Sections in This Document

1. Introduction

This section provides information relating to the Environmental Health and Safety (EHS) of the laboratory and serves as a general overview. It also serves as a reference for the EHS programs developed in the laboratory. The laboratory's EHS documents and standard operating procedures will provide more detailed step-by-step instruction.

Safety is the responsibility of all Food and Drug (FDA) employees. So that safety has real significance in the workplace, it is actively incorporated into all

programs, procedures, and analytical methods. Each person is responsible for following all EHS guidelines in the course of his or her duties. Employees are responsible for reporting any conditions that are or may be hazardous so that they can be mitigated. Employees are to wear their personal protective equipment (PPE), use all safety equipment in the manner for which it is designed, report any failures of safety equipment to management, familiarize themselves with the hazards of all chemicals, and report any potentially unsafe incidents or exposures. Management establishes and funds safety programs, provides PPE when needed, ensures employees are trained, provides information about the hazards through a hazard assessment process, and advises employees how to control them. The agency is responsible for and committed to creating and maintaining a safe working environment for all personnel. The Industrial Hygienist will act as the Chemical Hygiene Officer in accordance with 29 CFR 1910.1450 to provide guidance in the development and implementation of the Chemical Hygiene Plan (CHP) and ensures the CHP is reviewed and updated as necessary.

2. Laboratory Safety

A. A safe working environment manages hazards in a manner that minimizes any risk to or adverse effect on the following:

1. employee health,
2. physical safety,
3. work environment,
4. FDA property, and,
5. our neighbors.

B. ORA facilities strive to offer a safe working environment for all employees. Management strives to comply with all regulatory requirements under Federal, State, and local agencies that oversee laboratory operations. This includes the Environmental Protection Agency (EPA), the Occupational Safety and Health Agency (OSHA), the Department of Transportation (DOT), the Nuclear Regulatory Commission (NRC), the Center for Disease Control and Prevention (CDC), and the Drug Enforcement Agency (DEA).

C. Many of the samples tested in the laboratory are highly regulated commodities that may contain deleterious contamination. Safety hazards include harmful chemicals or disease producing agents and are acts or phenomena that have the potential to produce immediate physical or health harm, or other undesirable effect to some person or thing.

D. Risk assessment includes the following:

1. the probability, or chance that a certain activity could result in injury, damage, or loss;
2. quantifies hazards by evaluating the probability of the harm being realized; and
3. directly correlates the exposure one has with the hazard.

E. The goal of all EHS programs is to remove as much risk as possible to ensure the safest work environment.

2.1. Hazard Evaluation and Control

A. Effective hazard evaluation and control methods protect workers from workplace hazards by minimizing potential risks providing a safer and healthier work environment.

B. Controlling exposures to occupational hazards is a fundamental process for protecting workers in the workplace. Methods for controlling hazards in the workplace environment are prioritized with the industrial hygiene hierarchy of controls; a guiding framework to evaluate and rank hazard control processes. The hierarchy for controlling hazards begins with the most desirable option first and ends with the least desirable option as follows:

1. Elimination
2. Substitution
3. Engineering controls
4. Administrative controls
5. Personal protective equipment

C. The most desirable option for controlling hazards is to eliminate the hazard completely by physically removing the hazard from the workplace environment, thus preventing any potential exposure. The next option in the hierarchy of controls is substitution or replacing the hazard with something less hazardous, such as replacing a chemical with one less hazardous in a laboratory process.

D. Engineering controls come next in the hierarchy and are used to isolate workers from the hazard by controlling the exposure using equipment and machinery. Examples include self-capping syringe needles, ventilation systems such as fume hoods, sound-dampening materials to reduce noise levels, safety interlocks, and radiation shielding. Whenever possible, Labs should select equipment and machinery that

have an inherently safer design to prevent introducing hazards into the workplace.

E. Administrative controls follow engineering controls and are used to change the way people work in the workplace environment. Examples include modifications in work procedures, such as written safety policies, rules, supervision, schedules, and training with the goal of reducing the duration, frequency, and severity of exposure to hazardous chemicals or situations.

F. The use of PPE is the least desirable way to control hazards as PPE protects the worker by reducing exposure to the hazard; however, the hazard is still present. PPE only offers temporary protection with worker safety dependent on appropriate selection and use. therefore, it is critical that the proper PPE be assigned for the hazard with adequate training provided. PPE also has certain physical limitations in use and can fail or cause injury to the user if not used properly.

