office of Emergency Response (OER) serves as the FDA focal point for coordinating emergency response activities involving FDA-regulated products. The office coordinates intra-agency and inter-agency activities related to crisis management and emergency preparedness and response, including the planning, conduct, and evaluation of emergency scenario tabletop/simulation exercises. OER develops, manages, and coordinates incident management plans, policies, and programs for the FDA to ensure that an agency structure exists to respond rapidly and effectively to all hazards. OER provides strategic direction and oversight of the FDA's adoption of the National Incident Management System (NIMS), including all aspects of the development of plans, procedures, and training programs in support of the ICS.

10.7.2.2 – Division of Emergency Response (DER)

The Division of Emergency Response (DER) serves as the FDA's central emergency coordination point with FDA headquarters, centers, and field offices. The DER leads the following activities:

- Provides interagency coordination and response to adverse events, foodborne illnesses, injuries, product tampering, and man-made and natural disasters.
- Assists in the development of emergency operations plans and incident-specific annexes, and the design, implementation, and presentation of associated training and exercise programs.
- Represents the agency at federal, state, local, and foreign government meetings and workgroups on emergency preparedness and response.
- Provides a nationwide, 24-hour, seven-days-a-week emergency response system.

10.7.2.3 - Additional Emergency-related Sites

- Coordinated Outbreak Response, Evaluation & Emergency Preparedness (CORE+EP)
  Through CORE+EP, the FDA combines expertise in medicine, public health, and science to coordinate its efforts to find, stop, and prevent foodborne illness outbreaks.
- Emergency Response Coordinators
  OII's ERCs are located in Office of Field Operations and Response, Office of Emergency Response, Division of Emergency Response. The ERCs are dedicated to all-hazards emergency response coordination, exercises, training, and collaborations with federal, state, and local partners. ERCs are active in emergency response activities, engaged in all facets of emergency preparedness and response, and provide enhanced response capabilities for FDA/OII. ERCs train and support the implementation of the Incident Command System filling vital command positions at HQ and in the field. ERCs provide support to State Rapid Response Teams (RRTs), as well as CORE.
- Continuity of Operations Plan (COOP)
  Continuity of Operations (COOP) is the initiative that ensures federal government departments and agencies can continue operations of their essential functions under a broad range of circumstances, including all-hazard emergencies, as well as natural, man-made, and technological threats, and national security emergencies.
- FEMA Preparedness (Ready.gov)

Ready is a national public service campaign designed to educate and empower the American people to prepare for, respond to, and mitigate emergencies, including natural and man-made disasters. The goal of the campaign is to promote preparedness through public involvement.

- OSPOP's Emergency Preparedness Collaboration Site
  The purpose of the OSPOP Emergency Preparedness Collaboration site is to provide a platform where the FDA can share information about emergency preparedness and associated topics.

10.7.3 - Occupational Safety and Health Administration (OSHA)

With the Occupational Safety and Health Act of 1970, Congress created the Occupational Safety and Health Administration (OSHA) to ensure safe and healthful working conditions for workers by setting and enforcing standards, and by providing training, outreach, education, and assistance.

10.7.3.1 - OSHA Memorandum of Understanding (MOU)

FDA maintains a domestic MOU with OSHA (MOU 225-24-004) to facilitate information sharing between both agencies with respect to matters affecting the occupational safety and health of workers, and the safety and security of our nation's medical products, cosmetics and food supply in facilities where FDA regulated products are produced, processed, or held. This MOU formalized a referral agreement where if either agency uncovers serious regulatory violations outside its jurisdiction, they refer the relevant information to the other agency so it can follow up under its own enforcement authority.

FDA investigators who become aware (through direct observation or received information) of serious safety or health conditions at a firm that suggest a violation of safety and health requirements enforced by OSHA are encouraged to submit a brief description of the violation observation along with basic employee and establishment information through an FDA Interagency Referral Report (IRR). Examples of serious safety observations include employees reaching into moving machinery (e.g., rotating shafts, conveyor belts, slicers, mixers, blenders, pinch points on rollers), working on live electrical or standing under heavy loads, among other.

Additionally, FDA investigators who become aware of retaliation or are investigating whistleblower complaints under the Food Safety Modernization Act (FSMA) should inform the affected individual that they have the right to file a whistleblower complaint with OSHA within 180 days of the alleged retaliation. While the individual should personally contact OSHA, the FDA investigator can provide the contact information for the Directorate of Whistleblower Protection Programs: (202) 693-2199, OSHA.DWPP@dol.gov.

The FDA investigator should discuss such cases with their supervisormailto:FieldInvestigationsSafety@fda.hhs.gov.

10.7.3.2 - OSHA Severe Violator Enforcement Program (SVEP)

Additionally, while the vast majority of employers want to protect their employees, there are others who continue to expose workers to very serious dangers even after receiving citations for hazards causing serious injuries, illnesses, and deaths. On June 18, 2010, OSHA instituted the SVEP to more effectively focus enforcement efforts on recalcitrant employers who demonstrate indifference to the health and safety of their employees through willful, repeated, or failure-to-abate violations of

the OSH Act. You have the option, prior to going on an inspection, to review the OSHA-maintained and publicly available SVEP Log detailing the names, locations, and citations of employers in the program. The link to the document can also be found on the OSHA Enforcement page in the Policy and Guidance section. OSHA updates the log at the beginning of every quarter.

10.7.4 - Other Safety Agencies

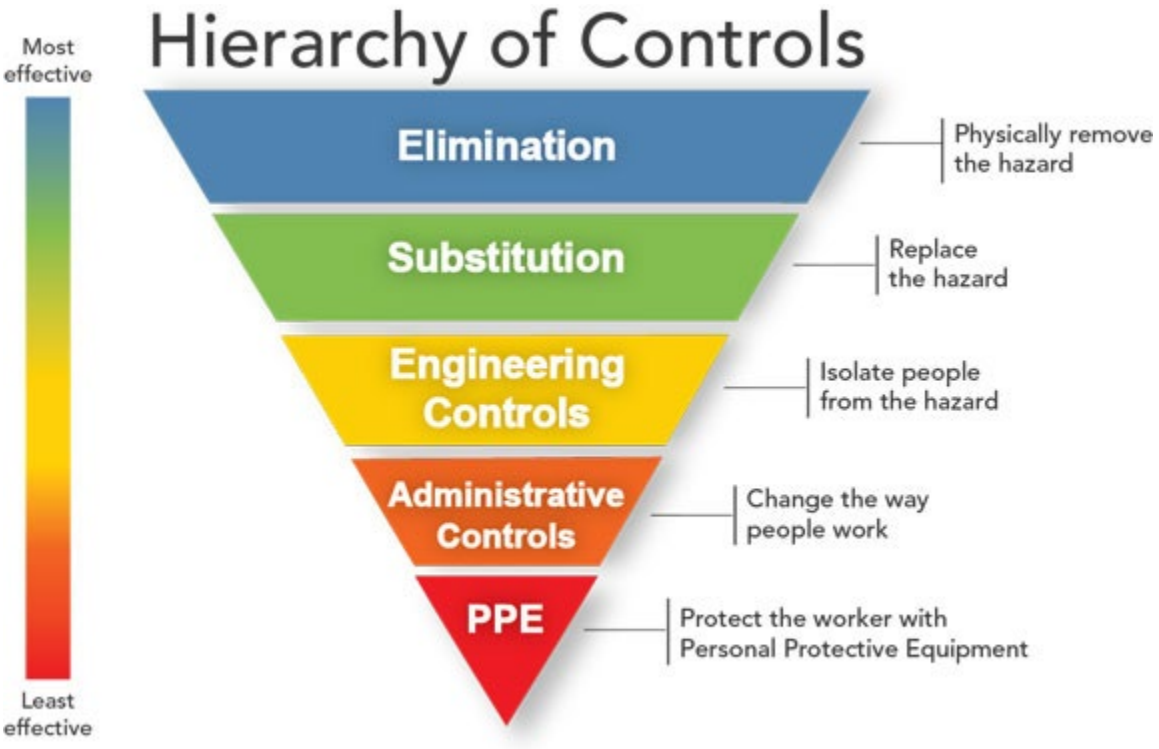
After first checking with FDA's Safety program, you can consult the following federal agencies for additional sources of workplace safety information:

- U.S. Environmental Protection Agency (EPA)
- Occupational Safety and Health Administration (OSHA)
  - All OSHA Publications
  - OSHA Fact Sheets
- The National Institute for Occupational Safety and Health (NIOSH)
  NIOSH is part of the U.S. Centers for Disease Control and Prevention, in the U.S. Department of Health and Human Services. NIOSH is a research agency focused on the study of worker safety and health and developing new knowledge in the field of occupational safety and health.
  - NIOSH Fact Sheets and Publications
  - NIOSH Emergency Response Safety and Health Database
  - NIOSH Workplace Safety and Health Topics
  - NIOSH Pocket Guide to Chemical Hazards
  - NIOSH Pocket Guide to Chemical Hazards Mobile Application

10.8 - Hierarchy of Controls

Although most investigations are conducted at sites FDA does not control, you are still able to take positive steps to mitigate hazards to which you might be exposed. The following information is provided to help you recognize effective mitigation options, and to approach occupational hazards using the same frameworks as the ROSS's Industrial Hygienists (IHs).

The Hierarchy of Controls model ranks hazard control strategies from most to least effective in preventing injuries and illnesses. Although you typically will not be able to implement higher level controls such as eliminating hazardous machinery or reformulating products to remove hazardous chemicals, the overall philosophy can be helpful for comparing your feasible options. For example, requesting that the firm restrain an aggressive farm dog behind a barrier (an engineering control) will be more effective than trying to remain aware of the dog's activities, and observing a hazardous chemical process from a safe location (another engineering control) will be more effective than wearing PPE while standing close to the process.



The idea behind this hierarchy is that the control methods at the top of graphic are consistently more effective and protective than those at the bottom. Control methods are as follows:

- Elimination and Substitution are usually limited to the design phase of a facility or process. Although you won't be able to apply these to a firm's facility, they are relevant to hazards of supplies and equipment you use during investigations. For example, a box cutter may be substituted for a pocketknife when opening packaged materials.
- Engineering controls either create a physical barrier between you and the hazard, or they physically remove a hazard before it can affect you. Classic examples are guards over pinch points on machinery, or exhaust ventilation to remove hazardous gases and vapors before they mix with the room air. Although you won't be able to implement these at an investigation site in most cases, it's important to recognize any existing engineering controls that are in use and not to interfere with their operation.
- Administrative controls are an approach to limiting chemical exposure by reducing the length of time you are exposed, rather than reducing the amount of the chemical you are exposed to. Administrative controls rely on mathematical calculations of the total exposure and should not be relied on without concurrence from the ROSS.
- Work Practice controls (not shown in the graphic above) are changes you make to the way you work, such as maintaining awareness of nearby hazards or attempting to use safe lifting practices. These are the least effective means of mitigating hazards, as the hazardous conditions are still present, and you are depending on your own vigilance for protection.
- PPE is an essential part of the overall investigation safety practices, but it should be viewed as a last line of defense in case higher-level controls are not completely effective.

10.8.1 – General Protective and Preventive Measures

Generally, the level of protection utilized during the inspection should be appropriate to the level of risk of exposure, and based on factors, such as, type of hazard present, potential exposure, the processes in which the hazards are being manipulated, and the potential outcome (injury) from exposure to the hazard. If exposure to hazards is a concern, or you feel at risk, exit to a safe area. Then contact your supervisor, or Regulatory Operations Safety Staff personnel, for additional guidance before proceeding any further.

General protective and preventive measures and guidance includes:

1. Determine if the firm has established safety precautions and procedures and follow them if adequate.
2. If there are signs of tampering or counterfeiting with the product being examined or inspected, consult your IH contact and your supervisor for any additional safety precautions needed. Based on the situation, protection could consist of work gloves worn over surgical gloves, full face respirator with appropriate cartridges, disposable coveralls, and work boots. If the situation changes, evolves, or escalates, exit and report to your supervisor.
3. As much as possible, do not touch. This means equipment, materials, reagents, animals, etc.
4. Wear protective clothing. Evaluate the needs for gowns, caps, masks, gloves, and shoe coverings, etc. and wear them where necessary. Protective clothing worn in a work area where a virus or spore-bearing microorganism is handled should not be worn into a work area for another product. As much as possible and with firm consent, leave all *used* protective clothing at the firm for proper disposal. Otherwise, consult with your IH and be prepared to transport the used PPE yourself.
5. Wash hands thoroughly after leaving each work area.
6. If the firm is processing viruses or other potentially infectious biological agents during the inspection, determine if it is advisable to enter the work areas. Chances of infection through aerosols are reduced when there is no active processing.
7. Vaccines are available for your protection against some organisms (e.g., *Rubella*). For information on inoculations and physical examinations, refer to FDA Occupational Health Services (OHS).

10.9 - PPE

PPE is protective clothing and equipment designed to reduce exposure to hazards and/or harm caused by hazards, prior to an exposure. You should identify and evaluate all hazards prior to selecting PPE. Ensure you have the proper training to use the needed PPE, and that the PPE is rated to protect you against the identified hazards.

Ideally, the primary means of protection from workplace hazards include avoiding hazards, remaining behind a barrier, or relying on engineering systems (such as exhaust ventilation) to physically separate from the hazard. However, due to the nature of ORA's investigative activities and the industries we regulate, there may be situations in which physical separation from hazards is not possible. In those situations, PPE is used as a barrier between you and the hazard. Numerous types of PPE are available, depending on work conditions and the part of the body that might be susceptible to a hazard. It is advisable to remember that a hazard is still present when relying on PPE for protection; the PPE provides a margin of safety from it.

Prior to any potentially hazardous situation, consult with your Industrial Hygienist (IH) Contact(s) if you are unsure as to the necessity for and/or adequacy of PPE. If you encounter situations in which you are not sure about the effectiveness of PPE, contact your supervisor and consult with your IH for guidance. If in any doubt about your safety, leave the area until all your concerns have been resolved. Also see Personal Protective Equipment - Overview OSHA and Personal Protective Equipment – OSHA.

Another aspect of safety/PPE is what clothing you wear during an inspection. Safety considerations, weather, type of work, hazards of the work, and many other factors will have an impact on what type of clothing is optimal for each situation you encounter. In addition to specific, situation-appropriate PPE, general clothing considerations/guidance are as follows:

- Be aware of drawstrings (for example, on hooded sweatshirts), ties, scarves, and other hanging, potentially entangling components of clothing and shoes (for example, shoelaces), as they can get caught up in rotating parts and on objects/equipment.
- Be aware of jewelry. Loose, protruding, or dangling jewelry poses safety risks when working around moving parts and machinery. As a note, OSHA prohibits conductive jewelry around live current since it can lead to an arc flash or blast, severe burns, the ignition of clothing, or electrocution. Metal jewelry also poses risks when in proximity to chemicals and has the potential to cause reactions. As jewelry can also harbor bacteria that cause food-borne illness, it is generally not recommended in food-handling facilities.
- Tie back long hair and use hairnets/hats to prevent entanglement. OSHA states that hair shall be “securely fastened” into a knot or bun without protruding pieces.
- Do not carry notebooks, credentials, pens, etc., in the outer pockets of your inspectional uniform because they could fall into equipment.
- Glasses, keys, and ID badges dangling from cords or chains can be hazardous; instead, use breakaway safety cords or lanyards.
- Wear clothing that fully covers the body, including arms and legs.
- Wear shoes that cover the entire foot, provide a stable platform, and have rubber or similar slip-resistant soles. Also, wear socks that cover the ankle.

10.9.1 - Eye and Face

Eye and face protection consists of safety glasses, face shields, and other specialized protective equipment. Safety glasses should be worn in environments where projective hazards exist, such as near grinding machinery. Face shields should be worn in environments where splash hazards to the eyes or face exist, such as near corrosive chemical dipping tanks. Specialized eye and face protection may be needed when working near processes involving electrical arcs and other sources of radiation. Consult with your supervisor and/or your IH Contact(s) if you encounter these situations. When selecting and purchasing general eye and face protection, ensure they meet American National Standards Institute ANSI/ISEA Z87.1-2020: Current Standard for Safety Glasses for impact resistance. For specialized eye and face protection needs and questions, consult with your IH Contact(s).

10.9.2 - Head

Head protection consists of hardhats and other specialized headwear. Hardhats should be worn in areas with overhead hazards, and specialized hardhats should be worn in areas where overhead hazards may present an electrical hazard. Specialized headwear may be needed when working in extreme temperatures (hot or cold) or in situations where side impacts to the head are likely. Consult with your

supervisor and/or IH Contact(s) if you encounter these situations. When selecting and purchasing hardhats, ensure they meet ANSI Z89.1 - Industrial Head Protection, Standard for Industrial Head Protection. ANSI Z89.1 - Industrial Head Protection, Standard for Industrial Head Protection. For specialized head protection needs and questions, consult with your IH Contact(s).

10.9.3 - Foot

Foot protection consists of crush-resistant boots/shoes, chemical-resistant boots/shoes, and other specialized foot coverings. Crush-resistant boots/shoes should be worn in environments where crushing hazards may impact the feet, such as in warehouses. Chemical-resistant boots/shoes should be worn in environments where hazardous chemicals may encounter the feet or lower legs. Specialized foot coverings maybe needed when working in extreme temperatures, in deep mud or snow. Consult with your supervisor and/or your local IH Contact(s) if you encounter these situations. When selecting and purchasing crush-resistant boots/shoes, ensure they meet ASTM International standard 2413-18. When selecting and purchasing chemical-resistant boots/shoes, ensure that they are compatible for use in protecting against the specific chemicals of concern in the environment. For specialized foot protection needs and questions, consult with your local IH Contact(s).

10.9.4 - General Body

Body protection consists of protective clothing and suits. Protective clothing and suits should fit properly and provide protection against the hazard. An example of protective clothing is the use of cold weather clothing while working inside a freezer. Consult with your local IH liaison when selecting and purchasing protective clothing and suits needed to protect against hazards, which include but are not limited to, chemicals, fire, electricity, and other specific hazards. The protective clothing should fit you and be appropriate for the environmental conditions in which you are working. Note that protective clothing can be hazardous to the wearer if improperly fitted and/or not appropriate to the working or environmental conditions.

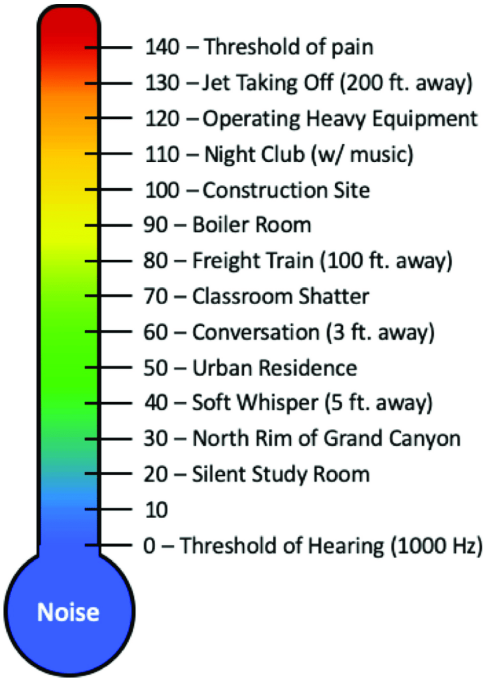
10.9.5 - Hands

Hand protection consists mainly of gloves. Gloves should fit properly and provide protection against the hazard. An example is the use of chemically compatible gloves when handling chemicals. When selecting and purchasing gloves, ensure they meet ANSI/ISEA 105-2016 standards for protection against cuts, punctures, abrasion, chemicals, heat, and/or vibration as applicable. Use appropriate gloves to avoid slivers and/or splinters when handling rough wooden cases or similar items. Use protective gloves when handling hot or cold items. Examples in which hand protection` would be warranted include working around steam pipes, or when handling frozen products or working in freezers. Use the appropriate, protective gloves when handling lead ingots containing radioactive materials to avoid hand contamination. If you are handling solvents, wear gloves that are impermeable to the solvent. Consult with your supervisor and/or your IH Contact(s) if you encounter situations in which you are unsure about which gloves to select for the task, or are unsure if the gloves made available to you provide adequate protection.