G. Appropriate control methods are essential to minimizing hazards in the laboratory, however, nothing replaces good work practices to promote a safe working environment.

H. Evaluation of hazards in the workplace environment is an important aspect of laboratory safety. The industrial hygienist plays a critical role in the hazard evaluation and control process by providing support to supervisors and employees in analyzing the potential hazards associated with laboratory operations. Based on these hazard evaluations, safety protocols will be developed identifying the potential hazards and steps needed to mitigate the associated risks. Appropriate hazard controls should be identified in applicable laboratory safety documents such as the Chemical Hygiene Plan (CHP), biosafety plans, relevant Standard Operating Procedures (SOPs) and job instructions.

I. Hazard evaluation includes such factors as the following:

   1. Identification of health and physical hazards associated with the material or procedures and the ramifications of that exposure
   2. Estimating the probable exposure by
      a. Considering the quantity and form of material
      b. Determining the distribution and degree of exposure, personnel exposed
   3. Determining stability, compatibility, and storage issues

4. Assessing the availability and use of various controls, including PPE, engineering controls, and administrative controls
5. Reviewing regulatory issues such as waste or shipping issues, cleaning up spills, contamination control.

J. A risk control assessment that fully addresses these issues and evaluates any alternatives should be the basis for a systematic plan or work instruction for projects in the laboratory.

2.1.1. Physical Hazards

A. Physical hazards are those caused by direct interaction with the mechanics of the work environment. For exposure limits and recommendations by the Occupational Health and Safety Administration (OSHA), see 29 CFR, Part 1910.

B. Potential physical hazards in the workplace include the following:

1. extreme hot and cold temperatures,
2. noise,
3. electricity,
4. sharps, and
5. electric and magnetic fields (EMF).

C. Other physical hazards include

1. injuries from slips, trips, and falls,
2. cuts,
3. falling and other moving objects,
4. dusty environments, and
5. poor ergonomic design.

D. In Appendix B to 29 CFR 1910.1200 -- Physical Hazard Criteria, OSHA defines physical hazards to mean a chemical that is the following:

1. explosive,
2. flammable (gases, aerosols, liquids, or solids),
3. oxidizer (liquid, solid or gas),
4. self-reactive,
5. pyrophoric (liquid or solid),
6. self-heating,

7. organic peroxide,
8. corrosive to metal,
9. gas under pressure, or in contact with water emits flammable gas.

E. Engineering controls physically modify a process, or process equipment, with the goal of preventing the release of contaminants into the workplace. Examples include the installation of fume hoods, tempering the air by heating or cooling, ensuring that Ground-Fault-Circuit-Interrupter (GFCI) receptacles are in place, providing floor mats to reduce the chance of slipping, and separate storage for incompatible compounds.

F. Physical hazards are responsible for the majority of workplace injuries such as improper lifting techniques, slips, trips and falls, and cuts. Proper housekeeping, paying attention to office and laboratory surroundings, and other good working practices can effectively complement engineering controls to minimize accidents in the workplace.

G. OSHA addresses some of the physical hazard issues in the general sections in 29 CFR 1910. The National Fire Protection Agency covers laboratories in NFPA 45 Standard on Fire Protection for Laboratories Using Chemicals (2019 Edition). The NFPA covers issues with flammability in NFPA 30 Flammable and Combustible Liquids Code, and compressed gases in portable cylinders in NFPA 55. Contact your local IH with questions about local regulations, codes, standards or recommended best practices.

2.1.2. Chemical Hazards

A. Chemical hazards can enter and harm the body by four main routes:
1. Absorption through the skin;
2. Inhalation;
3. Injection; and
4. Ingestion.

B. Chemical hazards can cause harm in the many ways:
1. Fire and/or smoke;
2. Explosion or violent reaction;
3. Corrosion to equipment or facilities;
4. Chemical burns or skin/eye irritation;

5. Causing chronic organ damage over time;
6. Causing an allergic reaction; and
7. Causing genetic or reproductive harm.

C. A chemical's potential for harm is affected by its properties, (e.g. solid, liquid or gas). If it is a solid, what size are the pieces - micron sized particles, granules, or large chunks? What is the temperature of the chemical? How easily is the chemical absorbed through the skin? Is it toxic? Does it persist in the environment, or is it easily dissipated? The effects of exposure not only depend on the chemical, its concentration, route of entry, and duration of exposure, but may also be influenced by personal factors such as the individual's smoking habits, alcohol consumption, medication use, nutrition, age, and sex.

D. The hazardous properties of many of the chemicals used in the laboratory have been extensively studied by the National Toxicology Program (NTP), the International Agency for Research on Cancer Monographs (IARC), and the American Conference of Government Industrial Hygienists (ACGIH). ACGIH has established Threshold Limit Values, or TLVs, for many chemicals. The TLV is an 8-hour time-weighted average (TWA) believed to be the average concentration most workers can be exposed during an 8-hour workday, day after day, five days per week, without harmful effects. Short-term exposure limits (STEL) establishes for materials that are more toxic the maximum concentration employees can be exposed for periods up to fifteen minutes that should not be exceeded at any time during a workday. Ceiling (C) is a maximum concentration never to be exceeded. OSHA adapted many of the recommendations of the ACGIH and listed the chemicals and their Permissible Exposure Limits in 29 CFR 1910.1000.

E. One of the easiest ways to gather information about the chemical hazards of a compound is to read the *Safety Data Sheet (SDS)* (formerly MSDSs or Material Safety Data Sheets). No employer may allow the use, handling, or storage of a hazardous product in a workplace unless the product carries a label, a safety data sheet, and the worker has received the training and information to carry out the work entrusted to him safely. The SDSs are required to be presented in a consistent user-friendly, 16-section format in accordance with 29 CFR 1910.1200. Every laboratory is required to have a SDS library containing an SDS sheet for every chemical in their inventory. Additionally, the SDSs are readily found on the websites of most of our suppliers.

Examples include the following:

http://www.vwrsp.com

http://www.fishersci.com

http://hazard.com/msds/ , and

http://www.ilpi.com/msds/index.html.

F. Contact your IH or supervisor to find the location for MSDS's in your laboratory and how to use them.

G. In addition to general safety standards, OSHA has standards for chemicals in various sections of 29 CFR 1910.1; these include formaldehyde, benzene, benzidene, arsenic, lead, cadmium and methylene chloride.

2.1.3. Biological Hazards

A. Biological hazards are biological agents and materials that can adversely affect humans, animals, and plants. Biohazards include infectious or etiologic agents, certain toxins and other biological material, bacteria, fungi, viruses, parasites, prions, Rickettsiae, recombinant products, allergens, arboviruses. Primary laboratory vectors for these hazards include decomposed foods, foods contaminated with insects, rodents, fecal material and other raw or unclean foods. In rare cases, your laboratory may accept samples that may carry blood-borne pathogens.

B. A biosafety program should be established for those laboratories performing microbiological work; there also may be some biosafety information in the laboratory's Chemical Hygiene Program (CHP). A Blood-borne pathogen program should be established for those laboratories working with blood borne pathogens. Information on the Blood-borne Pathogen program can be found in 29 CFR 1910.1030. All FDA laboratories working with animals must coordinate their analytical, training and research procedures involving animals through the FDA/ORA Institutional Animal Care and Use Committee (IACUC).

C. The following references offer guidance on the prevention of harm from biological agents:

1. *U.S. Department Health and Human Services, Center of Disease Control*, *National Institute of Public Health.* (1999). Biosafety in Microbiological and Biomedical Laboratories. (Stock no 017-040-00547). U.S. Government Printing Office. (BMBL)

2. *U.S. Department Health and Human Services, Center of Disease Control*, *National Institute of Public Health* (2002). Primary

Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, Second Edition, U.S. Government Printing Office., reference for ordering found on the website: http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm

3. http://www.absa.org/resources
4. http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm

D. Containment is the key consideration when working with biohazards. Class II Biosafety Cabinets are designed to protect both the user and the product through ventilation control. Laminar Flow Cabinets are dissuaded in most laboratories because there is no protection for the user. However, laminar flow hoods may be used for non-biohazard situations such as sterility testing and drying agar plates.

E. The BMBL classifies most of the biohazardous viable organisms into four biosafety levels with Biosafety Level 1 (BSL-1) assigned to those organisms not known to consistently cause disease in healthy adults. Some caution should be used when handling these organisms because they can cause problems for immuno-compromised individuals. BSL-2 organisms represent moderate risk to people and are associated with human disease of varying severity; most of the organisms handled in ORA laboratories are BSL-2. BSL-3 organisms are very difficult to contain and transmit serious or lethal infections; ORA has very limited work presently with BSL-3 organisms. BSL-4 agents pose a high individual risk of life-threatening disease; special practices, safety equipment, facility design, and construction are needed when working with these organisms. ORA is not performing any work with BSL-4 organisms.