10.9.6 - Hearing

Hearing protection devices consist of ear plugs and/or earmuffs. Hearing protection should be used when ambient noise exceeds 85 decibels (dB), or when impulse noise (for example, a hammer strike) exceeds 140 dB. Noise levels are typically above 85 dB when face-to-face communication becomes

difficult without shouting, and above 140 dB, when it is approximately as loud as a gunshot or explosive firework.



Noise Exposure Limits

	NIOSH	OSHA
Exposure Time	*dB SPL*	*dB SPL*
8 hrs	85	85
4 hrs	88	90
2 hrs	91	95
1 hr	94	100
30 min	97	105
15 min	100	110
7.5 min	103	115
3.75 min	106	120
> 2 min	109	-
> 1 min	111	-

NIOSH The National Institute for Occupational Safety and Health
OSHA Occupational Safety and Health Administration
dB SPL Decibel sound pressure level

When selecting and purchasing hearing protection devices, ensure they are EPA-rated and will reduce noise exposure to below 85 dB.

The NIOSH Sound Level Meter App is one tool available to the public to download on mobile iOS devices that measures sound levels and provides noise exposure parameters to help reduce occupational, noise-induced hearing loss.

Consult with your IH Contact(s) if you are unsure if hearing protection provided to you is adequate.

10.9.7 - Respiratory

Refer to the OII Respiratory Protection Program (RPP) (SOP-000449).

The purpose of the RPP is to establish uniform responsibilities and procedures in accordance with OSHA Respiratory Protection Standard (29 CFR 1910.134) and FDA's Respirator Protection Plan for the appropriate selection, use, and care of respiratory protection equipment issued to OII employees.

OII employees frequently perform work at worksites that are not under the control of FDA and may be exposed to physical, chemical, biological, and radiological inhalation hazards. When elimination, substitution or engineering controls are not feasible for protection against inhalation hazards, OII employees will use administrative controls to limit the duration of exposure. Respirators will be used in conjunction with administrative controls to minimize exposure.

The OII RPP addresses topics such as contacts, training, hazard assessment, respirator selection and respirator procurement.

Note that, per OSHA, respiratory hazards can exist in various forms: They may be gases, vapors, dusts, mists, fumes, smoke, sprays, and fog. Some of these substances can cause illness and/or death if inhaled. Certain respiratory hazards act quickly, like carbon monoxide - an invisible, odorless gas - which can make you unconscious or kill you within minutes. Other respiratory hazards can take years to make

you sick, like asbestos, which can cause lung cancer years, or even decades, after you've breathed it in. More examples of respiratory hazards include, but are not limited to:

- Dusts, such as those found when adding dry ingredients to a mixture.
- Metal fumes, from welding, cutting, and smelting of metals.
- Solvent vapors, from spray coatings, adhesives, paints, strippers, and cleaning solvents.
- Infectious agents, such as tuberculosis bacteria in healthcare settings.
- Chemical hazards, such as chlorine gas and anhydrous ammonia in chemical processing and use operations.
- Sensitizing vapors or dusts, such as isocyanates, certain epoxies, and beryllium.
- Oxygen deficiency, which might be found in confined spaces.
- Pharmaceuticals during the production of prescription drugs.

The following sources, sites, and situations have been identified as having the potential for respiratory hazards:

- Feed, drug, and tobacco plants.
- Fumigation or storage facilities where treated grain or produce is encountered--including trucks, vessels, railroad cars, and fumigation chambers.
- Facilities using ozone (or where ozone is produced as a byproduct of the manufacturing operation), methyl bromide, phosphine, or sulfuryl fluoride.
- Facilities where sterilizers utilize ethylene oxide gas (EO).
- Grain elevators or other grain storage facilities, which may present asphyxiation hazards, toxic decomposition gases, or pathological toxins such as aflatoxin.
- Spice grinders and repackers that potentially produce airborne respiratory irritants such as pepper.
- Any rodent-infested areas.
- Poultry houses, which generate exposure to particulates, chemicals, and possible infectious agents.
- Ammonia, which is still used in some facilities as a refrigerant and should be considered a potential hazard.

Respiratory Protection Resources can be found on the ROSS SharePoint site. OSHA's Respiratory Protection - Overview also provides general guidance and resources.

10.9.8 – Marine/Water/Flotation

Employees working over or near water, where the danger of drowning exists, should consider U.S. Coast Guard-approved life jackets or buoyant work vests. Personal flotation devices (PFDs) mitigate harm when there is a chance of falling into water such as working near unguarded edges, boarding, or leaving small boats, or working from scaffolds or staging. Lifesaving equipment such as life ring buoys with ropes and ladders should be available when working from floats, barges, or vessels.

When working in and around water on an open boat where water temperatures are below 70°F, reference Safety Guidelines: Falls Overboard. Also consult your IH Liaison.

10.9.9 - Common PPE

Common PPE to consider having on hand or to carry with you during inspections--not including specific inspection types warranting specialized PPE, such as egg, drug, Low Acid Canned Food (LACF), and others--include:

- Hard Hat
- Safety Shoes
- Hearing Protection
- Gloves
- Eye Protection
- Protective clothing, including coveralls, lab coats, reflective coats, freezer coats, rubber, or vinyl aprons, and disposable paper-like coveralls

Always plan in advance for any PPE that may be required for a particular location or situation.

You may have an option to utilize PPE provided by a firm. Firms may request that you use PPE they provide in conjunction with their safety programs and practices. If possible, attempt to determine if the provided PPE is adequate, or at least comparable to your FDA-supplied PPE and is compliant with recognized standards. Evaluate the provided PPE for cleanliness and sanitary status (particularly eye and head protection). If you feel that the firm's PPE is inadequate, do not enter and contact your supervisor or IH for next steps.

Additional non-PPE items that can be utilized in conjunction with your common PPE, include, but are not limited to, hair/beard nets, hand sanitizers, shoe covers, and face masks. Some of these items may be required by the inspected firm.

10.9.10 - PPE on/off sequence

Below is a generalized sequence for putting on and taking off PPE. The type of PPE used will vary based on the level of precautions required, such as standard and contact, droplet, or airborne infection isolation precautions. Note that the procedure for putting on and removing PPE should be tailored to the specific type of PPE and situation encountered. Follow the firm's procedures when required. If there are questions or concerns about a firm's procedure, consult with your supervisor or IH Contact(s).

Donning PPE (Putting on) as applicable	Doffing PPE (Taking off)
1. Perform hand hygiene. 2. Put on shoes/shoe covers. 3. Put on lab coat. 4. Put on mask/respirator. 5. Put on eye protection. 6. Put on gloves.	1. Remove shoe covers/shoes. 2. Remove lab coat. 3. Remove gloves. 4. Perform hand hygiene. 5. Remove eye protection. 6. Remove mask/respirator. 7. Perform hand hygiene.

The CDC Sequence for Donning and Removing Personal Protective Equipment provides options for safely donning (putting on) and doffing (removing) PPE.

Doffing techniques are particularly critical to mitigate self-contamination. There are a variety of ways to safely remove PPE without contaminating your clothing, skin, or mucous membranes with potentially infectious materials. For example, in instances when using a respirator: Remove all PPE before exiting,

except the respirator. Remove the respirator after leaving and closing the door. See CDC sequence document for this and other doffing options.

10.9.11 - Maintenance and Care of PPE

- Note any expiration dates and/or manufacturer's maintenance schedules (including recommended replacement periods and shelf lives) as applicable.
- Always inspect PPE for damage prior to donning (putting on) and after doffing (removing).
- Clean and disinfect, if applicable, PPE before storing it.
- Dispose of and replace damaged PPE as necessary and whenever signs of integrity damage are apparent.
- Properly store PPE and avoid conditions that could potentially damage it, such as excessive heat, light, moisture, and humidity.
- Do not store or use PPE in close proximity to chemical or biological hazards.
- Plan to replace PPE on regular intervals even if no apparent signs of degradation are present.

10.9.12 - Purchasing Protective Equipment

OII will provide required PPE for its employees. Employees can request safety shoes and/or prescription safety glasses by submitting completed request forms to their Supervisory Administrator Management Specialists (SAMs). ANSI-certified prescription glasses can be purchased from a vendor of your choice and convenience. OII will pay pre-defined allotments for regular lenses/bifocal lenses for prescription safety glasses and for safety shoes. The cost of eye exams is not reimbursable. Employees are responsible for costs exceeding allowed allotments. Please refer to SOP-000123, Prescription Safety Eyewear and Safety Footwear, for further information and to access request forms A and B for safety glasses or shoes.

10.10 – Regulatory Operations Safety Staff (ROSS)

The Office of Chief Scientist, Regulatory Operations Safety Staff, develops safety policy, training, and information for all OII employees. ROSS industrial hygienists work with OII programs at all levels to develop the best possible safety guidance.

10.10.1- ROSS Contacts

- Email: Regulatory Operations Safety
- IH Contact List

10.11 - Resources

10.11.1 - Respiratory Protection Resources

10.11.2 - QMiS

QMiS is the repository for OII's internal procedural documents and quality reports, including documents on safety, standard operating procedures, work instructions, templates, checklists, transmittal notifications, and reports--all organized by component and document type. Safety related QMiS content includes, but is not limited to:

SOP-000449	Regulatory Operations Respiratory Protection Program
SOP-000923	Screening Packages for Radioactive Contamination

SOP-000927	Radiation Dosimetry Program
TRNMAT-000013	WEAC Personal Protective Equipment (PPE) 2020
WEAC-TMPL.222	Certification of Hazard Assessment Form for PPE Use
SOP-000178	ORA Shipping
SOP-001074	Ross Radiation Safety Manual

10.12 - Special Safety Situations

10.12.1 - Fire/Explosion Hazards

Fire and explosion hazards may be a significant concern at many firms. The conditions leading to these hazards will usually exist beyond your control. Your safety will depend on your situational awareness and prompt action in the event that an emergency arises.

Most firms will be required by state or local authorities to maintain fire detection, alarm, and suppression systems. These will usually be similar to the systems you are familiar with from your FDA duty station, including alarm pull stations, smoke detectors, and sprinklers. If a firm has properly installed and maintained systems, the likelihood of a fire developing before you can evacuate is low. Asking the firm's management or an escorting employee what to do in the event of an alarm should be sufficient precaution in most cases.

Firms with very large quantities of flammable chemicals may be required by OSHA to operate under a Process Safety Management (PSM) plan. A PSM plan will contain detailed precautions for detecting chemical releases and notifying occupants of the need to evacuate. If you suspect the firm may need to operate under a PSM plan, discuss the alarms and immediate actions you should take with the firm's management.

If you have doubts about the adequacy of fire detection, alarms, and suppression systems, or if you are concerned that the firm does not have adequate plans for a quick evacuation, be alert for signs of increased fire risk. An exhaustive list of fire hazards in different industries is beyond the scope of the IOM, but some general principles apply universally.

Housekeeping practices can be a good indicator of fire risk. Accumulated dust and debris can potentially be ignited or contribute fuel to a fire, and disorderly or haphazard storage of materials and equipment can obstruct egress routes. Accumulations of grease on surfaces near cooking appliances can increase the risk of fire. Haphazardly stored materials are usually easier to ignite than the same materials stored in neat, managed stacks.

Electrical systems are a common ignition source for industrial fires. While it is not possible to assess a facility's electrical systems at a glance, if you notice any evidence of damaged or improvised wiring, exposed components or conductors, or heat-damaged building materials, you should consider the area to be a fire hazard.

Firms, depending on their types of operations, can be potential sources of explosion hazards. The National Electrical Code (NEC) defines hazardous locations as those areas "where fire or explosion hazards may exist due to flammable gases or vapors, flammable liquids, combustible dust, or ignitable fibers or “flyings".

FLAMMABLE LIQUIDS, GASES OR VAPORS	Acetylene, hydrogen, butadiene, ethylene oxide, propylene oxide, acrolein, ethylene, cyclopropane, ethyl ether, acetone, ammonia, benzene, butane, ethanol, gasoline, hexane, methane, methanol, methane, naphtha, natural gas, propane, and toluene
COMBUSTIBLE DUSTS	Combustible metal dusts: aluminum, commercial alloys, and magnesium Combustible carbonaceous dusts: carbon black, charcoal, coal, and coke dusts Other combustible dusts: Chemicals, flour, grain, plastic, and wood

MORE EXAMPLES OF POTENTIAL COMBUSTIBLE DUST MATERIALS (OSHA)		
AGRICULTURAL	**CARBONACEOUS**	**METALS**
Cellulose	Charcoal	Aluminum
Corn	Coal	Iron
Egg white	Lampblack	Magnesium
Fertilizer	Lignite	Titanium
Flour	Soot	Zirconium
Powdered milk	**OTHERS**	Zinc
Soy flour	Biosolids	**PLASTIC**
Spices	Dyes	Epoxy resin
Starch	Pharmaceuticals	Melamine
Sugar	Rubber	Phenolic resin
Tobacco	Soap	Polyethylene
Wood flour	Sulfur	Polypropylene

OSHA resources on combustible dust include:

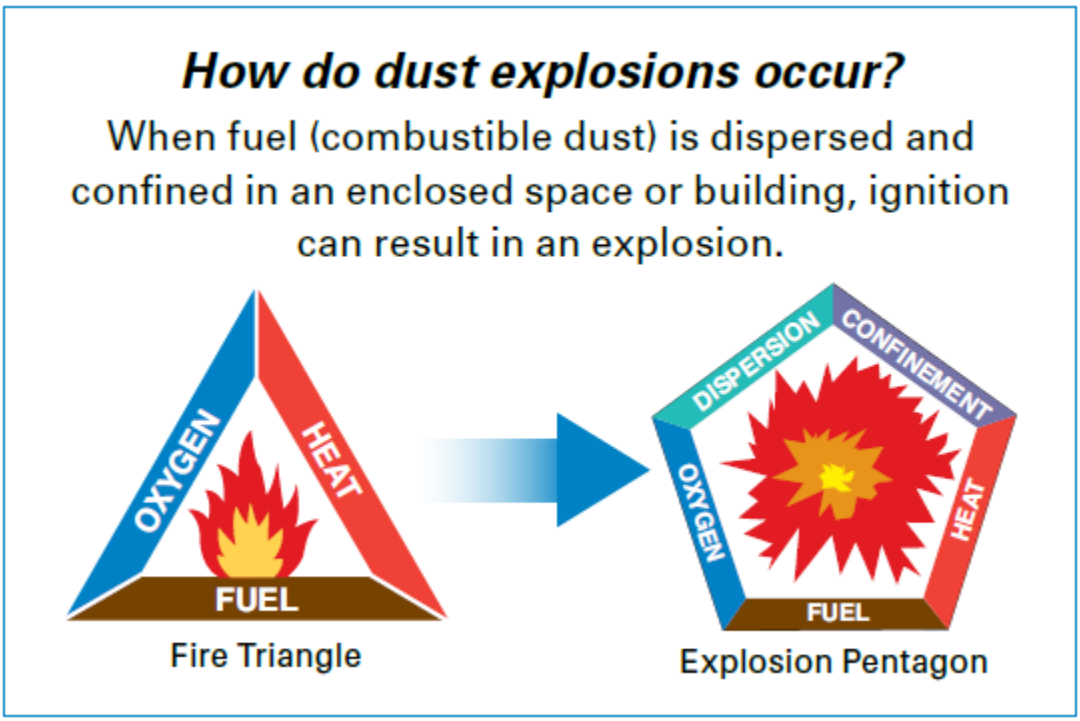
- Combustible Dust Explosions Fact Sheet
- Combustible Dust: Protecting Workers from Combustible Dust Explosion Hazards Fact Sheet

Per OSHA, five elements, as indicated below, are necessary to initiate a dust explosion, or what is often referred to as the “Dust Explosion Pentagon.”

- Combustible dust (fuel)
- Ignition source (heat)
- Oxygen in air (oxidizer)
- Dispersion of dust particles in sufficient quantity and concentration

- Confinement of the dust cloud

The first three elements are those needed for a fire and comprise what is commonly known as the “fire triangle.” Dispersion of dust particles in sufficient quantity and concentration can cause rapid combustion known as a deflagration. If the event is confined by an enclosure such as a building, room, vessel, or process equipment, the resulting pressure rise may cause an explosion. Note that if one of the five elements is missing, a dust explosion cannot occur.



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[Precautions for Firefighters to Prevent Dust Explosions - OSHA]

An initial (primary) explosion in processing equipment or in an area where fugitive dust has accumulated may dislodge more accumulated dust into the air or damage a containment system (such as a duct, vessel, or collector). As a result, if ignited, the additional dust dispersed into the air may cause one or more secondary explosions. These can be far more destructive than a primary explosion due to the increased quantity and concentration of dispersed combustible dust. Many deaths in past incidents, as well as other damage, have been caused by secondary explosions.

10.12.2 - Portable/Personal Electronic Devices (PEDs)

PEDs, including your mobile telephone, and their chargers, can provide potential ignition sources in explosion hazardous atmospheres. They can create electrical sparks, hot surfaces, electrostatic discharges, and other potential ignition sources via their batteries, motor brushes, pushbuttons, and/or damage caused by impact or related electromagnetic properties. Ignition can occur when the device is being used normally, while the device is being charged, or if the device is or has been damaged.

Examples of PEDs include mobile telephones, laptop computers, tablets, cameras, power tools, fitness monitors, watches/smart watches, calculators, temperature data loggers, car key fobs, flashlights, headlamps, gas monitors, testing equipment, medical devices, and defibrillators.

Equipment can be designed or modified for safe operation in hazardous locations. There are two general approaches for safe operation. One known as intrinsic safety, or non-incendive safety, limits the energy present in a device, so that it is insufficient to ignite a hazardous atmosphere under most conditions. This includes both low power levels and low stored energy. The second approach, explosion-proof or flame-proof equipment, is specifically constructed so that it will not ignite in a hazardous atmosphere, including in the presence of any sparks or explosions. Standards have been developed that identify what equipment may be used in hazardous locations. The suitability of equipment for specific hazardous areas must be tested by a Nationally Recognized Testing Laboratory, such as UL, FM Global, CSA Group, or Intertek (ETL).

Note that in the presence of known flammable vapors, OSHA stipulates to use *only* explosion-proof, self-contained temporary and portable lights (to include flashlights and headlamps) that have been approved for hazardous conditions by a nationally recognized testing laboratory (NRTL). OSHA defines such hazardous, flammable conditions as those in which the atmosphere is determined to contain a concentration of flammable vapors that are at, or above, 10 percent of the lower explosive limit (LEL), as specified in 29 CFR part 1915, subparts B and C.

Consult with your supervisor and/or your IH Contact(s) concerning PED/portable lighting usage and/or safety.

10.12.3 - Lithium Batteries

Per OSHA, small and wearable electronic devices used in workplaces (for example, body cameras) rely on a power source that stores a high amount of energy in a small space, in what is often referred to as high energy density. Lithium cells provide sustained power and often have the capability to recharge. When designed, manufactured, and used properly, lithium batteries are a safe, high energy density power source for devices.

While lithium batteries are normally safe, they may cause injury if they possess design defects, are made of low-quality materials, are assembled incorrectly, are used or recharged improperly, or are damaged. Lithium batteries are generally safe and unlikely to fail-- however, when lithium batteries do fail to operate safely or are damaged, they may present a fire and/or explosion hazard. Damage from improper use, storage, or charging may also cause lithium batteries to fail.

OSHA Preventing Fire and/or Explosion Injury from Small and Wearable Lithium Battery Powered Devices discusses the specifics of lithium battery-powered devices and their use in hazardous atmospheres.

10.12.4 - Confined Spaces

Referencing Confined Spaces - Overview OSHA: Many workplaces contain areas that are considered "confined spaces" because they are not necessarily, or optimally, designed for people, and only large enough for workers to enter and perform certain jobs. A confined space also has limited or restricted means for entry or exit and is not designed for continuous occupancy. Confined spaces include, but are not limited to tanks, vessels, silos, storage bins, hoppers, vaults, pits, manholes, tunnels, equipment housings, ductwork, pipelines, etc.