F. The BMBL provides information on good work practices, proper PPE, safety equipment, laboratory facility design for each Biosafety Level.

G. Some biological hazards can be mitigated using vaccines. ORA will provide vaccinations for laboratory personnel for the following biological agents: hepatitis A, hepatitis B vaccination series, anthrax, rabies, tetanus, influenza, . Contact the CHO or supervisor for more information. Vaccinations are presently voluntary and may cause untoward reactions in people. A risk assessment is performed with any biohazardous project to assess the need for mandatory vaccinations.

2.1.4. Radiological Hazards

A. ORA laboratories have limited use of radiological materials. The most common uses of ionizing radiation are sealed Nickel-63(Ni-63)

detectors in instruments such as gas chromatographs, and x-rays in instruments such as XRFs and XRDs. Radiation sources within these instruments are heavily shielded. Biannual swipes, required for all Ni-63 detectors to ensure there is no leakage of radioactive material, are forwarded to Winchester Engineering and Analytical Center (WEAC) for analysis. Records of their swipe history are maintained where the detector are located. The procedures for this are described in ORA's Radiation Safety Manual.

B. Two ORA laboratories actively work with radiolabeled tritium (H-3) for shellfish toxin research.

C. Every Laboratory with radioactive materials falls under ORA's Radiation Safety Program. Labs using tritium or other unsealed radioisotopes are covered by ORA's Nuclear Regulatory Commission (NRC) site license. Anyone who may be exposed to external doses of ionizing radiation must use dosimeter badges to record any exposures. Training is provided annually. Other requirements are expressed in ORA's NRC license and Radiation Safety Manual.

D. Contact your lab's industrial hygienist for more information about radiological hazards. ORA IHs work closely with ORA's Radiation Safety Officer to implement programs at their assigned labs. Any new program involving radiation should be coordinated through ORA's RSO to ensure the work is permitted on the license.

2.1.5. Respiratory Hazards

A. There are various types of respiratory hazards in the laboratory. Examples of potential respiratory hazards include, but are not limited to:

1. Oxygen-deficient air
2. Particulate contaminants
3. Gas and vapor phase contaminants

B. Particulate, gas, and vapor contaminants are the most probable respiratory hazard in the laboratory. When a respiratory hazard is identified, several methods may be used to reduce exposure. The preferred way of managing these hazards is through engineering controls or capture devices, as these will remove or mitigate the hazard.

C. The ORA laboratories use some of the following engineering controls:

1. Directional airflow between rooms and corridors
2. Frequent air exchanges within rooms

3. Chemical hoods
4. Biosafety cabinets
5. Weighing hoods

D. Fume hoods and other engineering controls should be used to mitigate respiratory hazards. This ubiquitous source of protection is one of the best defenses in the laboratory. The analyst should use the following procedures when working in the hood:

1. Place the sash down low enough to protect the face and neck;
2. Always work at least six inches inside of the hood;
3. Never block the rear air vents;
4. Keep the amount of materials used in the hood at a minimum; and
5. Dissuade fellow employees from disturbing the air patterns when the hood is in use.

E. Engineering controls and capture devices should be tested and certified annually to ensure proper functioning and adequate performance.

F. Other ways to mitigate respiratory hazards include the following:

1. Use of vacuum systems near dust producing operations,
2. Higher number of air exchanges in laboratories than in normal office settings, and
3. Non-recycled laboratory air through office portions of the building

G. Some circumstances may warrant the use of respirators.

1. Laboratory exposure to respiratory hazards may not be controlled using the usual ventilation devices in instances where the TLV or PEL level for safe exposure is very low.
2. An employee might want additional protection even though the respiratory hazard has been mitigated to levels considered safe by OSHA or other governing bodies.
3. Any use of respirators requires the laboratory to develop a Respiratory Protection Program as defined by 29 CFR 1910.134. The Industrial Hygienist is typically designated as the Respiratory Program Administrator for their respective laboratory for implementation of the program.

4. Prior to wearing a respirator, the employee must be medically cleared to wear a respirator, trained about the hazard, instructed how to use a respirator, and fit-tested.
5. The Respiratory Program Administrator will provide assistance to ensure the employee is assigned a respirator designed to control the particular potential exposure.
6. Respirators are commonly used in the laboratory for dust control in grinding operations use P100 filters. Those involved with hazardous waste consolidation may be fitted with half mask respirators and organic acid vapor cartridges. Some analysts involved with counterterrorism activities may also be fitted with half-mask respirators with P100 or and Defender cartridges. Consult your Respiratory Protection Program and Respiratory Program Administrator for more information on respiratory hazards and their mitigation.