OSHA uses the term "permit-required confined space" (permit space) to describe a confined space that has one or more of the following characteristics: contains or has the potential to contain a hazardous atmosphere; contains material that has the potential to engulf an entrant; has walls that converge inward, or floors that slope downward and taper into a smaller area, which could trap or asphyxiate an

entrant; or contains any other recognized safety or health hazard, such as unguarded machinery, exposed live wires, or heat stress. Confined spaces shall be identified by the firm who shall then inform potentially exposed parties of the existence and location of such spaces and their hazards.

Confined Spaces - Standards OSHA addresses specific OSHA standards for general industry, maritime, and construction and highlights OSHA standards and documents related to confined spaces.

Confined spaces may be encountered in virtually any occupation; therefore, their recognition is the first step in preventing fatalities. Since deaths in confined spaces often occur because the atmosphere is oxygen-deficient, toxic, or combustible, confined spaces that contain or have the potential to contain a serious atmospheric hazard should be classified as *permit-required* confined spaces and should be tested prior to entry and continually monitored. The references at Confined Spaces - Hazards and Solutions OSHA aid in recognizing and evaluating hazards and possible solutions related to confined spaces.

The following is a partial list of examples work areas that are confined spaces: ship cargo holds, import/shipping containers, walk-in freezers, walk-in refrigerators, and walk-in autoclaves.

Suggested behaviors and actions when encountering potentially confined spaces and situations:

1. Prior to entering a closed area, ascertain if it has been fumigated and, if so, has the space been aired out sufficiently. Do not enter if you are uncertain of either condition.
2. When sampling or inspecting at rendering plants or fishmeal plants, be alert to possible hydrogen sulfide accumulations in dump pits and other areas. These fumes can be deadly.
3. Be alert and take proper safety precautions in plants, silos, bins, pits, and any closed areas where semi-solid buttermilk or other liquid dairy products, silage, or other bulk products are stored. If not properly stored, improperly handled, or in a state of decomposition, certain products can produce dangerous amounts of carbon dioxide, or other gases, or may deplete the oxygen supply in these areas.
4. When transporting dry ice or packages containing dry ice in your car, have some external ventilation.
5. When sampling from the top of a grain elevator, do not jump down, stand on, or walk across the top of grain. There may be a cavity caused by crusted grain which could break and result in you being buried in grain or being in an atmosphere of fumigating gas.
6. Be alert when entering storage areas having controlled atmospheres, for example, where oxygen has been replaced by carbon dioxide to prolong fruit storage, or sulfur dioxide added for preservation purposes, etc. These areas should be aerated and deemed safe by the firm prior to your entering.
7. Contact your supervisor or IH Contact(s) if you require guidance to determine what hazards or DOT regulations may be applicable to a substance when it's being transported.
8. Be aware that such spaces may not open from the inside and verify that an escape is possible.

10.12.5 - Thermal Processing/Retorts

Canning retorts are considered confined spaces and are to be regarded as hazardous.

DO NOT ENTER RETORTS OF ANY KIND UNDER ANY CIRCUMSTANCES.

Should an inspectional need arise where entering a retort becomes necessary, notify your management who will then notify the Program Liaison IH and HFP Division of Food Processing Science and Technology. Such inspectional activity occurs on an as-needed, mission-critical basis ONLY. Retorts should *never* be entered routinely.

There is the potential to request an employee of the firm to enter the retort on behalf of the agency, with an FDA camera and/or equipment and take measurements or photos. Note that such a request is not routine; it is completely voluntary, done at the firm's discretion, and subject to refusal.

Note that all applicable FDA inspectional forms have been adjusted to eliminate any need for entering retorts.

10.12.6 Altered/Oxygen-Deficient Atmosphere Environments

FDA-regulated products are often manufactured and stored using processes that require altered atmospheric conditions. Examples include fumigation treatment of food storage areas with pesticides, fruit, and vegetable ripening rooms, import containers, truck trailers, railroad cars, and device or drug processing spaces. Hazards commonly associated with altered atmosphere environments include asphyxiation, fires, explosions, and toxic effects. The substance or combinations of substances used to alter the atmosphere determine the specific hazards created. Substances commonly used to alter atmospheres include nitrogen gas, ozone gas, and fumigants (such as ethylene oxide).

When interviewing staff at a firm that uses altered atmospheres for processing, gather the following information and documents before proceeding with your inspection:

- Safety Data Sheets (SDS) for all substances used to alter the atmosphere.
- Safety controls used to prevent altered atmosphere exposure and associated hazards.
- Processes used by the firm to alter the atmosphere.
- Processes by which the firm returns the atmosphere to normal, safe conditions after altering it for a process.
- Processes by which the firm verifies that the atmosphere is in a normal, safe condition after being altered.
- Emergency procedures if someone enters the altered atmosphere environment, or the atmosphere is altered while an individual is in a processing space.

Once the above information has been gathered and you have determined that a risk assessment is needed, contact your supervision who can then contact your IH liaison before proceeding with any inspectional activities in the affected space(s). Note that altered atmosphere environments are commonly associated with confined spaces. Be sure to follow all applicable safety precautions if confined spaces are encountered.

10.12.6.1 - Ammonia

Ammonia is a colorless gas with a distinct odor. It can pose a health hazard because it is corrosive to skin, eyes, and lungs. Exposure to 300 parts per million (ppm) is immediately dangerous to life and health. Ammonia is also flammable at concentrations of approximately 15% to 28% by volume in air. When mixed with lubricating oils, its flammable concentration range is increased. It can explode if released in an enclosed space with a source of ignition present, or if a vessel containing anhydrous ammonia is exposed to fire. Ammonia spills and releases pose a significant threat to workers from skin contact, inhalation, and fire and explosion.

Anhydrous ammonia is widely used as a refrigerant in many industrial facilities, including:

- Meat, poultry, and fish processing facilities
- Dairy and ice cream plants
- Wineries and breweries

- Fruit juice, vegetable juice, and soft drink processing facilities
- Cold storage warehouses
- Other food processing facilities
- Petrochemical facilities

While refrigeration systems are closed systems, ammonia release could occur during receiving, storage, or due to leaks. Follow facility safety protocols and in the event of an ammonia leak or discharge, immediately evacuate the facility. When conducting field operations due to recalls or potential adulteration of product from ammonia, do not enter the facility until, or unless, it has been deemed safe to do so. Some inspections may require you to enroll in a Respiratory Protection Program for your safety. For example, all investigators conducting egg farm inspections or investigations should be medically cleared, fit-tested and trained in the proper use and limitations of the issued respirator. You need to determine as much as possible if a chemical hazard, such as ammonia, is present at the facility prior to arriving or conducting field work, as applicable. If ammonia is identified as a potential hazard, firm management should be asked whether ammonia levels are regularly monitored. During egg inspections, for example, you should have your respirator with cartridges with you in the event a chemical hazard arises. The hazard of ammonia may also need to be considered during other production environments, such as in cheese ripening or aging rooms.

Consult your supervisor or the Safety Liaison for your program or division regarding any inspectional safety concerns.

10.12.6.2 - Fumigants and Fumigation

The use of chemical fumigants for the control of insect infestation can result in hazardous exposures to those involved in the handling of both fumigants and fumigated products, like those associated with controlling insects in grains. Fumigants can include pesticides, insecticides, and hazardous preservatives. Controlled atmosphere storage of certain food products is also a form of fumigation where, in a controlled atmosphere, most of the air in an enclosed storage area, or packaging, is replaced with a gas such as carbon dioxide.

Fumigant toxic effects can include permanent central nervous system damage, heart and vascular disease, lung edema, and cancer.

The increased use of fumigants and increases in the handling of fumigated products, coupled with the insidious nature of these toxicants, makes it imperative that you take special care during your inspection with respect to fumigated areas and products.

Substances used as fumigants and their usual physical state when applied for that purpose:

Fumigant and Chemical Structure	Physical State of Fumigant as it is Applied
Acrylonitrile (CH_2=CHCN)	Liquid
Aluminum phosphide (AlP)	Solid
Anhydrous ammonia (NH^3)	Liquid (gas)
Calcium cyanide (Ca $(CN)_2$)	Solid (gas)

Fumigant and Chemical Structure	Physical State of Fumigant as it is Applied
Carbon disulfide (CS_2)	Liquid
Carbon tetrachloride (CCl_4)	Liquid
Chloroform ($CHCl_3$)	Liquid
Chloropicrin (CCl_3NO_2)	Liquid
Cyanogen bromide (BrCN)	Liquid
Cyanogen chloride (ClCN)	Gas
1,3-Dichloropropene ($CHCl=CHCH_2Cl$)	Liquid
Ethylene dichloride (CH_2ClCH_2Cl)	Liquid
Ethylene oxide (CH_2 - CH_2)	Gas
Hydrogen cyanide (HCN)	Liquid (gas)
Magnesium phosphide (Mg3P2)	Solid
Methylbromide (CH3Br)	Gas
Methylene chloride (CH2Cl2)	Liquid
Naphthalene ($C_{10}H_8$)	Solid
Para-dichlorobenzene ($C_6H_4Cl_2$)	Solid
Phosphine (PH3)	Gas
Propylene dichloride ($CH_2ClCHClCH_2$)	Liquid
Propylene oxide (CH_2 - CH-CH_3)	Gas
Sulfur dioxide (SO2)	Gas
Sulfuryl fluoride (SO2F2)	Gas
1,1,1-trichloroethane (CH_3CCl_3)	Liquid

Source: American National Standard for respiratory protection during fumigation, ANSI Z88.3-1983

Notes: Aluminum and magnesium phosphide are solid substances that react with moisture to produce phosphine gas. At high concentrations, phosphine is spontaneously combustible. Calcium cyanide, a solid, reacts with acids to produce HCN, a gas.

Signs shall be clearly posted by the firm in instances where fumigants, pesticides, or hazardous preservatives have created a hazardous atmosphere. These signs shall note the danger and specific chemical hazards, as well as provide appropriate information and precautions, including instructions for the emergency treatment of employees affected by any chemicals in use. In the case of containerized shipments of fumigated products, the contents of the container shall be aerated by

opening the container doors *for a period of 48 hours after the completion of fumigation*. When products are inside or within shipping cases having polyethylene or similar bag liners, the aeration period shall be *72 hours*. The firm should be able to provide written warranty stating that the appropriate aeration period has been met.

10.12.6.2.1 - Fumigant Use by Regulated Firms

Further references for fumigant use include the 40 CFR 171 promulgated by the EPA and the Agricultural Marketing Service Fumigation Handbook.

Fumigants present a potential respiratory hazard when used in regulated establishments subject to inspection which include, but are not limited to, fumigation or storage facilities where raw agricultural commodities (RACs) are encountered, including trucks, vessels, railroad cars, shipping containers and fumigation chambers.

Do not enter any structure or conveyance or sample any product that is being treated with the fumigants including, specifically, methyl bromide, phosphine or sulfuryl fluoride. If a sampling area is suspected of having been fumigated with a fumigant and has not been cleared according to EPA requirements, contact your local IH for guidance as to how to ensure that the area is safe to enter. *Do not enter the area until it is appropriately aerated and tested.*

Areas and/or products being treated with fumigants are required by the EPA to be placarded, and the placards not to be removed until the treatment is complete (a process usually taking from 12 hours to 4 or more days) and the areas and/or products are clear of fumigant gases (with, specifically, phosphine at <0.3 ppm and methyl bromide at <1 ppm).

Although there should be no occasion where you should encounter hazardous fumigant concentrations, it is advisable to be fully aware of the symptoms of exposure to fumigants. Note that, in any situation where exposure to fumigants is unknown/questionable and/or there is moderate to high exposure, you should seek medical attention immediately.

Using phosphine as an example:

1) Symptoms of exposure to phosphine include:
   a) Slight or mild poisoning, which may lead to feelings of fatigue, ringing in the ears, nausea, pressure in the chest, and uneasiness. All symptoms typically dissipate when the person is removed to fresh air.
   b) Moderate exposure, which may lead to general fatigue, nausea, gastrointestinal symptoms accompanied by vomiting, stomachache, diarrhea, disturbance of equilibrium, strong pains in the chest, and difficulty breathing.
   c) Exposure to very high concentrations, which rapidly causes strong difficulty in breathing, bluish-purple skin color, difficulty in walking or reaching, subnormal blood oxygen content, unconsciousness, and death. Death can be immediate or may be delayed until several days later.
2) Treatment:
   a) The EPA-approved label contains information regarding practical treatment regimes. If any of the symptoms previously described are experienced, a physician should be contacted immediately.
   b) To expedite proper treatment, it is advisable to have a copy of the EPA-approved label available for the physician. Generally, the most up-to-date information

regarding medical treatment for exposure is available from the fumigant manufacturer. The EPA approved label contains the manufacturer or distributor name, address, and phone number.

10.12.6.2.2 - Fumigants Related to Sampling

When collecting samples that may contain live insects, it may be necessary to fumigate and/or preserve the sample.

As soon as possible, freeze any sample containing, or suspected to contain, live insects—as long as freezing will not change or damage the product, or break the container. If freezing is inappropriate for maintaining the integrity of the sample, fumigation may be carried out using air-tight containers (such as a mason-type jar with inner ring, or a polypropylene container with air-tight lid), with sufficient fumigant to kill the insect infestation.

Moth crystals, containing paradichlorobenzene (PDB), are an alternative fumigant. Do not use mothballs or moth flakes containing naphtha or naphthalene. Do not use moth crystals in or near plastics, particularly Styrofoam and other polystyrenes as crazing or melting may occur. Crazing is the phenomenon that produces a network of fine cracks on the surface of a material, for example in a glaze layer. Crazing frequently precedes fracture in some glassy thermoplastic polymers. Other alternative fumigants include liquid household ammonia or ethyl acetate--either of which can be used by dampening on a cotton ball and placing in an appropriate container; or by cutting small portions of commercial pesticide strips and placing in container. Contact your servicing laboratory for guidance on alternative fumigants.

Follow safety precautions when fumigating and/or preserving samples. Guidance is as follows:

1. Whenever possible, freeze the sample. If freezing is not practical, contact your servicing laboratory for alternative fumigants and preservatives.
2. When fumigants or preservatives are used, exercise care to limit your exposure to these chemicals. Minimize transfer and exposure time. Avoid getting chemicals on hands or clothing. DO NOT MIX CHEMICALS. Contact ROSS for the appropriate precautions necessary with these chemicals.
3. Safety Data Sheets (SDS) for each of these chemicals should be available at each duty site (for example at, division offices and resident posts), and can also be obtained from the chemical manufacturer. These sheets list the hazards involved with these chemicals and precautions to take for their use. You should read and follow the instructions in the SDS prior to using the chemical. As for shipping, if a measured amount of chemical fumigant or preservative is present, and considered a regulated hazardous material, follow the guidance and properly ship the item. Again, if you have any questions regarding safety, or shipping concerns, contact ROSS.
4. Carry all alcohols, fumigants, and other hazardous liquids in approved safety containers.
5. Ensure DOT regulations and guidance, and International Air Transport Association (IATA) guidelines are followed when mailing or shipping samples containing fumigants or preservatives. Exceptions for small quantities are listed in 49 CFR 173.4.
6. The sample identification data on your packaging, the FDA-525 and C/R, must always identify the fumigant and method of fumigation, and/or preservative used.
7. SDSs for each chemical fumigant or preservative used must be enclosed with the shipped sample. Read and follow all instructions and precautions listed on the SDS.

Additional information on fumigants for preservation can be found at

- USDA Collecting and Preserving Insects and Mites: Techniques And Tools
- Paradichlorobenzene General Fact Sheet
- Naphthalene General Fact Sheet

10.12.6.2.3 - Procedures for Fumigation

Place a small amount of fumigant, in an airtight container. Separate the fumigant from the sample with a piece of paper, paper napkin, or unscented facial tissue. Put specimen or product into container and seal tightly. Do not reopen container unless absolutely necessary. If possible, use a glass container with a lined screw lid. A mason-type jar with inner ring is also acceptable.

10.12.6.2.4 - Exceptions to Fumigation

When submitting samples or exhibits to show live infestation, do not fumigate. Consult with your supervisor or your servicing laboratory PRIOR to sending or bringing a live infestation into the laboratory to permit preparation for proper handling and storage. Do not fumigate sample when submitting samples for pesticide residue analysis.

10.12.6.2.5 - Preservation Liquids

Insects may be killed and preserved in 70% ethyl alcohol, or a 1:1 mixture of 70% ethyl alcohol and glycerin (may be labeled glycerol). These chemicals can be obtained from your servicing laboratory. Do not collect rodents or animal tissues unless specifically instructed. Ensure all vials or bottles of preservation liquids are tightly sealed to avoid leakage. Identification labels may be placed in containers but must be written in India ink or 2H pencil only. Keep all preservation liquids away from excessive heat or open flame.

Identify the preservative used on FDA 525, C/R, and on sample container. Enclose a copy of the SDS with the shipped sample. Follow DOT and IATA guidelines when shipping or mailing samples with preservatives, as stated under fumigants.

10.12.6.3 - Ethylene Oxide (EtO)

EtO is a highly flammable, colorless gas at temperatures above 51.3 ºF (10.7 ºC) that smells like ether (sweet, fruity, pungent) at toxic levels (above 500ppm). EtO is found in the production of solvents, antifreeze, textiles, detergents, adhesives, polyurethane foam, and pharmaceuticals. Smaller amounts are present in fumigants, sterilants for spices and cosmetics, as well as during hospital sterilization of surgical equipment. Per Ethylene Oxide - Overview OSHA, EtO is produced in large volumes and is primarily used as an intermediate in the production of several industrial chemicals, the most notable of which is ethylene glycol. It is also used as a fumigant in certain agricultural products and as a sterilant for medical equipment and supplies. Unfortunately, EtO possesses several physical and health hazards that merit special attention. EtO is both flammable and highly reactive. Acute exposures to EtO gas may result in respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis. Chronic exposure has been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.

Unmonitored and inadequate ventilation will allow EtO buildup of extremely high concentrations, especially in facilities using malfunctioning or leaking equipment. Door gaskets, valves, and threaded fittings are typical areas where leaks have been observed. Additionally, exhaust vents from the sterilizer and the sterilizer room should not be located near air conditioning intake vents or vented

directly into work areas. If the odor of EtO is detected, ventilation and containment are evidently inadequate. Leave the area and report the situation to your supervisor for further inspectional guidance. Special EtO monitoring equipment is available upon request from the Office of Regulatory Science.

OSHA standard regulating employee exposure to EtO is presently 1 ppm, over an 8-hour day. You should avoid all unnecessary and preventable exposure to it. Adhere to any procedures the firm has established for protection of personnel from overexposure to EtO. Where improper venting procedures or defective equipment are observed, take adequate precautions, for example, do not enter potentially hazardous areas, and/or wear protective clothing and a respirator. 29 CFR 1910.134 contains basic requirements for proper selection, use, cleaning, and maintenance of respirators.

Ethylene Oxide - Hazard Recognition OSHA consolidates references that aid in recognizing and evaluating ethylene oxide hazards.

10.12.6.4 - Nitrogen

Nitrogen gas may be used during product packaging and manufacturing in both food and pharmaceutical operations to preserve freshness, prevent microbial growth, and enhance quality by preventing the negative impacts of oxygen exposure. Nitrogen flushing is popular for use in food packaging because it displaces oxygen, thereby maintaining a long shelf life and preventing spoilage. Liquid nitrogen may be used to freeze or cool products during production, and for other processes including grinding, mixing, and coating. Food firms may use liquid nitrogen in the production of a variety of foods, such as meat, poultry, seafood, fruits, vegetables, baked goods, beverages, and prepackaged meals. Laboratories requiring specific environments will utilize nitrogen to reduce oxygen levels, humidity, and temperature for sensitive procedures and equipment.

Nitrogen is odorless, colorless, and tasteless--attributes accounting for its increased risks in the absence of appropriate monitoring. Hazards of nitrogen may include asphyxiation and frostbite. While refrigeration systems are closed systems, nitrogen release can occur during receiving, storage, or in instances of leaks. When liquid nitrogen is exposed to the air during leaks, it will evaporate, changing from a liquid to an oxygen-depleting gas.

Follow facility safety protocols, and in the event of a nitrogen leak or discharge, immediately evacuate the facility. When conducting field operations due to recalls or potential adulteration of product from nitrogen, do not enter the facility until, or unless, it has been deemed safe to do so. Consult your supervisor or the safety liaison for your program or division regarding any inspectional safety concerns.

10.12.6.5 - Ozone

Ozone is used in many industries during food production, for example, in produce, meat, seafood, and water/beverage production; for sanitization purposes; and as a disinfecting agent. Ozone gas may be colorless, or appear blue, and has a pungent odor. Exposure to ozone may cause headaches, coughing, dry throat, shortness in breath, a heavy feeling in the chest, and fluid in the lungs. Respiratory protection may be needed if entering an area with a high concentration of ozone.

10.12.7 - Lockout/Tagout (LOTO)

The absence of an appropriate Lockout/Tagout (LOTO) method consistently ranks as one of OSHA's most frequently cited violations, with the agency citing an average of 120 fatalities and 50,000 injuries each year that could otherwise be prevented by instituting/using an LOTO program.

LOTO is used across industries as a safe method of operating, or working on, hazardous equipment. Employees servicing or maintaining machines or equipment may be exposed to serious physical harm or death if power sources and access/exits to the machinery are not properly controlled. Machine-related injuries or fatalities can occur during maintenance and servicing tasks when workers are exposed to an uncontrolled release of energy, including during equipment startup, or if faced with an inability to exit, due to confined spaces or other factors.

LOTO involves the adoption and implementation of practices and procedures to shut down equipment, isolate it from its energy source(s), and prevent the release of potentially hazardous energy while maintenance and servicing activities are being performed. LOTO use can apply to any source of electric, mechanical, hydraulic, pneumatic, chemical, thermal, or other energy, which, if not controlled, could create a hazard. Firms have the flexibility to develop LOTO programs that are suitable for their respective facilities.

The following are definitions for Lockout (LO) and Tagout (TO), respectively:

- LO is a positive means, such as a key or combination-type lock (with a chain as necessary), to hold an energy-isolating device in a safe position and prevent energizing a machine or piece of equipment.
- TO involves a prominent warning device, such as a tag and a means of attachment, which can be securely fastened to an energy-isolating device, according to established procedure. The TO device shows that the energy-isolating device and the equipment being controlled may not be operated until the warning device is removed by the authorized employee who placed the TO device on the energy-isolating device.

LOTO ensures that no one can unlock and reenergize a piece of equipment while you are in the vicinity of, or in process of inspecting, equipment. LOTO procedures are required if the equipment can expose you to the unexpected startup or release of stored energy that could cause injury. For FDA, and especially OII staff, the standard definition of LOTO is expanded well past the “control of hazardous energy” to encompass additional potentially harmful situations. Such additional LOTO-related situations include instances when:

- You are inspecting machines or equipment on which the guards or other safety devices have been removed or bypassed, whether intentionally or accidentally, during cleaning or maintenance.
- Parts or portions of your body are exposed to, or could potentially come within, the danger zone associated with the equipment, such as its point of operation. Also known as the “working area”, the danger zone is any place in or about a machine or piece of equipment where an employee may be struck by or caught between moving parts, caught between moving and stationary objects or parts of the machine, caught between the material and a moving part of the machine, burned by hot surfaces, or exposed to electric shock.
- You need to inspect equipment with entrapment hazards that include walk-in freezers/coolers, grain silos, tractor/semi-trailers, import shipping containers, among others.

10.12.8 – Reproductive Hazards and Pregnant Employees

Where you work, how you work, and what you work with can affect your reproductive health and/or your family's health. OSHA notes that "exposure to reproductive hazards is an increasing health concern." From the Preamble to NIOSH's National Occupational Research Agenda (NORA) Statement on Reproductive Hazards: "While more than 1,000 workplace chemicals have shown reproductive effects in animals, most have not been studied in humans. In addition, most of the 4 million other chemical mixtures in commercial use remain untested. Physical and biological agents that may affect fertility and pregnancy outcomes are practically unstudied. The inadequacy of current knowledge coupled with the ever-growing variety of workplace exposures pose a potentially serious public health problem." Three-quarters of women of reproductive age are in the workforce. Over half of the children born in the United States are born to working mothers. See OSHA articles The Effects of Workplace Hazards on Female Reproductive Health and The Effects of Workplace Hazards on Male Reproductive Health for more information.

Reproductive hazards are substances or agents that may affect the reproductive health of women or men or the ability of couples to have healthy children. Hazards may be chemical, physical, or biological. Examples of reproductive hazards are lead (chemical), radiation (physical) and certain viruses (biological). You may be exposed to reproductive hazards by breathing them in (inhalation), by contact with skin (dermal) and by swallowing them (ingestion). Potential health effects include infertility, miscarriage, birth defects and developmental disorders in children. You can expose your family to these hazards by bringing them home from the workplace, for example, on your skin, hair, clothes, shoes, tools, or car. It is important to prevent these exposures by the use of workplace engineering controls, proper work practices and good hygiene.

NIOSH also provides information resources on pregnancy and reproductive health hazards associated with workplaces.

Per NIOSH, pregnancy can affect your safety as a worker. If you are pregnant, discuss possible job hazards with your physician, supervision, and your ROSS as soon as possible. Many pregnant women are able to adjust their job duties temporarily or take extra steps to protect themselves. By law, you have the right to receive information on hazards in your workplace and to receive training on how to stay safe. See Legal Rights of Pregnant Workers under Federal Law for more information on pregnancy in the workplace.

Pregnant employees should take special note that any and all current occupational exposure limits, including those established by OSHA, are set based upon studies of nonpregnant adults. In other words, what is considered safe for you, may *not* be safe for your fetus. Although many employees choose to safely continue their jobs throughout pregnancy, pregnancy can sometimes affect worker safety.

If you are pregnant and working, consider the following physiological attributes and/or changes experienced during pregnancy that may be in conflict with your usual workplace activities or demands:

- Changes in your metabolism can increase how quickly you absorb some chemicals, including some potentially hazardous metals.
- Because of physical changes, the PPE that you wore correctly before pregnancy may no longer fit properly. This includes lab coats and respirators. Consider refitting and/or acquiring new PPE as appropriate. Reference Personal protective equipment use while pregnant.

- Changes in your immune system, lung capacity, and even ligaments can alter your risk of injury or illness due to some workplace hazards.
- A fetus might be more vulnerable to some chemicals because of its rapid growth and development, particularly early in pregnancy when its organs are developing.

Consult with your physician, your supervisor and/or your IH Contact(s) for further information about any reproductive workplace-related health and pregnancy concerns you may have.

10.13 - Biological Hazards

Biological hazards may be present during various field investigation and inspection operations. Whether you find yourself working in agricultural fields, animal facilities, processing plants, drug, and clinical settings, or import operations, you should be cognizant of potential biological hazards and understand the appropriate steps needed to mitigate the risks of hazardous exposures. Biological hazards, also known as *biohazards*, are substances of biological origin that pose a health risk or threat to living organisms.

Possible sources of biological hazards vary widely and may include animal and animal products, blood and other bodily fluids, and biological waste streams from various processing facilities. Having a better understanding of potential biological hazards--through knowledge, appropriate planning, awareness of safety practices and preventative medical treatments available (for example, vaccines) can minimize the incidence of occupational exposures. Biological hazards may be present while performing work tasks; but, regardless of the source, appropriate safety measures can mitigate the risks and limit exposure. Appropriate PPE (gloves, N-95 masks, Tyvek protective clothing or coverings, and goggles) can mitigate exposure to biological hazards in the environment and are indicated based on the level of hazards present and the likely routes of contamination during work activities. Although a comprehensive list of biological hazards is not possible, potential biological hazards and their sources will be addressed in the following sections.

10.13.1 - Microorganisms

Microorganisms are a large diverse group of microscopic organisms present in the environment. Only a small percentage of the total microorganism population are considered pathogenic, or disease-producing, with the capability to infect and negatively impact humans, animals, and plants. Along with the capability of producing disease directly, some microorganisms or agents cause additional harm by producing secondary products or toxins.

10.13.2 - Viruses

Viruses are small infective agents made up of a collection of genetic code (RNA or DNA) that replicate or multiply within living host cells. Viruses do not have the capability of replicating on their own but use the host cell components to reproduce. Antibiotics are not effective against viral disease. Available antiviral medications or vaccines are used to reduce, treat, and manage viral disease. Some examples of viral diseases include Human Immunodeficiency Virus (HIV), measles, and COVID-19.

10.13.3 - Bacteria

Bacteria are single celled organisms found everywhere on the planet with only a small contingent that are pathogenic or capable of causing disease. Bacteria are classified by their basic shape: sphere, rod, comma, spiral or corkscrew. Replication of bacteria occurs by binary fission or division with one cell

dividing into two identical daughter cells. Antibiotics can be effective on specific bacteria, but antibiotic resistance may develop over time or under specific conditions. Some bacteria can form dormant structures called spores or endospores as a survival mechanism during unfavorable conditions. Spores can be very resistant to destruction methods.

10.13.4 - Fungi

Fungi, such as yeasts and molds, are organisms that feed on other organic matter to survive. Fungi are similar to plants but are separate as they do not contain chlorophyll and have unique cell wall and membrane components. As a group, fungi are very diverse and include molds, yeast, mildews, rusts, smuts, and mushrooms. Reproduction of fungi occurs by fragmentation, budding, or the production of spores. Some fungi are beneficial and essential to food processes, including for beer, wine, bread, and some cheeses. Other fungi can cause harm directly, or by producing a secondary metabolite that can be detrimental such as mycotoxins. Mycotoxins, like aflatoxins, are naturally produced, secondary metabolites of certain molds capable of causing disease. They can be found on grains, nuts, spices, and other food sources.

10.13.5 - Parasites

Parasites are organisms that live on or within another organism, called the host, often harming it. Parasites depend on its host for survival. They can be microscopic (like protozoa) or macroscopic (like helminths, or worms and ectoparasites). They can be transmitted through fecal oral route (like protozoa and helminths) and affect the gut of the host, by attaching to or burrowing into skin (including ectoparasites like mites and lice) or transmitted through insect bites (like protozoa such as plasmodium). Food can become contaminated with parasites resulting from the use of contaminated water or improper food handling, and cause infection in consumers who unwittingly ingest such contaminated foods. Outdoor environments (including farms, surface water zones and areas, and animal production areas) are the most likely sources of parasites. Proper hygiene and PPE can mitigate risks of transmission.

10.13.6 - Prions

Although not a microorganism or living thing, a prion is a protein capable of causing normal proteins in the brain to fold abnormally and clump together. These misfolded proteins cause disease by damaging the central nervous system and brain tissue. Prion diseases, also known as transmissible spongiform encephalopathies (TSEs), impact both humans and animals and can potentially be spread by infected animal products, although the nature of the prion transmission is still not well understood. TSEs are progressive neurodegenerative brain disorders, have long incubation periods, progress rapidly once symptoms develop and are always fatal. Bovine spongiform encephalopathy (BSE) is a degenerative neurological disorder caused by prions that damages the central nervous system of cattle and is an example of a transmissible spongiform encephalopathies (TSEs).

10.13.7 - Biological Allergens

Biological allergies can result from exposure to certain plants or animal proteins. Some plants can produce allergens that cause skin dermatitis, rhinitis, or asthma as a result of exposure pathways of direct contact, ingestion, or inhalation. Protein allergies from exposure to animal urine, feces, hair, saliva, and dander can also cause allergic reactions in sensitized people.

10.13.8 - Biological Toxins

Biological toxins are hazardous substances produced by microorganisms, animals, insects, and plants that can cause harm upon exposure. Depending on the toxin, and amount and route of exposure, health effects can range from minor to severe. Toxins may be a secondary product produced by a microorganism, such as Clostridium botulinum toxin, or mycotoxins from molds found on such crops and food sources as corn and legumes.

10.13.9 - Routes of Infection/Intoxification

The routes of infection and intoxication are listed below:

- Inhalation can lead to infection/intoxification via the respiratory tract, when a person inhales aerosols, dust, mists, or vapors containing biological hazards.
- Direct contact can lead to infection/intoxification through contact with broken skin or eyes (mucous membranes).
- Ingestion can lead to infection via the digestive tract from consuming drinks or food (including chewing gum and tobacco) in work areas where hazardous chemicals are present. Poor hygienic practices, such as not washing hands after exiting a work area, can also result in the unintended ingestion of contaminants when eating, drinking, smoking, or applying makeup.
- Intoxification occurs when live bacterial cells are ingested which then produce toxins in the body.

Adverse health effects will not occur unless infectious or toxic substances enter the body. Common routes of entry include inhalation, skin absorption and ingestion; however, entry can occur by more than one route. For some pathogens, the symptoms of disease vary based on routes of contamination.

10.13.10 - Sources of Biological Hazards

10.13.10.1 - Animals and Animal Origin Products

Animal biological hazards may be encountered during various field investigation and inspection operations, including inspections of animal origin products, inspections of farms and outdoor areas, and/or inspections that have pest infestation issues.

Animals, including insects, can be a source of transmission of biological hazards. Animals have the potential to be the direct source of a pathogen, or vector, that transmits the pathogen. When around animals, you should take the time and care to understand the possible biological hazards that might be present from the animal, or its skin, feces, urine, etc.

Animal origin products, including foods, may also transmit the same hazards as the originating animal; hence the same caution should be taken when handling or manipulating animal origin products. Examples of such products include feed, milk, and imported bush meat, as well as potentially hazardous handling situations, such as thyroid-processing inspections. The appropriate PPE, based on the anticipated hazards of the animal or animal products, should be worn based on the exposure risk of the operations involved (see IOM 10.9). When inspecting animal or animal origin products, the firm's safety procedures are to be followed to mitigate exposure risk and contamination. If the firm safety measures do not seem adequate for the situation, have a discussion with your supervisor and the program IH.

10.13.10.2 - Rodent-Infested Areas - Hantavirus

Hantaviruses are a group of viruses primarily spread by rodents that can cause disease in humans. Hantavirus can be spread to humans through aerosolization of virus shed in rodent feces, urine, saliva, and, less frequently, from an infected animal bite.

If inspecting crawlspaces, sheds, or warehouses, there is the potential for you to encounter biological hazards associated with rodents and other small animals. Although the exposure risk is low in most cases, evaluation of the potential exposure and risk should be taken along with any precautions, like use of PPE, needed when entering these areas.

When encountering known or suspected rodent-infested areas, the following protective and preventive measures should be implemented:

- Avoid direct contact with rodents dead or alive. Limit your exposure to rodent feces, urine, etc.
- Avoid, as much as possible, moving items around in dusty areas to limit the aerosolization of particulates when inspecting crawlspaces, sheds, or warehouses, and when performing necessary field exams and during breakdown of dusty pallets. If aerosolization of particulates is unavoidable, wear appropriate PPE.
- Wear appropriate PPE for the associated risk, which may include gloves, coveralls, eye protection, and a respirator, depending on the potential hazards and risks.
- Use good hygiene practices. Avoid touching your face, mouth, or eyes with potentially contaminated gloves. After removing gloves, wash hands with soap and water thoroughly.
- Follow any specific guidance issued by federal, state, or local health departments on hantavirus in the area or locality in which you are working.

10.13.10.3 - Poultry Houses

You may be exposed to biological hazards when entering poultry houses such as zoonotic diseases including Salmonellosis, Campylobacteriosis, Chlamydiosis, Tuberculosis, Newcastle Disease, and Avian Influenza that may be present in the facility. Influenza and tetanus vaccinations are recommended for these inspections. Additionally, appropriate PPE is necessary to prevent personal exposure to potential biological hazards when entering these types of facilities. PPE is also used for biosecurity measures, and to prevent the transference of biological hazards between houses and locations. PPE for poultry and egg houses typically includes Tyvek coveralls, boot covers, eye protection, gloves, hair nets, and a respirator, but be sure to follow specific program guidance. Other safety hazards can also be associated with poultry and egg houses including physical and chemical hazards.

10.13.10.4 - Animal Feed

The Bovine Spongiform Encephalopathy (BSE) inspection and feed testing program investigators have the potential to encounter BSE-infected products during animal feed truck inspections and product sampling. Appropriate PPE for such tasks includes gloves and a respirator, which should be worn if there is potential for the animal feed particulate to become aerosolized, or airborne, during inspection and sampling operations.

10.13.10.5 - Sub-human Primate and Animal Testing Facility Hazards

During inspections or investigations of sub-human primate facilities (for example, Good Laboratory Practice (GLP) inspections, non-clinical laboratory testing facilities, animal holding facilities, etc.), do *not* enter rooms housing any sub-human primates. Monkeys housed in these facilities have the potential to carry Herpes-B Virus (also known as B virus, Simian B Virus, Herpes B, herpesvirus simiae, herpesvirus B, monkey B virus or monkey virus). B virus infection can lead to severe brain damage or death if you do not get treatment immediately. Be sure to follow the firm's safety protocols, including recommended use of any PPE.

During inspections of this type, you are not to enter any rooms which hold or house sub-human primates. Bioresearch monitoring (BIMO) inspection information should be obtained from firm personnel interviews and record evaluations. Review of study records is to be completed *outside* of the primate housing areas. Information on animal room activities is to be obtained through firm personnel interviews.

In addition to your IH contact(s), consult the references below for animal exposure situations:

- OSH Animal Safety
- Occupational Health and Safety in the Care and Use of Nonhuman Primates
- Occupational Health and Safety in the Care and Use of Research Animals

10.13.10.6 - Plants and Plant Products

10.13.10.6.1 - Psyllium

Psyllium is a type of soluble dietary fiber that can generate an allergic reaction in some sensitive individuals. Psyllium production facilities may require additional safety measures prior to entering their facilities. Allergen pretesting may be needed, including a radioimmune assay (RAST) blood test, prior to entry. Follow the safety guidance for the manufacturing facility and according to the relevant Regulatory Operations Safety Staff (ROSS) Grab and Go document.

10.13.10.7 – Human Biologics (Blood, Tissue, Plasma and Other Bodily Fluids)

Blood banks and plasma inspections pose the potential for exposure to blood and other bodily fluids. Investigators should be cautious and take suitable precautions to prevent infection in firms such as tissue and blood banks or other places where they may be subject to contact with infectious substances. Blood and tissues should be considered potentially infectious and capable of transmitting disease, including HIV and hepatitis. Follow all PPE protocol and precautions as determined by the risk evaluation for the job task.

Bloodborne Pathogens (BBP) are infectious microorganisms carried in blood and Other Potentially Infectious Materials (OPIM) that when transmitted from an infected individual can cause disease.

Exposure to BBP can occur across a variety of situations, with exposure potentially occurring through sharps, including needle sticks, via broken skin and mucous membranes. The pathogens of primary concern are hepatitis B (HBV), hepatitis C (HCV), and HIV that causes acquired immunodeficiency syndrome (AIDS). Other bloodborne pathogens exist too and are covered by the OSHA Bloodborne Pathogen (BBP) Standard. The OLS and OHS provide a Bloodborne Pathogen Exposure Control Plan (BBPECP), with an HBV vaccine available to individuals who work with, or who may be potentially exposed to BBPs on the job. The FDA Bloodborne Pathogens Exposure Control Plan is for employees who may encounter blood (human or animal) or Other Potentially Infectious

Materials (OPIM). The plan complies with OSHA's Bloodborne Pathogens Standard and is designed to guide workers on how to identify and minimize risks associated with exposure to bloodborne pathogens or OPIM.

10.13.10.8 - Biohazardous Waste

Waste streams have the potential to be contaminated with biological hazards. Biohazardous waste or infectious waste shall be treated in accordance with federal, state, and local regulations, and be handled and disposed of properly. Disposal of biohazardous waste is often conducted through a regulated waste vendor or contract service. Biohazardous waste types you may encounter during investigations, include sharps, infectious waste, and solid waste, all of which has the potential to transmit disease.

10.13.10.9 - Processing Facilities

Various facility processes have the potential to increase the generation of aerosols-- including filling, blending, grinding, spinning, pressurized rinsing, extruding, and spraying—all of which can increase the risk of transmission of biological hazards by inhalation and/or distribution of potential hazards through exposed contact surfaces.

An increase in biological hazards can occur during the processing of raw animal products, the processing of toxin-producing organisms themselves **(**mycotoxin on corn), or processing that propagates or use a biological hazard (vaccine manufacturers).

Although food can be contaminated with pathogens indirectly by contaminated water, animal intrusion, or improper food handling, levels are not expected to be high enough to present a high risk of transmission during sample collection at food processing plants. Additional information on hazards associated with foods can be found in Potential Hazards for Foods and Processes**.**

Processing and manufacturing facilities typically have safety controls and procedures in place to mitigate exposure to the possible hazards during production, including biological hazards. Follow IOM protocol and discuss facility safety measures with firm personnel *prior* to visiting the site when possible, or when on location. You should follow the firm's procedures for mitigating exposure risks during an inspection, to include any administrative, engineering, or PPE controls. PPE may include gloves, face shields, eye protection, coveralls, booties, and appropriate respirators for the specific hazards.

10.13.10.9.1 - Precautions - Blood and Plasma Inspections

Be alert around blood banks or blood-processing operations to the possible dangers of infectious agents.

Keep in mind the following:

1. Do not handle lab instruments, blood samples, containers, or reagents in blood bank labs unless *absolutely necessary*. Wear lab coats with long sleeves. Disposable lab coats that are impervious to blood are an optimal choice. Upon completion, such coats should be left in the laboratory area to be disposed of at the facility.
2. Do not smoke, drink, eat, or meet in blood banks, or in testing areas for Hepatitis B Surface Antigen (HBsAg), HIV, or any other infectious agents.
3. Do consider blood samples, antigens, and antigen testing kits, and other associated HIV-, HBsAg-, and other test reagents as potentially infectious.

4. Do consider the possibility of aerosol contamination if there is spilling or splashing of test reagents or blood samples.
5. Use care when placing inspectional or personal equipment in any lab or testing areas. Wash hands thoroughly after these inspections. *Hepatitis can be transmitted by hand to mouth.*
6. Use disposable gloves. Spills may be adequately addressed by wiping with a 5% sodium hypochlorite solution, and/or solutions such as Wescodyne or Betadine. Autoclaving is the preferred method (121 degrees C for 60 minutes) for sterilizing reagents, samples, and equipment. Note: When accidental spills or similar incidents occur in your presence, you are *not* required to participate in cleaning or disposing of materials. These activities are the firm's responsibility.
7. Use scrupulous adherence to standard/universal personal hygiene practices at all times in the blood bank, and in the testing areas for HBsAg, HIV, and other infectious agents.

10.14 - Chemical Hazards

The following basic information and steps can assist you in recognizing hazardous chemicals, thus enabling you to anticipate potential exposures, and follow preventive measures and practices when preparing for and during site visits. Research any prior inspection histories (file jacket, OSAR, FACTS…) and the type of trade or commodity to be inspected to gain knowledge about the type of chemicals you may encounter in establishment you will be visiting. You may also consult with your supervisor and the program's Regulatory Operations Safety Staff for guidance. In addition, while on site, you should also have access to and the opportunity to review information on chemicals that are present, including SDSs and labeling systems.

The following paragraphs provide an overview of the health and physical hazards posed by some chemicals, as well as reliable sources of information that can be used as reference:

Hazardous chemicals are substances that have the potential to cause harm to human or animal health, the environment, or are capable of damaging property. Chemical hazards can be present and in facilities of the industries that we regulate. Chemical hazards can be in solid, liquid, or gas form. Some are safer than others; but to some workers, who are more sensitive to chemicals, even common forms can cause illness, skin irritation, or breathing problems. You can even experience chemical exposures without direct handling of substances or products. Chemicals can be toxic, corrosive, flammable, and/or combustible. As such, they can pose health risks to workers and become hazards if inhaled, ingested, or absorbed through the skin. Chemical hazards can cause acute harm, such as burns, irritation, and vomiting--or create chronic, long-term health issues, such as asthma, liver damage, and cancer. Identifying potential and actual hazards and taking proper precautions to minimize the hazard(s) and protect yourself is key to avoiding any health problems or complications.

Employers in the United States are required by law to assess the hazards posed by the chemicals present in their workplaces and to implement measures to protect personnel from exposure to those hazardous chemicals. However, some unforeseen incidents, such as equipment failures, or accidental spills or releases may occur, thus increasing the possibility of exposures. While some chemicals have evident warning properties, such as a pungent odor at low or harmless concentrations that helps facilitate their detection, others have no detectable warning properties at all and require monitoring instruments to detect and measure their concentrations in air to determine if levels are safe. Awareness of the

properties and hazards posed by chemicals present aid personnel in taking appropriate action to stay safe while performing tasks at different worksites.

Due to the nature of ORA's field investigations and the industries we regulate, there may be situations in which you may or may not anticipate, or be aware of chemical hazards, until you are in the field. The following information provides a guide to some common chemical hazards but is *not* all inclusive. It is recommended that you conduct a brief chemical hazard assessment with the regulated firm upon your arrival to ensure your personal safety. This may be as simple as asking the firm representative, during the opening discussion, if there are any known chemical hazards within the facility. Firm management is often aware of the chemical hazards that exist at their facility and will have safety guidelines and procedures that you will be expected to follow. If you determine that there is a chemical hazard, and you are unsure, or concerned, about the effectiveness of the firm's control of the hazard or your ability to minimize your exposure to the hazard through the use of physical separation and/or PPE, contact your supervisor and consult with your Program's IH Contact(s) for guidance. If in any doubt about your safety, you should leave the area until all of your concerns have been resolved.

For any known chemical hazards that you identify prior to going out to conduct the inspection (based on your knowledge of the regulated commodity, pre-inspectional web searches, previous Establishment Inspection Report, etc.), be sure to also look through the available "Grab and Go Safety Guidance tools that have been developed and/or posted on the ROSS SharePoint page available to all OII employees.

10.14.1 - Chemical Hazard Basics

10.14.1.1 - Routes of entry for Chemical hazards

To cause health problems, chemicals must enter your body. There are three main "routes of exposure," or ways by which a chemical can enter your body. Common routes of entry include inhalation, skin absorption, and ingestion; however, entry can occur by more than one route.

- Inhalation happens when absorption occurs through the respiratory tract.
- Direct contact happens when absorption or injections occur through the skin, mucous membranes, or eyes.
- Ingestion happens when absorption occurs through the digestive tract.

10.14.1.1.1 - Inhalation

Through inhalation of vapors, fumes, mists, aerosols, or dusts, the breathed chemical enters the bloodstream though the lungs. Once in the bloodstream, chemicals may then be carried throughout the body and affect other organs.

10.14.1.1.2 - Skin Absorption

Skin (or dermal) absorption is another route of entry that may cause localized effects, such as irritation or damage of the tissue in direct contact with the hazardous chemical. Absorption can also lead to other responses, such as sensitization and systemic effects. If chemical sensitization occurs, subsequent skin exposures to that chemical may lead to allergic reactions in the skin or even at sites remote from the skin, such as the respiratory tract.

10.14.1.1.3 Ingestion

Another route of exposure is ingestion (or oral), which may happen when drinking or eating food, or notably, chewing gum or tobacco in work areas where hazardous chemicals are present. Poor hygienic practices can also contribute to chemical ingestion exposure.

10.14.2 Chemical Health Hazards

The following table from OSHA's Hazard Communication - Guidance For Hazard Determination further identifies chemical hazard categories:

CHEMICAL PHYSICAL HAZARDS		
Fire Hazards	***Reactive Hazards***	***Explosion Hazards***
Combustible liquid Flammable liquid Flammable aerosol Flammable gas Flammable solid Oxidizer Pyrophoric	Organic peroxide Unstable (reactive) Water-reactive	Compressed gas Explosive
CHEMICAL HEALTH HAZARDS		
Systemic Effects	***Target Organ Effects***	
Carcinogen Toxic agent Highly toxic agent Corrosive Irritant Sensitizer	Hepatotoxin Nephrotoxin Neurotoxin Blood/hematopoietic toxin Respiratory toxin Reproductive toxin Cutaneous hazard Eye hazard	
OTHER IMPORTANT CHEMICAL HEALTH HAZARDS		
Cardiovascular toxicity Gastrointestinal toxicity Immunotoxicity Skeletal/muscular effects Connective tissue effects Endocrine system toxicity Sensory organ toxicity (sight, hearing, taste)		

10.14.2.1 – Toxicity

Toxic chemicals may enter the body through any route of exposure and cause significant health effects at different levels.

- **Acute toxicity.** Substances with high acute toxicity may be fatal or cause damage to target organs (organ in the body that is most affected by the specific chemical, drug, bacteria, or other substance) as a result of a single exposure, or exposures of short duration. Examples of substances with high acute toxicity include hydrogen cyanide and hydrogen sulfide.
- **Reproductive toxicity**. Chemicals that cause adverse effects on any aspect of human reproduction, including the impairment of male or female reproductive organs, fertility, and fetal development.
- **Specific target organ toxicity** (can occur via single or repeated/prolonged exposure). Chemicals that can significantly impair the function of a target organ system after either a single or repeated exposure. Effects may be reversible, or irreversible, and can be immediate or delayed.

10.14.2.2 - Corrosives / Irritants (Skin, Eye, Respiratory)

Corrosive substances have the ability to cause visible destruction or irreversible alterations in living tissues by chemical action at the site of contact. Irritants can generate reversible damage upon contact, affecting skin, eyes, and respiratory tract.

10.14.2.3 - Sensitization (Skin, Respiratory)

A sensitizer is a chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

10.14.2.4 - Germ Cell Mutagenicity

Mutagens are chemicals that can modify the genetic material in the nucleus of cells in ways that allow the changes to be transmitted during cell division. Some mutations may result in cell death or the transmission of a genetic defect to other cells in the same tissue.

10.14.2.5 - Carcinogenicity

Carcinogens are substances capable of inducing or causing cancer or malignant tumor development, typically after repeated or chronic exposure. Carcinogens may cause no immediate harmful effects and may only become evident after a long latency period. Many factors influence the development of cancer, including the carcinogenic potency of the substance, the level and duration of exposure, and individual susceptibility to the carcinogenic action of the substance.

Entities, including the National Toxicology Program (NTP) and the International Agency for Research on Cancer (IARC) classify carcinogens after an extensive scientific review process. OSHA, NTP, and IARC all provide lists of specific substances identified as carcinogens.

In addition to chemicals, infectious agents--such as viruses, toxins, and physical agents, such as X-rays and ultraviolet radiation--may be classified as carcinogens.

10.14.2.6 - Aspiration Hazards

Aspiration hazards are substances that have the potential to enter the trachea and lower respiratory system through the oral or nasal cavity during inspiration, or breathing, in causing asphyxiation, injury, or other negative health effects. The hazard relates to the possibility of lung damage after

swallowing the product. There are different categories of aspiration hazards, ranked according to their level of toxicity. Essential oils sometimes have an aspiration toxicity hazard, which is common for low-viscosity hydrocarbon substances.

10.14.2.7 - Simple Asphyxiants

Simple asphyxiants are inert gases or vapors that can displace oxygen in ambient air when they become too concentrated. Inhaling ambient air with an oxygen level below 19.5% will cause inadequate oxygen supply to blood and organs within minutes after the exposure. Depending on the severity of the oxygen deficiency, the exposed person may experience symptoms including impaired attention, thinking or coordination; fatigue; nausea; vomiting; lethargy; loss of consciousness; and death. Symptoms may appear suddenly, and damage caused by lack of oxygen may be irreversible.

Some examples of simple asphyxiants include nitrogen, helium, neon, argon, krypton, xenon, methane, and ethane. Since these colorless and odorless gases offer no detectable warning properties, oxygen monitors are often used to verify oxygen levels in processes involving the use of these substances.

Another type of asphyxiant, chemical asphyxiants, can cause suffocation by either preventing the uptake of oxygen in the blood, or by preventing the normal oxygen transfer from the blood to the tissues or within the cell itself. Examples of these chemical asphyxiants include hydrogen cyanide and carbon monoxide.

Oxygen levels can also be consumed/reduced/displaced by rusting metals, ripening fruits, the drying of paints and coatings, combustion, and bacterial activities.

10.14.3 - Chemical Physical Hazards

OSHA states that a chemical is a physical hazard if it is likely to burn or support fire; may explode or release high pressures that can inflict bodily injury; or can spontaneously react on its own, or when exposed to water. OSHA Appendix B to 1910.1200 lists the physical hazards and definitions that will be discussed in this section. Appendix B also contains more detailed information on each physical hazard, if needed.

10.14.3.1 - Corrosive to Metals

A chemical that is corrosive to metals is a chemical that will materially damage or destroy metals by causing a chemical reaction.

10.14.3.2 - Explosives

An explosive substance (or mixture) is a solid or liquid that is, in and of itself, capable (by chemical reaction) of producing gas at such a temperature and pressure, and at such a speed as to cause damage to its surroundings. Pyrotechnic substances are included in this category even when they do not involve gases. A pyrotechnic substance (or mixture) is 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.

If you suspect a chemical could be potentially shock-sensitive and/or explosive, do not move the container in which it is found or held. Movement of containers containing potentially unstable chemicals could cause an explosion due to shock, heat, and friction sensitivity. Furthermore, be on the lookout for the following warning signs associated with potentially unstable chemicals that could

lead to an explosion: deterioration of the chemical's container, crystal growth on the inside or outside of the chemical's container, and/or discoloration of the chemical itself.

10.14.3.3 - Flammables and Combustibles

Flammable and combustible materials come in many forms, including gas, liquid, solid, and aerosol. These types of materials are associated with two main hazards: fires and explosions.

- **Flammable Gases** are flammable in air at 68°F and at a standard pressure of 101.3 kPa (14.7 psi).
- **Flammable Liquids** have a flash point of not more than 199.4°F. Substances and mixtures of this hazard class are assigned to one of four hazard categories based on their specific flash point.
- **Flammable Solids** are readily combustible or may cause or contribute to fire through friction.
- **Flammable Aerosols** are aerosols that contain any component classified as flammable according to the criteria for flammable liquids, flammable gases, or flammable solids.
- **Readily Combustible Solids** are powdered, granular, or pasty substances that are dangerous as they can be easily ignited if exposed to an ignition source--such as a burning match--and the flames will spread rapidly.

10.14.3.4 - Self-reactive Chemicals

Self-reactive chemicals are inherently unstable and susceptible to rapid decomposition, and/or can react alone in a violent, uncontrolled manner. This definition excludes chemicals classified as explosives, organic peroxides, oxidizing liquids, or oxidizing solids. They are thermally unstable liquids, or solids, liable to undergo a strongly exothermic thermal decomposition, even in the absence of oxygen (air).

10.14.3.5 - Pyrophoric (liquids or solids)

Pyrophoric liquids or solids are liable to ignite within five minutes after coming into contact with air, even if present in small quantities.

10.14.3.6 - Self-heating substances

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 type 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). Self-heating of a substance or mixture is a process in which the gradual reaction of that substance, or mixture with oxygen (in air), generates heat.

10.14.3.7 - Water-reactive materials

Water-reactive materials emit flammable gases when in contact with water. They 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.

10.14.3.8 - Oxidizers (liquid, solid or gas)

Oxidizers are chemicals or materials that have the ability to oxidize other substances, or, technically speaking, accept another substance's oxygen electrons. Oxidizers pose a safety concern due to their potential to promote and enhance fires. Fires need fuel, oxygen, and ignition sources. Oxidizers supply the oxygen, and, as a result, can facilitate burning or make fires burn hotter and longer.

Special precautions should be taken around oxidizers in which visible crystalline growth or discoloration of the chemical is observed or noted. Common oxidizing agents include:

- Oxygen
- Ozone
- Hydrogen peroxide and other inorganic peroxides, Fenton's reagent
- Fluorine, chlorine, and other halogens
- Nitric acid and nitrate compounds such as potassium nitrate, the oxidizer in black powder
- Potassium chlorate
- Sulfuric acid
- Peroxydisulfuric acid
- Peroxymonosulfuric acid
- Hypochlorite, chlorite, chlorate, perchlorate, and other analogous halogen compounds like household bleach
- Hexavalent chromium compounds such as chromic and dichromic acids and chromium trioxide, pyridinium chlorochromate (PCC), and chromate/dichromate compounds such as Sodium dichromat
- Permanganate compounds such as potassium permanganate
- Sodium perborate
- Nitrous oxide, Nitrogen dioxide/Dinitrogen tetroxide
- Sodium bismuthate
- Cerium (IV) compounds such as ceric ammonium nitrate and ceric sulfate
- Lead dioxide

10.14.3.9 - Gases Under pressure

Gases under pressure are gases that are contained in a receptacle at a pressure not less than 200 kPa (29 psi) or are gases that are liquefied or refrigerated. This covers four types of gases, or gaseous mixtures, to address the effects of sudden release of pressure or freezing which may result in serious damage to people, property, or the environment, independent of other hazards the gases may pose. The four types of gases under pressure are compressed gases, liquefied gases, refrigerated liquified gases, and dissolved gases.

10.14.3.10 - Organic Peroxides

An organic peroxide is any organic (or carbon-containing) compound having two oxygen atoms joined together (-O-O-). Organic peroxides are thermally unstable chemicals that may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

- Be liable to explosive decomposition.
- Burn rapidly.
- Be sensitive to impact or friction.
- React dangerously with other substances.

Given their instability, organic peroxides can rapidly decompose, leading to flammable vapors that can easily catch fire and burn intensely. This is due to the peroxides providing both the fuel and oxygen needed for the fire. Some chemicals become explosive peroxides during storage, further enhanced in their explosiveness by exposure to light and heat. Others become more dangerous as they are concentrated.

The plastics and rubber industries are the largest users of organic peroxides. They are used as accelerators, catalysts, hardeners, activators, and more.

10.14.4 - Additional Chemical Hazard Information/Resources

OSHA's Hazard Communication Standards webpage highlights OSHA standards, preambles to final rules (background to final rules), directives (instructions for compliance officers), and standard interpretations (official letters of interpretation of the standards) related to hazard communication including:

General Industry (29 CFR 1910)

- 1910 Subpart Z, Toxic and hazardous substances
  - 1910.1200, Hazard communication
    - Appendix A, Health Hazard Criteria
    - Appendix B, Physical Criteria
    - Appendix C, Allocation of Label Elements
    - Appendix D, Safety Data Sheets
    - Appendix E, Definition of "Trade Secret"
    - Appendix F, Guidance for Hazard Classifications Re: Carcinogenicity
  - 1910.1201, Retention of DOT markings, placards, and labels

OSHA's HAZARD COMMUNICATION: Hazard Classification Guidance for Manufacturers, Importers, and Employers provides guidance on the processes involved and identifies considerations in the conduct of hazard classifications. Guidance on the allocation of the hazard communication label elements is provided in the OSHA Brief on Labels and Pictograms, located on the Hazard Communication webpage.

Under the *Hazard Communication Standard* (29CFR1910.1200) established by OSHA, chemical manufacturers and importers are required to perform hazard classifications on the chemicals they produce or import. That information is available in SDS, formerly known as MSDSs, that employers are required to have readily available for review for each one of the chemicals present at their worksites. In general, SDSs provides information on the hazards of the product--including the physical and chemical properties, toxicology, handling and storage guidance, exposure controls, recommended PPE, first aid, firefighting and accidental release measures and any other applicable information. SDSs have sixteen sections; **carefully review sections 2 and 4** as the substance's hazards and first aid measures are listed under these two sections. SDSs can also easily be located online.

Labels and pictograms also aid in communicating chemical hazards information to personnel sharing the work environment.

The OSHA Occupational Chemical Database is OSHA's one-stop shop for occupational chemical information. It compiles information from several government agencies and organizations. Information available on the pages includes:

- Chemical identification and physical properties.
- Exposure limits.
- Sampling information.
- Additional resources.

10.14.4.1 - Chemical Labeling

When evaluating chemical hazards, review the chemical SDSs and any precautionary labeling. When conducting inspections of firms using chemicals, like pesticides, ask to review the SDSs for the

products involved to determine what, if any, safety precautions you should take. This could include the use of respirators or other safety equipment.

Sometimes, products encountered during field activities fall under alternate labeling requirements than cited references. For example, pesticides, food additives, and food and drug/cosmetic ingredients, and their facilities, may use specific databases for confidentiality reasons. **Regardless of any alternate labeling systems, the hazard information should always be disclosed to you.**

Terminology and standards may vary by country or region. If there is any confusion, contact your supervisor before entering potentially hazardous areas. If safety procedures at a foreign firm are inadequate for your protection, take precautions based on your training and experience with domestic activities. If you have any doubts about your safety at a foreign worksite, you should immediately move to a safe location, suspend the inspection as necessary, and contact your supervisor(s) for guidance.

Also review any precautionary labeling, such as Globally Harmonized System of Classification and Labeling of Chemicals (GHS), which is available. The primary purpose of GHS labels is to communicate chemical hazards to workers, or recipients, through signal words, pictograms, hazard statements, and precautionary statements.

OHSA maintains a section on its website with more in-depth information on GHS labeling and classification at: https://www.osha.gov/hazcom. The following, however, provides you with a basic description and pictogram of each of the nine GHS label chemical hazard classifications.



CORROSION

Health hazards: Skin Corrosion/Burns, Eye Damage, and other hazards.

Corrosives are highly reactive substances that cause obvious damage to living tissue. Corrosives can either directly destroy the tissue or indirectly by causing inflammation. They can also be corrosive to metals.



EXCLAMATION MARK

Health hazards: Irritant (skin and eye), Skin Sensitizer, Acute Toxicity (harmful), Narcotic Effects, Respiratory Tract Irritant, Hazardous to Ozone Layer (Non-Mandatory).

Chemicals or materials that can cause an immediate skin, eye or respiratory tract irritant, or narcotic



EXPLODING BOMB

Explosives, Self-Reactives, Organic Peroxides – Chemicals or materials that are highly unstable and at high risk of exploring even without exposure to air. A peroxide is a substance in which two oxygen atoms are linked together by a single covalent bond. This bond makes these peroxides capable of causing a severe fire or explosion hazard



FLAME

Flammables, Pyrophorics, Self-Heating, Emits Flammable Gas, Self-Reactives, Organic Peroxides - Chemicals or materials that can self-ignite when exposed to water or air, or which emit flammable gas. Pyrophoric refers to the property of a substance to ignite spontaneously upon exposure to air



FLAME OVER CIRCLE

Oxidizers - Chemicals or materials that have the ability to oxidize other substances, that is, they accept their oxygen electrons. As a result, these chemicals can facilitate burning or can make fires burn hotter and longer



GAS CYLINDER

Health hazards: Gas cylinders have numerous hazards ranging from direct or indirect exposure from the chemical gas itself, fire or explosion as the gas is under high pressure, and even trauma from improper handling such as sprains, strains, falls, bruises, or broken bones.

Gases Under Pressure – Chemical gases that are stored under pressure, such as ammonia or liquid nitrogen.



HEALTH HAZARD

Health hazards: Carcinogens are substances known to cause cancer. Mutagens are substances known to cause or increase the rate of changes to genes (sections of DNA in body's cells), these changes can be passed along as the cell replicates. Sensitizers are substances known to cause an allergic reaction in normal tissue upon exposure.

		Carcinogen, Mutagenicity, Reproductive Toxicity, Respiratory Sensitizer, Target Organ Toxicity, Aspiration Toxicity – Chemicals or materials that cause damage over time (a chronic, long-term health hazard).
	**SKULL AND CROSSBONES**	**Health hazards:** Acute Toxicity (fatal or toxic) - Chemicals or materials that have an immediate and sever toxic effect. Acute toxicity describes the adverse effects from a single exposure to a substance. These adverse effects can come from either oral (mouth) or dermal (skin) contact from a single dose of a substance, or multiple doses within a short period of time (24 hours), or inhalation exposure (4 hours)
	**ENVIRONMENT (NON-MANDATORY)**	Aquatic Toxicity - Chemicals or materials that are toxic to aquatic wildlife

10.14.4.1.1 - Resources related to Hazard Communication (HAZCOM)/chemical labeling

- OSHA Hazard Communication Publications
- OSHA Labels and Pictograms
- OSHA Hazard Communication Wallet Card
- 33 Hazard Classes | Postal Explorer (usps.com)
- US Department of Transportation Nine Classes of Hazardous Materials

10.14.5 – Special Chemical Hazards

Please note that this list is provided for your awareness and does not include every chemical hazard that you may encounter while working in the field. Be prepared to assess the chemical hazards on-site, ask questions of firm management, and consult with your supervisor and your IH *Contact(s)* for guidance to determine if you need to take additional precautions to protect yourself.

10.14.5.1 - Allergens/Hypersensitivities

Food allergies and food hypersensitivities occur when the body's immune system reacts to certain proteins in food. Food allergic reactions vary in severity from mild symptoms, including hives and lip swelling to severe, life-threatening symptoms, often called anaphylaxis, that may involve fatal respiratory problems and shock. In 2004, the U.S. Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA), which identifies eight foods as major food allergens: milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, and soy. On April 23, 2021, the Food Allergy Safety, Treatment, Education, and Research (FASTER) Act was signed into law, declaring sesame as the ninth major food allergen recognized by the United States. More than 160 foods have been identified to

cause food allergies in sensitive individuals. There are also several food ingredients that cause nonallergic hypersensitivity reactions in sensitive individuals. These ingredients include, but are not limited to, gluten, colorings, and food additives.

If you or a team member has an allergy or hypersensitivity to the commodity, or something related to the processing of the commodity, to be inspected, remember that your personal safety comes first. Consult with your supervisor about the potential to reassign the inspectional work, or to discuss the appropriate precautions to be taken. When discussing appropriate precautions, consider consulting with the Safety Liaison for your program or office.

10.14.5.2 - Animal Food Ingredients

Most animal food manufacturing establishments are no more unsafe than most human food manufacturing establishments. Many of the relevant safety hazards are addressed in this section, and include chemicals, allergens, fumigants, and confined spaces. Some feed manufacturers may have Type A medicated articles and/or concentrated minerals in their inventory to be used in manufacturing, so if you intend to sample or otherwise handle those materials, please read the label and observe any safe handling precautions.

If you are going to be conducting an inspection at a facility that manufactures Type A medicated articles, concentrated minerals (such as copper or selenium premix), or other specialty feed ingredients, it is helpful to know those substances in advance, so that you can be sure to have the appropriate PPE with you. You may need to wear a smock, dust mask, and gloves if you need to handle the materials (if you are sampling, for example). Feed manufacturing facilities may also be dusty, so if you are sensitive to dust, you may wish to wear a dust mask. Unless you are allergic to the chemicals present, a respirator should not be necessary, but if you think you would require one, consult with your supervisor and IH liaisons. Wash hands and other exposed skin when you are done.

Biosecurity is also important. Do not travel from an animal production facility or farm to a feed manufacturing facility on the same day, or in the same clothes or PPE, so as not to introduce hazards into any facility.

For any related questions or concerns, contact CVMAnimalFoodProgram@FDA.hhs.gov prior to conducting an inspection.

10.14.5.3 - Dry Ice- Transport and Use for Shipping Samples

Dry ice is potentially dangerous and requires caution in handling and shipping. Dry ice can cause cold burns and frostbite. Be sure to protect yourself by using the appropriate PPE, including safety goggles to protect your eyes from splashes; a face shield to protect sensitive tissues such as your mouth, nose, and other facial areas; and gloves to protect your hands (which should fit loosely so that they can be easily removed). When handling dry ice, also ensure that all other skin is covered with proper attire and that you wear closed toed shoes.

Dry ice can also contribute to an asphyxiation hazard. Dry ice should be stored and handled in well-ventilated areas. Dry ice should *not* be stored in sealed containers to prevent the risk of explosion. Do not handle with unprotected hands, transport in your car without adequate ventilation, or place inside tightly closed metal, plastic, or similar type containers that do not breathe. If it is necessary to use this type of container, adequately vent it to prevent pressure buildup. Do not use glass containers for packaging or storing dry ice. Again, make note that a failure to adequately vent a

container containing dry ice may cause a dangerous pressure build-up, resulting in serious risks to sample integrity and the personal safety of all those handling the container).

When shipping frozen samples using dry ice, packages shall be identified in accordance with CFR 49, the International Air Transport Association (IATA) Dangerous Goods regulations and the UPS Dangerous Goods Agreement and Checklist. See IOM 4.7.3.5.1 when shipping packages containing dry ice.

Any FDA employee who ships items subject to Department of Transportation's (DOT) hazardous materials regulations must complete Shipping Dangerous Goods Safety Training.

10.14.5.4 - Opioids

Opioids are substances derived from the opioid poppy or manufactured synthetic analogues. When conducting opioid sampling, adequate safety precautions should be observed during the sampling process. **Do not handle opioids, including fentanyl and fentanyl analogues, without appropriate PPE,** which may include nitrile gloves, coveralls, goggles, and a respirator, depending on the situation and exposure risk. Possible routes of opioid exposure may include inhalation, ingestion, and dermal contact. Opioids have the potential to be inhaled in situations where drug samples are disturbed, and particles have become airborne. Avoid tasks that may aerosolize fentanyl or other opioids. Change gloves if they become contaminated. Avoid contact with eyes, mouth, nose, or unprotected skin with contaminated gloves. Wash hands with soap and water immediately after sampling, or as soon as feasible. **Do NOT use alcohol-based hand sanitizers to clean contaminated skin as these products could increase the drug absorption.**

Opioid overdose symptoms include respiratory distress with slow, shallow breathing, small constricted "pinpoint" pupils, confusion, drowsiness, nausea and vomiting, and loss of consciousness. The opioid antidote medication Naloxone (Narcan) nasal spray can reverse the effects of opioid overdose and restore normal breathing. Naloxone (Narcan) training is available for individuals at risk for exposure to opioids. Contact a supervisor or industrial hygienist for training information. Additional information can be found at Preventing Occupational Exposure to Fentanyl and Fentanyl: Incapacitating Agent (includes PPE recommendations).

**Special and similar safety considerations should also be made for firms responsible for penicillin antibiotics, dietary supplements, and CBD products.*

10.15 - Physical and Radiation Hazards

Conditions at a firm may present a risk of injury to OII investigators. This section covers situations or conditions that may cause traumatic injuries, and physical agents, such as noise and radiation (ionizing and non-ionizing), that may lead to certain occupational illnesses. It will focus on specific topics that you should be vigilant about before and during a site visit.

Physical hazards are factors within the environment that can harm the body. Physical hazards include activities or natural substances in a work environment that pose health risks. Extreme temperatures, poor air quality, and excessive noise and radiation can all harm workers, potentially causing respiratory problems, hearing loss, and cancer, among other problems. This category also includes traumatic injuries, which are the most common physical hazards. Physical hazards are present in most workplaces, at one time or another, and include unsafe conditions that can cause immediate and acute injury, illness, or death.

10.15.1 - Traumatic Injury Hazards/Industrial Injuries and Energy Related Illnesses

10.15.1.1 - General Environmental Conditions

The OSH Act requires employers to comply with hazard-specific safety and health standards. In addition, pursuant to Section 5(a)(1) of the OSH Act, employers shall provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.

In some circumstances, **heat or cold stress** could be considered conditions that require training and other mitigation actions to be implemented. ROSS can be contacted if you have concerns regarding heat or cold stress. Temperature extremes can adversely impact the investigation process and put you at risk for heat or cold stress injuries. If you anticipate hot and/or humid conditions due to either the geographic location or the type of industry, attempt to staff the inspection team with members who are acclimated to similar conditions if possible. Inspections in potential heat stress conditions should be conducted by a team of two or more, with members observing each other for any signs of heat-related illnesses. If you anticipate significant exposure to cold conditions, prepare for the inspection by wearing suitably insulated clothing, or bringing appropriate PPE. In situations of extreme heat or cold, it may be necessary to plan work schedules to minimize the length of exposure. Information on temperature-related injuries and illnesses can be found on the OCS Regulatory Operations Safety Staff (ROSS)

Poor lighting can increase the risk of injury due to other causes, for example, by making it difficult to see tripping hazards. It may be possible in some cases to request a firm turn on additional lighting, or to wait for a time of day when natural lighting is better; but most likely the best solution will be using flashlights or other portable lighting.

Moving work surfaces, for example conveyor belts, can increase the likelihood of slip/trip/fall injuries or of striking/being struck by objects. Options for mitigating these increased risks may be limited. Supervisors should avoid assigning these inspections to individuals with medical conditions that may impair balance or equilibrium. Motion sickness may also be a concern. You should discuss potential working conditions with the firm and ask for the same advice that would be given to a new employee at the firm. FDA's Occupational Health Service (OHS) may be able to provide consultation and prescriptions to help deal with motion sickness for sensitive individuals.

10.15.1.2 - Slips, Trips and Falls

Fall hazards can be related to floor conditions, as well as elevated walking surfaces. Poor floor conditions can put you at risk for slipping or tripping. Slipping results from not having enough traction between footwear and the floor surface, while tripping results from either too much friction or uneven surfaces. Common slipping hazards in industrial facilities include ice, highly polished or worn floors, or fine powders on the floor. Under good lighting, any of these hazards are generally easy to spot, but it can be easy to overlook changes in floor conditions when moving from one area of a firm to another, especially in poor light conditions. For example, entering cold storage areas may put you at risk for slipping on icy or slushy floors. Similarly, tripping hazards due to slight changes in floor level are common where buildings have been added or extended over the years.

A fall from any height can cause injury, but federal safety regulations require protection at heights of 48 inches or more. The most common practice in industry is to install standard guard rails where a fall of 48 inches or more is possible, or where a shorter fall would result in exposure to a hazard

below, such as landing on machinery. Standard guard rails in industrial facilities exist as they do in most other buildings, with a top rail that is roughly at waist height for most adults, and an intermediate rail halfway between the top rail and the floor. Avoid moving closely to ledges that are not guarded by a substantial rail, and remain at least far enough away that slipping, tripping, or being bumped or knocked into would not put you at the edge.

Some firms use personal fall restraint or fall arrest systems near unguarded ledges. Fall restraint systems use a belt or harness attached to a short lanyard, generally preventing workers from getting close enough to the edge to fall off. A fall arrest system uses a harness and shock-absorbing lanyard that will decelerate should a worker fall, bringing them to a stop before reaching the floor. Note that a successful fall arrest is still likely to result in injuries but reduces the chances of more significant ones. Fall restraint and arrest systems require careful fitting and significant training to use safely. **Do not use fall restraint or fall arrest systems provided by a firm.** If you are in a situation in which such a system seems to be the optimal, or only, option for completing an inspection, contact your supervisor and seek advice from your supporting Industrial Hygienist.

10.15.1.2.1 - Manlifts

A manlift is a device consisting of a power-driven, endless belt moving in one direction only, outfitted with steps or platforms and attached handholds, for the transportation of personnel from floor to floor.

Do not ride on a rotating belt, manlift style elevator at any time.

10.15.1.2.2 - Aerial Work Platforms

Many firms have aerial work platforms, mobile aerial devices, or bucket trucks to provide temporary access to elevated areas of a facility. The major causes of injuries and fatalities involving aerial lifts are falls, electrocutions, and collapses or tip-overs. Aerial devices include boom-supported aerial platforms, such as cherry pickers or bucket trucks, aerial ladders, and vertical towers. (Note that OSHA regulates scissor lifts as mobile scaffolds, not as aerial devices).

Do not operate or ride in firm aerial work platforms. Specific operational and safety training is required to utilize the equipment. If you are in a situation in which it appears necessary to use such a platform to complete an inspection, contact your supervisor and seek guidance from your supporting IH.

10.15.1.2.3 - Non-Permanent Scaffolding

A scaffold is an elevated, temporary work platform. There are two basic types of scaffolds:

- Supported scaffolds, which consist of one or more platforms supported by rigid, load-bearing members, such as poles, legs, frames, outriggers, etc.
- Suspended scaffolds, which are one or more platforms suspended by ropes or other nonrigid, overhead support.

Note that other types of equipment, principally scissor lifts and aerial lifts, can be regarded as other types of supported scaffolds.

Potential injuries associated with all scaffolds:

- Falls from elevation, due to lack of fall protection.
- Injuries due to collapse of the scaffold, caused by instability or overloading.
- Injury as a result of being struck by tools, work materials, or debris that have fallen from the scaffold.

- Electrocution, due to the proximity of the scaffold to overhead power lines.

Do not stand on non-permanent scaffolding at any time.

10.15.1.2.4 - Ladders

Per OSHA Fact Sheet on Fall Protection Standards: Falls from ladders account for 20 percent of all fatal and lost work-day injuries in general industry. In general, ladders must be capable of supporting their maximum intended load, while mobile ladder stands and platforms must be capable of supporting four times their maximum intended load. **Each ladder must be inspected before initial use in a work shift to identify defects that could cause injury.**

Fixed Ladders – Fixed ladders are permanently attached to a structure, building, or equipment. These include individual-rung ladders, but not ship stairs, step bolts, or manhole steps. New OSHA rules have phased in a requirement for employers to have ladder safety or personal fall arrest systems for fixed ladders that extend more than 24 feet, phasing out the use of cages or wells for fall protection.

Portable Ladders – Portable ladders usually consist of side rails joined at intervals by steps, rungs, or cleats. They can be self-supporting or lean against a supporting structure. Firms must ensure that:

- Rungs and steps are slip-resistant.
- Portable ladders used on slippery surfaces are secured and stabilized.
- Portable ladders are not moved, shifted, or extended while a worker is on them.
- Top steps and caps of stepladders are not used as steps.
- Ladders are not fastened together to provide added length, unless designed for such use.
- Ladders are not placed on boxes, barrels, or other unstable bases to obtain added height.

If you find it unavoidable to use a ladder, follow OSHA Ladder Safety, including the following guidelines:

- Inspect the ladder being used/provided by the firm. If the ladder provided by the firm is not in good repair, ask the firm for another ladder.
- As available, read and follow any manufacturer's labels or markings on the ladder, including the maximum load rating.
- Do not use ladders that are damaged or in disrepair.
- Do not use makeshift ladders, or ladders that are positioned on top of boxes or unstable bases.
- Always maintain a three-point contact with the ladder when climbing.
- If possible, avoid carrying supplies or materials in your hands while climbing a ladder.
- Do not stand on the top rung unless it is designed for that purpose.
- If using a ladder, follow a 4:1 ratio for maintaining the proper angle of a ladder--that is, for every four feet of ladder height up to where the ladder rests on a surface, position the ladder base one foot away from the wall, with three feet extending beyond the upper landing surface.
- Do not overextend the ladder.
- Have someone hold the ladder while you are using it.

- If collecting samples while on a ladder, extreme care should be taken to not overreach, or lean too far beyond the center of the ladder and increase the risk of falling.

10.15.1.2.5 - Overhead Hazards

Overhead hazards are defined as hazards located above you that you may encounter or that can fall on you. They also include hazards associated with work activities that require you to do something above your head. Some overhead hazards include dropped objects, powerlines, and flying/fixed objects.

You should never walk under a suspended or elevated load. Avoid walking under powerlines if possible. Work conducted in areas with overhead hazards should be limited to only what is necessary. Proper head protection should be worn at all times.

10.15.1.2.6 - Machinery Hazards

You will encounter a variety of machinery types during your inspectional activities. Per OSHA, each piece of machinery has its own unique mechanical and nonmechanical hazards. Machines can cause severe injuries, such as amputations, fractures, lacerations, or crushing injuries. Machines can also cause minor injuries, such as bruises, abrasions, sprains, strains, burns, or cuts.

Examples of mechanical hazards that can hit, grab, or trap are:

- Hazardous motions.
- Points of operation.
- Pinch points and shear points.

There are different types of hazardous mechanical motions and actions:

- Hazardous motions such as rotating parts, reciprocating parts, or traversing parts.
- Hazardous actions such as cutting, punching, shearing, or bending.

Nonmechanical Hazards can also injure operators, or those nearby, and include flying chips, splashes, or sprays that are created when a machine is running.

Normal practice in industry is to enclose, or guard, any moving parts or pinch points on machinery that could strike, entrap, or otherwise injure workers. Typically, such practice is required for any point of operation hazards within seven feet of the floor or other walking surface. Do not assume the machine guarding meets an OSHA standard. Extreme care should be taken when working in or around moving parts of equipment.

10.15.1.3 - Energy Hazards

Energy sources, including electrical, mechanical, hydraulic, pneumatic, chemical, nuclear, thermal, gravitational, or other sources in machines and equipment, can be hazardous. Be aware of the potential for any of these types of energy hazards.

10.15.1.3.1- Thermal Energy

Thermal energy occurs when heat or cold is produced by mechanical devices (combustion and/or friction), electrical resistance, or chemical reactions (or changes of state like cryogenic materials). Boiling water is an example of thermal energy. Burns can occur due to both cold and hot forms of thermal energy, with the severity of the burn dependent on temperature and duration, or contact.

10.15.1.3.2 - Residual Energy

Residual or stored energy is energy within the system not being used, but when released, can cause severe injuries, even though equipment has been turned off or locked out.

10.15.1.3.3 - Electrical Energy

Electrical energy is the most identified form of energy in workplaces. It can be available through power lines, induced, or stored, for example, in batteries or capacitors.

10.15.1.3.3.1 - Electrical Systems

Many inspectional activities are performed in poorly lit areas, or in older, poorly wired buildings. Be alert for low hanging wires, or bare, exposed, or worn wires, and broken or cracked electrical outlets.

When you are using portable power tools, etc., be extra cautious of the shock hazard. See Inspection Technical Guide # 22, Ground Fault Circuit Interrupter, regarding Ground Fault Circuit Interrupters. Use one if feasible.

10.15.1.4 - Powered Industrial Vehicles

10.15.1.4.1 - Forklifts

Forklifts are powerful vehicles commonly used for lifting and moving heavy loads. Some of the most common forklift accidents include overturns, being struck by a forklift, and falls from a forklift. *You are not to operate a forklift* as specialized training is required.

Accidents/injuries can be the result of forklifts and pedestrians traveling or moving in the same area. Forklift traffic should be separated from pedestrians wherever possible. Be aware of and stay within any floor markings, walkways, or aisles that delineate where you should be walking or that separate pedestrians from forklift and other vehicle traffic.

Additional forklift safety/vehicle reminders:

- Be aware that vehicles cannot stop suddenly. They are designed to stop slowly, to minimize load damage and maintain stability.
- Stand clear of vehicles in operation, including lifting and moving loads.
- Avoid a run-in. The driver's visibility may be limited due to blind spots.
- Be aware of the vehicle’s wide, rear-swing radius.
- Never pass under an elevated load.

10.15.1.4.2 - Moving Cranes

Moving cranes are used for lifting and moving heavy loads; but, unlike a forklift, the load is suspended overhead from a cable attached to the crane. Both the crane and the load attached can pose a serious hazard. Ensure you maintain a safe distance from the crane if the crane/load tips or shifts.

10.15.1.4.3 - Mobile Elevated Work Platform (MEWP)

A MEWP, also known as a cherry picker, is a movable platform to help with high-level access tasks. Due to the heights involved, a serious fall or electrocution from a MEWP may be fatal. Due to the specialized training to operate this vehicle, consult with your supervisor and the ROSS before entering the basket of this type of vehicle.

10.15.1.4.4 - Semi Trucks

Semi-trucks and attached trailers have larger blind spots and require extra space to maneuver. Loading docks, where semi-trucks pickup or drop, are frequent locations of accidents due to these blind spots. As with any type of moving vehicle, maintain a safe distance from any moving semi-trucks.

You may be required to enter the trailer or take a sample from the top of the trailer. Prior to any activities inside or from the top of a trailer, ensure the truck is properly blocked in a way to prevent anyone from moving the truck while you are in or around it. Also ensure that you cannot be trapped or locked inside a trailer, via LOTO, or with the aid of another person.

Take frequent breaks if you are entering a trailer in hot weather.

If you take samples from the top of the semi-trailer, ensure proper safety precautions for climbing ladders. Never enter a trailer from the top.

10.15.2 - Radiation Hazards

Potential exposure to radiation can be found in nearly every OII program because many FDA-regulated facilities use or manufacture radiation-emitting electronic products, including laser products, x-rays used in medical devices and blood banks, radioactive material used in positron emission tomography, and radiopharmaceuticals. Additionally, import and domestic inspectors may be asked to collect FDA-regulated products that possess potential radioactive contamination. Portable instrumentation used by OII inspectors may also have an associated radiation hazard, including handheld or benchtop chemical analyzers.

Below is a brief overview of these hazards. For a full list of up-to-date radiation safety resources, including, but not limited to training requirements and contacts, visit ROSS Radiation and Laser Safety Resources.

10.15.2.1 - Examinations with Non-Ionizing Radiation Hazards

Equipment that produces non-ionizing radiation can be found in nearly any inspection. Typical non-ionizing radiation encountered includes lasers, radiofrequency waves, microwaves, and ultraviolet light. Protective eyewear and other equipment for non-ionizing radiation must be provided by the manufacturer. If you see signs or placards indicating the presence of non-ionizing radiation hazards (for example, a sign marked “Laser Area”) do not enter the area unless provided with proper protective equipment.

If you believe there is a non-ionizing radiation hazard and you have *not* been given PPE by the firm, either do not enter the area, or tell a representative from the firm to power-off all equipment producing non-ionizing radiation hazards before continuing.

10.15.2.2 - Examinations with Ionizing Radiation Hazards

OII strives to limit exposures to the Nuclear Regulatory Commission’s (NRC’s) public limit and considers 99% of the OII inspectorate as non-radiation workers. OII issues radiation dosimeters, radiation pagers, and radiation awareness summaries to employees engaged in the following activities or assignments:

- Operations involving an XRF analyzer.
- Import examinations. CBP also utilizes some radiation-based technologies to screen incoming shipments.

- Positron emission tomography inspections.
- Radiography x-ray inspections.
- Radiopharmaceutical inspections.
- Fluoroscopy inspections.
- Mammography inspections.
- Computed tomography inspections.
- Sterility facility inspections.
- Blood bank facility inspections.
- Imports/domestics (in cases of radiologically contaminated products).

Dosimeter Monitors are assigned to individuals by OII Program Management, who are responsible for distributing and collecting dosimeters at the end of each wear period. For an updated list of dosimeter monitors, see ROSS Radiation and Laser Safety Resources.

It is important to keep in mind that dosimeters only record radiation exposures, which can only be discovered after a potential radiation exposure event has occurred. Radiation Pagers, on the other hand, will warn an inspector of dangerous radiation while in the field, in-situ. If a Radiation Pager alarms, immediately leave the area. See Radiation Awareness for Dosimetry and Pager Users.

Upon inspecting a facility that contains ionizing radiation, OII employees should expect to be given a firm-issued dosimeter, or other device, to measure radiation exposure. Per NRC and Agreement State regulations, visitors to facilities are considered members of the general public. If you do not receive any equipment from the firm, proceed with caution.

10.15.2.2.1 - When to stop examinations/collections due to Ionizing Radiation Hazards

If you encounter any of the following situations during an inspection, stop work immediately and contact your supervisor(s):

- Radiation levels above the general public limit (as alerted via pager alarms).
- The use of any uncontained, volatile, or loose radioactive material.
- Collection of radioactive samples that cause pager to alarm above public limit.
- Collection of radioactive samples that are powdery or volatile.

Individuals assigned to these duties are considered radiation workers. In addition to completing awareness training and carrying a dosimeter and pager, these individuals must complete hands-on classroom radiation safety and advanced equipment training approved by the ROSS health physicist (HP).

10.15.2.3 - Radioactive Product Sampling

Sampling of potentially contaminated FDA-regulated products from all FDA programs could result in potential internal and external exposures to ionizing radiation. Safety equipment required for working around these products includes radiation dosimeters and radiation pagers. Sampling of volatile or powdery material containing radioactive particles requires special training. Air monitors or use of respirators may also be required. DOT and IATA regulations pertain to shipping radioactive samples. Contact Supporting IH and ROSS HP for details at ROSS Radiation and Laser Safety Resources SharePoint Site.

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10.15.2.3.1- Pager Alarm Levels

There are multiple models available to OII Staff. Some models show a dose rate (i.e. µrem per hour or µR per hour) and others show a unitless number (i.e. 1-8) corresponding to a dose rate. It is critical to correctly interpret the displayed values on the specific pager you are using. Consult the **ROSS Radiation and Laser Safety Resources SharePoint Site** for guidance specific to the model of pager you are using.

10.15.2.3.2 - Radiation Pagers and the FDA's Derived Intervention Levels

- Radiation Pagers are an appropriate tool for warning OII Inspectors of high external radiation fields and potentially dangerous dose rates. However, these instruments are not suitable for determining whether samples are safe to consume per the FDA's Derived Intervention Levels (DILs). The Office of Import Operations has access to Radioisotope Identification Devices (RIID) which are capable of detecting radionuclides near the FDA DIL levels. Contact your supervisor to request an RIID.

10.15.2.4 – Field Instrumentation That Contains Hazards

The following handheld and benchtop instruments used during some field investigations contain radiation hazards:

• X-ray fluorescence Spectrometer and other xray equipment with external ionizing radiation hazards.

• Ion Mobility Spectrometer with potential radioactive contamination hazards.

• Raman Spectrometer with laser hazards to the eyes. Details on using these instruments safely can be found on the ROSS Radiation and Laser Safety Resources SharePoint Site.

10.15.3 - Animal Hazards

Inspections, particularly of farms and outdoor operations, have the potential to have animals and insects present.

As an investigator, you may encounter domesticated animals such as, dogs, cats, cattle, horses, chickens, sheep, etc., as well as wild animals, such as foxes, coyotes, badgers, wolverines, martens, rodents, spiders, and snakes, etc., during farm and outdoor operations. Be aware that any animal species can be dangerous, depending on circumstances. You may also experience infectious disease transmission from mosquitoes and ticks, small animal bites and swelling, or mild to severe allergic reactions from stinging insects.

Animal behavior can be unpredictable; you should remain constantly alert and watch for warning signs of animal aggressiveness and fear. These vary with animal breeds, but may include raised fur, flattened ears, twitching tails, or bared teeth. If a potentially hazardous encounter occurs, you should make no attempt at engaging with the animal and instead should vacate the area immediately and notify firm management as necessary.

Wear appropriate clothing for the situation. Wear long pants and sleeves, and boots taller than the ankle, as appropriate for the inspection and area. Use insect repellant. Stay out of tall grass and keep hands and feet out of areas you cannot directly see. If an encounter with an animal occurs in which you are injured, including a snake/spider/dog bite, seek emergency help immediately.

For snake bites, responding quickly is crucial. Immediately call for emergency medical attention. While waiting for emergency help to arrive, wash the area with soap and water if possible and apply a cold

compress. Keep the bitten area lower than the heart and remove any constricting clothing and jewelry from the extremity as the area may swell. Note the time and location of the bite to report to emergency room personnel. Try to remain calm while waiting for help to arrive.

10.15.3.1 - Dog bites/attacks

If you are going to be conducting an inspection or investigation where you may encounter dogs--such as, but not limited to, the private residence of an individual, a shell egg producer, farm facility, or warehouse--you should exercise caution. If the inspection or investigation will be pre-announced, ask if there are farm or guard dogs on the property, and if so, whether they will be leashed or kenneled before your scheduled arrival. If the inspection will not be pre-announced, observe the area carefully prior to exiting your vehicle. Be aware of common places that dogs may hide, including under parked cars and hedges, or on porches. Upon exiting the vehicle, be aware of your surroundings to see if any noises from the vehicle, shutting doors, etc., have aroused the attention of a dog on the property. If an employee is present on the property, ask if any dogs are present. If you are entering a fenced-in area, rattle the gate before entering to alert animals to your presence and reduce chances of conflict. If you are bitten by a dog, seek medical care and report the incident to your supervisor. For additional information, refer to:

- ROSS Guide for Dog Encounters
- Dog bite prevention | American Veterinary Medical Association (avma.org)
- Dog Bite Prevention | ASPCA
- Dog Attack Information for All Mail Carriers (usps.com)
- Be Aware: Any Dog Can Bite - Postal Posts (uspsblog.com)
- 'Watch That Dog' explains basic protection and provides insight into the mannerisms of various types of dogs. This video from the Oregon OSHA Workplace Education and Training Grant Program https://osha.oregon.gov, tells how to protect yourself from possible attack and injury.

10.15.4 - Specific Industries

10.15.4.1 - Grain Handling Facilities

Grain storage structures, such as grain elevators and feed mills, can present life-threatening hazards. It is always preferable to inspect them or collect samples from the outside. If it is not possible to collect the samples from the outside, consult your supervisor prior to collection.

Before entering a grain storage structure, be sure to:

- Meet with the facility's operator to discuss hazards that may be present in the storage structure, including entrapment or engulfment in grain, asphyxiation, or the presence of toxic or flammable atmospheres, as well as procedures to be followed in the event of an emergency.
- Confirm that the operator will lock out any moving equipment within the storage structure, such as conveyors and augers, and will conduct atmospheric tests for oxygen, combustible gases, and toxic gases. Contact your supervisor for any questions.
- Refer to Man Lifts and Ladders for guidance. Do not use a man lift without supervisory approval.
- Make sure cross-rungs on ladders are safe.

- When stepping off of ladders or man lifts, be sure the floor is a true floor and not a bin covered with canvas, cardboard, or other temporary non-supportive cover.
- Never stand or walk across the surface of the material stored in a silo. The surface may only be a “thin crust” over a hollow space in the silo. Breakthrough the crust often causes death by engulfment of the material and subsequent asphyxiation.
- Make sure walkways between bins are sturdy.
- Use caution when sampling from high bins or tanks. Wet or icy conditions may prevail, so check these conditions.
- When brass grain bombs are used to collect bin samples, do not drop the bomb to the surface of the grain. This activity could cause sparks if the bomb hits the bottom or side of a bin. Instead, lower the bomb gently to the grain surface, then raise it four to five feet and let it fall to the grain surface to collect the sample. ***Do not use steel grain bombs***; use only brass bombs for sampling.
- Do not use flash units in dusty areas because of the possibility of explosion hazards. Any electrical devices used, including flashlights, cell phones, communication radios, and similar devices, should be explosion-proof.
- Do not enter a grain storage structure without appropriate PPE, or if you see that any grain is frozen or caked to the walls. Wear PPE during inspection and sampling, including for bump caps.

10.15.4.2 - Rail Safety

10.15.4.2.1 - Railyards

Railyards are dangerous areas. If there is a Safety Office at the yard, inquire about specific information concerning current hazards.

Maintain a safe distance from equipment in motion and cross tracks at right angles, whenever possible, without stepping on rails. Be aware of the pressure wave created as a train (or any moving vehicle) passes. This force can knock people down and into the path of subsequent cars.

10.15.4.2.2 - Railcars

When sampling railcars, make sure doors are propped open to avoid accidental closing if the car is bumped while you are in it. Display a warning flag or similar device to alert others that you are in the car. Always have a railroad yardman or another FDA investigator present. When entering the car, make sure the ladder is secure. On hot days, or after a car has been fumigated, it should be aired out prior to entering, preferably by opening both doors. Observe "No Smoking" in rail cars. Never crawl under railcars –walk around them. Avoid any cables between the railroad tracks. These are often used to move cars on sidings. A cable snapping taut can kill or maim.

10.15.4.3 Other Industries

Other inspected commodities that can pose **unique** safety challenges include, but are not limited to:

- Egg-producing facilities
- Compounding pharmacies
- Seafood
  - Vessels
- Produce farms
  - Irrigation canals

- Sprouts
  - Chlorine solutions
- ITS
  - Watering points
  - Airports
  - Cruise ships
- Imports/IMF
- Tissue/drug residues

With the above special situations, and others like them, be sure to consult any available compliance programs , assignments, commodity SMEs, InsideFDA.gov SharePoint sites, QMiS, as well as your IH liaison for safety considerations and precautions.

10.16 - Ergonomic

Per OSHA: Musculoskeletal disorders (MSDs) affect the muscles, nerves, blood vessels, ligaments and tendons. You can be exposed to risk factors at work, such as lifting heavy items, bending, reaching overhead, pushing, and pulling heavy loads, working in awkward body postures, and performing the same or similar tasks repetitively. Exposure to these known risk factors for MSDs increases your risk of injury. Ergonomics --- fitting a job to a person --- helps lessen muscle fatigue, discomfort, pain and reduces the number and severity of work-related MSDs. Ergonomic risk factors are workplace situations that cause wear and tear on the body and can cause injury. These include repetition, awkward posture, forceful motion, stationary position, vibration, and extreme temperature. Exposure to multiple factors increases the risk of developing MSDs.

Ergonomic injuries occur when the type of work, body positions, and/or working conditions you must engage in put strain on the body. Symptoms, the strain on your body or the harm that these hazards pose aren't always immediately noticeable. Short-term exposure may result in "sore muscles" the next day or in the days following exposure, while long-term exposure can result in serious long-term illnesses. Poor ergonomics can lead to health issues for employees, such as cumulative trauma disorders, repetitive motion injuries, and musculoskeletal disorders. Often, ergonomic hazards arise due to poor or inadequate workplace design.

If needed, Regulatory Operations Safet Staff (ROSS) can provide advice on selecting tools and equipment that CSOs will use in the field as well as on work techniques to minimize the risk of musculoskeletal disorders. Consult with your supervisor and/or contact Regulatory Operations Safety Staff.

10.16.1 - Force

Tasks that require large amounts of force and/or large amounts of force relative to the affected body part increase the risk for ergonomic injury. Examples include forces on the lower back when lifting heavy objects and forces on the elbow while striking an object with a hammer. Examples of force-based hazards may include lifting/carrying/lowering/pushing/pulling heavy objects such as samples, sample supplies, or inspectional equipment.

When possible, reduce the amount of force on your body when performing tasks. Effective strategies include using proper tools and equipment, designing and/or planning work to avoid unnecessary forces on the body, and using safe work practices, such as team lifting of heavy and/or awkwardly shaped objects.

10.16.2 – Awkward, Same Posture/Improper Adjustments

Working in awkward body positions and/or with equipment not properly designed for the user increases the risk of ergonomic injury. Examples may include hunching over a workstation that is too short or using equipment that hasn't been adjusted to an individual's preference/size. Whenever possible ensure equipment and tools are properly adjusted to ensure user comfort and ergonomically sound positioning.

10.16.3 - Repetition

Tasks that require multiple repetitions put cumulative stress on the affected body parts, increasing the risk of ergonomic injury. Examples of tasks often done repetitively or for extended periods of time include collecting swab samples or using a mouse and keyboard. When possible, plan work to reduce the number of repetitions of a task you must complete, take frequent breaks, and avoid repeatedly performing tasks that require large amounts of force and/or awkward positions.

10.16.4 - Cold Temperatures

In combination with any one of the other risk factors, cold temperatures may also increase the potential for MSDs to develop. For example, many of the operations in food processing occur with a chilled product or in a cold environment.

10.16.5. - Vibration

Both whole body and hand-arm vibration can cause a number of health effects. Hand-arm vibration can damage small capillaries that supply nutrients and can make hand tools more difficult to control. Hand-arm vibration may cause a worker to lose feeling in the hands and arms resulting in increased force exertion to control hand-powered tools in much the same way gloves limit feeling in the hands. The effects of vibration can damage the body and greatly increase the force which must be exerted for a task.

10.16.6 - Special Ergonomic Situations

Inspectional and investigational tasks with an increased likelihood of exposure to ergonomic hazards include sampling and processing equipment inspections that could involve lifting, improper adjustments and repetition. Strategies for reducing the likelihood of ergonomic injury are listed below.

10.16.6.1 - Sampling

Sampling can involve repetitious motion in awkward positions, and the transportation of sampling supplies to and from a firm can require large amounts of force. When sampling, try to minimize time spent in awkward or uncomfortable positions, and switch roles with other members of the sampling team periodically to reduce bodily strain. Use containers and bags that are easy to lift, preferably with handles on them, to transport sampling supplies. If a bag or container is heavy, request help from another member of the sampling team.

10.16.6.2 - Processing Equipment Inspection

Inspecting processing equipment can require moving and or staying in awkward body positions for extended periods. When inspecting, use equipment such as cameras or mirrors, when possible, to visually inspect equipment without assuming an awkward position. If you must assume an awkward position, ensure you have your flashlight, camera, and/or other equipment necessary for evidence collection ready, to avoid remaining in the positions for longer than necessary.

10.17 - Employee and Traveler Health and Safety

10.17.1 - FDA Occupational Health Services (OHS)

FDA OHS has health units established for employees to receive occupationally related medical services. Each health unit provides access to on-site first aid and urgent care services; onsite clinical care, referral, and follow-up for work related injury and illness; immunizations; health risk appraisals; health screenings; health counseling; and health and wellness education. Services are provided by appointment only. To request OHS services **Outside the National Capital region**, send an email to occupationalhealthservices@fda.hhs.gov. Call 911 for medical emergencies.

10.17.2 - Immunizations

FDA provides operating field personnel with various immunizations for protection from infection or injury on the job. Utilize the following CDC sites, tools, and schedules to determine your immunization status:

- Adult Vaccination Home Page
- Adult Vaccine Assessment Tool
- Adult Immunization Schedule

10.17.2.1 - Domestic Work

You may need vaccines based on your age, health conditions, job, lifestyle, or travel habits. Learn more about what other vaccines the CDC recommends for you and talk to your OHS about which vaccines are right for you.

10.17.2.2 - Foreign Travel

Reference the Immunizations and Other Health-Related Topics site for information on immunizations and/or prophylactic medications for foreign travel.

Consult with your supervisor and trip planner, well in advance of planned foreign travel, as to specific requirements of the countries to be visited. *FDA employees are responsible for ensuring they have received recommended immunizations and/or prophylactic medications specific for their official travel destinations.* Immunizations and prophylactic medications are provided at no cost to employees that travel internationally as part of their official duties.

10.17.3 - Physical Examinations

There is no requirement for periodic physical examinations. Even so, it is your responsibility to adhere to good personal hygiene and health practices. If any firm management demands evidence of recent physical examination before permitting inspection, consult your supervisor. A mere request to examine your hands for sores, etc., is not unreasonable. However, do not accede to a physical examination.

10.17.4 - Traveler Health

10.17.4.1 - Domestic Travel

Refer to your division/supervision, DTO and CDC Travelers' Health-United States for domestic travel health issues.

10.17.4.2 - Foreign Travel

In addition to the immunization information above for foreign travel, the Division of Travel Operations (DTO) has captured materials and resources that serve as a supplement to the trip-

specific communications that are sent to the foreign traveler. Be sure to visit the: Pre-Travel, During Travel, Post-Travel, Contact Information links below to find useful information that may assist you through all aspects of the foreign trip process.

The Foreign Travel Resources Page is a list of helpful resources for use when conducting foreign travel:

- Policy, Procedures and Guidelines
- Pre-Travel
- Health Information
- Commonly Used Terms Associated with Foreign Travel
- During Travel
- Post-Travel

All investigators conducting OII foreign inspections shall take required courses and trainings prior to departure. You should contact your program office for information on these courses.

- The online training CT401 found at https://sis.fsi.state.gov/MySISWeb/s/coursesearch was developed for staff who spend *90 days or less* outside of the country per year. The training remains good for six years.
- Staff who spend *90 days or more* outside the United States (including OII foreign cadre staff), are required to attend and complete training CT650 found at https://sis.fsi.state.gov/MySISWeb/s/coursesearch . All assigned overseas staff shall attend this intensive course. This training remains good for six years.

10.17.4.2.1 - **Pre-Travel**

If the CDC has issued a Travel Notice (Level 1: Watch, Level 2: Alert, Level 3: Warning) for your destination, make sure to discuss the notice with your supervisor/trip coordinator and during your health appointment.

10.17.4.2.2 - **During Travel**

This page details important information for the traveler while on official government travel.

10.17.4.2.2.1 - Medical Emergencies and/or Medical Assistance Abroad

In case of any emergency such as illness, injury or safety concerns, travelers should seek medical attention immediately. After treatment, contact your supervisor, trip coordinator (if unavailable, the coordinator's supervisor) or any other OII contacts provided on the itinerary. Never postpone seeking medical attention if seriously ill or injured. Federal employees are covered by the Federal Employees' Compensation Act (FECA) while on government business abroad for work-related injury or illness. Review Medical Emergencies and/or Medical Assistance Abroad for additional information.

Before travelling internationally, FDA employees should check with their private medical insurance providers regarding what services and coverage they will have in case they become ill or injured in a foreign country. ***FDA does not provide separate medical insurance or reimbursement for non-work-related medical treatment while on foreign travel.***

Commissioned Corps Officers in TDY/TAD OCONUS may seek medical care through use of the Tricare Overseas Program (TOP). For more information, call 1-888-777-8343 (from the U.S.), visit TOP site for country-specific contact information or access the website at

TRICARE Overseas Program. Also see the MyCare Overseas™ Beneficiary Mobile App and Portal, available via laptop or personal computer, providing easy-to-access services, such as checking your TRICARE Health Plan, verifying TRICARE covered services, finding a TOP Network Provider, and offering connections to 24/7 assistance to the local Near Patient Team (in specified locations), the Global First Call Desk, the Beneficiary Support Center (BSC), as well as Technical Support. There is also a self-service ChatBot feature that provides immediate answers to Frequently Asked Questions, and, if needed, a link to chat directly with the BSC. Reference the TRICARE Overseas Handbook for additional information.

After obtaining any necessary emergency treatment, use the Employees' Compensation Operations and Management Portal, ECOMP - U.S. Department of Labor (dol.gov), for completing required incident reports (OSHA-301) and worker's comp forms (CA-1 or CA-2). OSHA-301 shall be completed within seven days of injury or illness. CA-1/CA-2 shall be completed within 30 days. If unable to access ECOMP website, or to complete forms, contact your trip coordinator, or your division representative within FDA Human Resources.

10.17.4.3 - Travel Health Kit

The CDC offers a plethora of traveler health information at CDC Travelers' Health and CDC Traveler Advice. At CDC Pack Smart, the CDC provides a checklist to prepare for your next trip. The website states that, particularly if travelling abroad, to make sure to bring items with you, since the quality of items bought overseas cannot be guaranteed. Not all items may be relevant to you and your travel plans. Additional travel tips include:

- Keep any needed routine prescription meds in your carry-on luggage and bring extra meds, if applicable, for possible travel delays. Bring copies of all prescriptions (meds, devices, glasses/contacts). Have letterhead letter from your health care provider for any controlled or injectable meds. Check with the relevant U.S. Embassy, prior to your departure, to ensure your meds are allowed in the country. Leave a copy of prescriptions at home with your designated contact person.
- Keep your health insurance card and contact information with you when abroad. Keep proof of yellow fever vaccination, too, if required.
- Keep your Emergency Contact Card with you, along with a list of local hospitals/clinics/emergency services. You should also carry with you the name of your local POC, and their address and phone number at the closest U.S. Embassy or Consulate.
- Additional items for consideration in your health kit include, inhalers, epinephrine auto-injectors, medical alert bracelets, special prescriptions for trip/travel (antibiotic for traveler's diarrhea, commercial suture/syringe kits for use by local physician, anti-altitude sickness meds, anti-malarial meds, etc.), over-the-counter meds (antacid, diarrhea meds, mild laxative, motion sickness, mild sedative, decongestant, pain and fever med, antihistamine, cough drops, saline nose spray, cough suppressant/expectorant, etc.), preventive items (hand sanitizer/wipes, insect repellant, permethrin, bed net, sunscreen, sunglasses, safety equipment, earplugs, etc.), first aid kits (first aid creams, wound bandages/blister care, elastic bandage wrap, eye drops, water purification tablets, oral rehydration salts, equipment-gloves, thermometer, scissors, swabs, tweezers, etc).

10.17.4.4 - General Precautions During Trip

The CDC states at The CDC Survival Guide to Safe and Healthy Travel that, whatever your reason for traveling, you should be prepared when it comes to your health—before, during, and after travel. Additionally,

- Practice personal security
  - Carry contact information for the nearest U.S. Embassy/Consulate.
  - Carry a photocopy of your passport and entry stamp/form.
- Note that motor vehicle crashes are the leading killer of healthy U.S. citizens in foreign countries.
- Follow safe eating and drinking practices.
- Prevent bug bites.
- Prepare for possible weather extremes.
- Avoid animal contact.
- Wash hands.
- Avoid sharing body fluids. If medical or dental care needed, make sure local clinic or hospital employs good medical hygiene.

Note that, in the e-clearance form provided in your foreign travel process documents, you have a registered country clearance with the U.S. Embassy/Consulate in that location. Your country clearance will be obtained for you by the Passport Office. The e-clearance form includes contact information, health information, security threat, immigration/customs/quarantine, climate, and transport information. In "Contact Information" box on the form, you will see Embassy telephone numbers for business and after-hours. For any situation of physical or medical threat, you can contact the Embassy 24 hours/7 days a week.

10.17.4.5 - Additional travel resources

10.17.4.5.1 - Travel.State.Gov

At Travel.State.Gov, the U.S. Department of State's Bureau of Consular Affairs provides services that protect U.S. citizens and their interests abroad, ensure U.S. border security, facilitate the entry of legitimate travelers, and foster economic growth. Resources housed at this site include:

- Travel Advisories
- U.S. Citizens in an Emergency
  - If you are overseas and in need of emergency assistance contact the nearest U.S. embassy or consulate.
  - Call: From the U.S. and Canada: 1-888-407-4747. From overseas: +1 202-501-4444.

10.17.4.5.2 - CDC Travelers' Health

The CDC/Traveler's Health website is committed to updating the public with current and accurate information regarding COVID-19, COVID-19 related vaccines and medicines, along with other travel advice/recommendations, notices, and resources. You are encouraged to review this site frequently in advance of travel.

10.17.5 - Employee and Traveler Safety

10.17.5.1 - Employee Safety

See references to personal safety in this chapter and IOM Chapter 5.

10.17.5.2 - Traveler Safety Tips

- Conduct research into your destination(s).
- Keep travel plans private but check in with a trusted network often.
- Write down emergency information.
- Keep photocopies/scans/photos of important documents.
- Lock up your valuables.
- Don't draw attention to yourself.
- Don't share too much information with strangers.
- Stay "tethered" to your bags/equipment.
- Practice situational awareness; be aware of your surroundings.
- Avoid unsafe, "sketchy" vicinities.
- Don't advertise valuables.
- Use ATMs wisely.
- Trust your instincts.
- Do not bring anything with you that is irreplaceable if stolen.
- Drink alcohol responsibly.
- Choose safe foods and drinks when traveling per the CDC and consider the following suggestions:
  - Eat at popular places with long lines.
  - Try to watch how your food is prepared.
  - Pack translation cards to document your allergies.
  - Fully cooked, hot food is always the safest.
  - Only eat peelable fruit to avoid bacteria.
  - Avoid fresh salads and other raw foods.
  - Do not drink the tap water or use ice in developing countries.
  - Drinks from unopened, factory-sealed bottles or cans are best.

10.17.5.3 - Motor Vehicle Safety

Per the CDC/NIOSH Transportation Safety | Motor Vehicle Safety | CDC Injury Center, driving or riding in a vehicle as part of your job can add to your risk of injury. Motor vehicle crashes are a public health concern both in the United States and abroad. In the United States, motor vehicle crashes are a leading cause of death, and kill over 100 people every day. However, motor vehicle crash injuries and deaths are preventable. There are proven strategies that can help prevent these injuries and deaths. Whether you are a driver, passenger, cyclist, or pedestrian, you can take these steps to stay safe on the road:

- Make sure your vehicle works properly.
- Always use seat belts, obey speed limits, and keep a safe following distance.
- Stay focused on the driving task by avoiding distractions.
  - Don't talk on hand-held cell phones or use other handheld devices. Avoid hands-free phones too – *any phone conversation can be a distraction*.
  - Don't text.
  - Don't adjust controls.
  - Don't eat or drink.
  - Don't drink alcohol and drive.

  - Don't be distracted by passengers.
  - Keep your eyes on the road, and your hands on the steering wheel.
- Slow down when you get near intersections.
- Drive cautiously, especially when you see objects in or next to the road.
- Make sure you are well rested before you start driving.

Before operating a vehicle, check the following:

1. Tires, check for tread wear, inflation, etc.
2. Mirrors, for proper adjustment
3. Brakes for operability as much as possible
4. Windshield for visibility
5. Lights: headlight, turn signals and brake
6. Gasoline and oil gauges to determine levels
7. Spare, jack, lug wrench, first aid kit, flares, etc.

Note: Fire extinguishers are no longer required in vehicles.

When transporting materials of trade, or items that when shipped commercially would be regulated as hazardous materials/dangerous goods, it is strongly recommended to adhere to US DOT regulations, even though it may not in all instances be required. Ensure that all volatile solvents--either in the sample collection kit or contained in a sampled material--are properly packaged and sealed to prevent spills or leakage. Be especially aware of the hazards associated with transporting dry ice as a concentration of carbon dioxide gas can occur, potentially causing a dangerous over-pressurization, and/or a loss of oxygen, which can in turn, lead to hazards for users/handlers, such as feelings of drowsiness, or even an asphyxiation. Storing dry ice adequately, in a proper container, and transporting it in an adequately ventilated vehicle (windows cracked/down) reduces such risks.

10.17.5.3.1 - Global Road Safety

Per the CDC, whether you're on the road at home or abroad, you should know the risks and take steps to protect your health and safety both domestically and globally. When travelling by vehicle globally:

- Always use a seat belt on every trip, no matter how short--and no matter if you are seated in the front or the back of a vehicle.
- Always wear a helmet when driving or riding on motorcycles, motorbikes, or bicycles.
- Do not drive while impaired by alcohol or drugs, or with a driver who is impaired.
- Obey speed limits.
- Drive without distractions. For example, don't use a cell phone, or text, while driving.
- Be alert when crossing streets, especially in countries where motorists drive on the left side of the road.
- Ride only in marked/official taxis or ride share vehicles. Try to ride in taxis or ride share vehicles that have seat belts available in all seating positions.
- Avoid riding in overcrowded, overweight, or top-heavy buses or minivans.
- Check the Association for Safe International Road Travel (ASIRT) website for information about driving hazards and road safety risks, by country.
- For more information about road safety, overall safety, and security in every country of the world, visit the country information page on the U.S. Department of State website.

- Reference the CDC Health Information for International Travel (Yellow Book 2020). Chapter 8 – Travel by Air, Land & Sea – Road & Traffic Safety. Available at: https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/road-and-traffic-safety.

10-1- OSLA "Quick Steps" Employee's Guide to Incident Reporting

Office of Science and Laboratory Advancement
Regulatory Operations Safety Staff

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Regulatory Operations "Quick Steps" Employee's Guide to Incident Reporting

In Case of Occupational Injury or Illness, employees have a right to obtain first aid or medical treatment. All work-related incidents, injuries, illnesses, near misses or property damages must be reported. This is a Guide describing the steps an employee should follow to get first aid, and the steps an employee should follow to report occupational injuries and illnesses.

If you have sustained a work-related injury, please follow the steps outlined below:

1. If situation is severe call 911 for immediate medical assistance. If the situation is not severe, report the incident to your supervisor and management. You may choose to visit the Occupational Health Clinic or a private physician, if needed.
2. Obtain the following forms from your supervisor and provide those to the physician, at the clinic you are visiting for medical treatment:
    a. A completed and signed **Form CA-16**, "Authorization for Examination and/or Treatment". Where emergency treatment was received, the CA-16 should be issued within 48 hours after treatment
    b. A completed copy of **Form CA-17**, "Duty Status Report", in order for the physician to document any work restrictions, if assigned.
    c. If you decide to be treated by a private physician, please take a copy of the American Medical Association Standard Billing Form (AMA) OWCP-1500 along with the **Form CA-16**.

All work-related incidents, injuries, illnesses, near misses, or property damages must be reported using the following step(s):

3. File the incident report as soon as possible in the employee Incident Portal, pOSH+ (within 7 days from the date of incident). An employee Getting Started in pOSH+ Guide is available for help completing the report. Additional employee resources can be found on ROSS Sharepoint. Complete all required fields denoted with red asterisk*.
    a. Save your report as you complete each step.
    b. Submit your report once all information has been entered by clicking the "submit" button in the upper right-hand corner of the page.
    c. Your supervisor will receive an email notification of the pOSH+ incident report. They will review, sign, and submit the report.
    d. The Regulatory Operations Safety Staff (ROSS) Incident Team will review, investigate, sign, and submit a completed report to pOSH+.

4. If you want to file a "Worker's Compensation Claim", you must register in ECOMP, file an OSHA 301 Injury and Illness Incident Repot, and then either **Form CA-1** "Federal Employee's Notice of Traumatic Injury and Claim of Continuation of Pay/Compensation" or **CA-2** "Notice of Occupational Disease and Claim for Compensation".
   Note: If the incident is *OSHA-recordable* or you used the CA-16 from step #3 above, you will be *required* to file in ECOMP. The ROSS IH Incident Investigator or your supervisor will notify you if filing is needed.
    a. The **CA-1** must be filed along with medical documentation associated with the injury within **30 days** from the date of injury, to be eligible for continuation of pay (COP). COP and medical evidence supporting disability must be provided within **10 calendar days** after submitting the claim for COP.
    b. See procedures for workers' compensation instructions for injured employees. Contact the Worker's Compensation representative for additional guidance.
    c. Your supervisor will review and complete the supervisor portion of the report in ECOMP.
    d. ROSS Incident Team will review, investigate, complete, and file the final OSHA 301 report in ECOMP.

10-2 - OSLA "Quick Steps" Supervisor's Guide to Incident Reporting

Office of Science and Laboratory Advancement
Regulatory Operations Safety Staff

FDA OSLA • ROSS

Regulatory Operations "Quick Steps" Supervisor's Guide to Incident Reporting

In Case of Occupational Injury or Illness, employees have a right to obtain first aid or medical treatment. All work-related incidents, injuries, illnesses, near misses, or property damages must be reported. This is a Guide describing the steps a supervisor should follow to assist an employee during an occupational injury and illness.

If an employee has sustained a work-related injury, please follow the steps outlined below:

1. Check on the employee.
2. If situation is severe call 911 for immediate medical assistance. If the situation is not severe, refer the employee to the Occupational Health Clinic, if available, and/or to a private physician, if needed. The employee may choose where they want to be treated.
3. Provide the following forms to the injured employee when requesting to seek medical treatment:
    a. Completed and signed Form CA-16, "Authorization for Examination and/or Treatment", to the employee within four hours of the request for medical treatment and prior to seeking medical attention. You must obtain a copy of the CA-16 from the Worker's Compensation representative. Refer to the Office of Workers' Compensation Programs Supervisors' Guide for additional guidance and exceptions on providing the CA-16.
        i. Form CA-16 *should not* be issued if more than a week has passed since the injury.
        ii. If you doubt whether the employee's condition is related to their employment, you should indicate this on Form CA-16 (item 6.B.2).
        iii. Form CA-16 should not be issued retroactively for treatment already received, except in the case of emergency treatment. Where emergency treatment was received, the CA-16 should be issued within 48 hours after treatment.
    b. Completed Form CA-17, "Duty Status Report", with the employee's position description in order for the physician to document any work restrictions, if assigned.

All work-related incidents, injuries, illnesses, near misses, or property damages must be reported using the following step(s):

4. Refer your employee to the Incident Portal, pOSH+ to file a report. An employee Getting Started in pOSH+ Guide is available to help complete the report. Visit the ROSS Sharepoint for additional resources.
    a. Once the employee completes and submits the pOSH+ incident report, you will receive an email that the investigation is ready for your review.
    b. Review, sign, and submit the pOSH+ Incident Investigation as soon as possible. A supervisor's guide, How to Review an Incident Report Submitted by an Employee, is available.
5. If your employee wants to file a "Worker's Compensation Claim", refer them to ECOMP to register, file an OSHA 301 Injury and Illness Incident Report, and Form CA-1, "Federal Employee's Notice of Traumatic Injury and Claim of Continuation of Pay/Compensation" *or* Form CA-2, "Notice of Occupational Disease and Claim for Compensation".
    Note: If the incident is *OSHA-recordable* (discuss with ROSS IH Incident Investigator) or the employee used the CA-16 from step #3 above, they are *required* to file in ECOMP.
    a. Inform your employee the OSHA 301 must be filed within 7 days from the date of the injury and the CA-1 must be filed within 30 days from the date of injury to be eligible for continuation of pay (COP).
    b. Once the employee completes and submits documents in ECOMP, you will receive an email that the incident is ready for your review.
    c. Review the employee's OSHA 301 and CA-1/CA-2, if applicable. Complete the supervisory portion in ECOMP as soon as possible, but no later than 7 days. Supervisors will receive reminder emails from ECOMP if not completed within 2 days.
6. ROSS will review, investigate, complete, and file the final pOSH+ and OSHA 301 reports.

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