2.2. General Safety Guidelines

A. The "Laboratory Standard," 29 CFR 1910.1450, requires laboratories to develop a Chemical Hygiene Plan to protect laboratory worker from harm due to hazardous chemicals. The Industrial Hygienist is responsible for implementing the plan and is designated as the Chemical Hygiene Officer (CHO). Procedures for safe laboratory work are listed in your laboratory's Chemical Hygiene Plan.

B. General safety guidelines include, but are not limited to the following:

1. Never work alone in the laboratory
2. Never mouth-pipette, or use mouth to start a siphon
3. Wear eye protection in the laboratory at all times, including over contact lenses. Prescription glasses do not qualify as laboratory eye protection when worn alone.
4. Never sniff any chemicals
5. Practice personal hygiene rules, (e.g. always wash hands before leaving the laboratory)
6. No eating, drinking, applying cosmetics, or chewing gum in the laboratory
7. Never bring or store personal consumable products in the laboratory
8. Do not wear laboratory coats outside the laboratory area

9. Review all chemical safety information mentioned in the Safety Data Sheets (SDS), prior to use or transport of any chemical.
10. Know the location and proper use of emergency equipment including eye wash, fire alarm and safety showers
11. Be aware and follow the appropriate emergency procedures: including evacuation routes, spill clean-up procedures and proper waste disposal
12. Personal protective equipment (PPE), follow proper personal hygiene practices and use appropriate PPE
    a. Wear protective lab coat
    b. Wear closed toe, sturdy shoes and full-length garments
    c. Inspect all protective equipment prior to use and discard defective equipment
    d. Use hearing protection when appropriate
    e. Wear appropriate hand protection based on the chemicals and/or task
    f. Use appropriate eye and face protection (e.g. safety glasses, goggles, face shield)
13. Practice good housekeeping techniques
    a. Keep walkways and path of egress clear
    b. Ensure all eye wash stations, emergency showers, fire extinguishers, and exits are always unobstructed and accessible
    c. Properly label containers
    d. Store hazardous chemical in appropriate cabinets
    e. Use proper methods of transporting chemicals within the facility
    f. Promptly clean up all spills in the laboratory. See Spills handling procedures for your laboratory for details
    g. Keep work areas clean and tidy
14. Follow proper waste disposal procedures:
15. Consult the Chemical Hygiene Plan and the CHO for additional laboratory specific safety guidance.

C. Accident reporting:

1. Immediately report all accidents and complete the appropriate forms

D. Fire Safety

1. Call emergency or security, pull/sound the fire alarm, and immediately evacuate the building

2.3. Emergency Response

While accidents or serious mishaps in the laboratory are rare, it is extremely important to be prepared and know what to do in case of an emergency. Laboratories are outfitted with specialized equipment and kits for chemical spills, fires, and personal injuries. Written procedures specifying what one should do in emergencies are available. Refer to your local Occupant Emergency Plan (OEP) for specific site information on responding to emergencies in your lab.

2.3.1. Emergency Preparedness

A. Know laboratory policies and procedures.

B. Read the laboratory's Chemical Hygiene Plan and Occupant Emergency Plan to determine the steps needed in different emergencies. The emergency response plan and occupant emergency plan can provide useful information. These documents provide the following information: who to contact in an emergency, when and how to clean up a chemical spill, where the Safety Data Sheets (SDSs) are located, and when one should use a fire extinguisher. If clarification is needed on any of these or other emergency procedures, ask a supervisor or the Industrial Hygienist.

C. Be familiar with laboratory surroundings. From the laboratory bench, know where the nearest exit(s), eyewash fountain, safety shower, MSDS, fire extinguisher, and first aid kit are located. It is a good practice to identify two exits in case one is inaccessible. Before working in a different location, identify the location all safety equipment. If anyone cannot locate any of the above-mentioned items, ask the Industrial Hygienist, a supervisor or a co-worker for assistance.

D. Practice. The best way to understand something thoroughly is to run through a mock exercise or drill. Consider instances where one may need to walk from a hood to the eyewash station if one's eyesight is impaired due to acid splashed in the eye. Know how to activate the eyewash as well as the length of time required to apply the water rinse. This exercise can also be applied an accident that would need the use of safety showers.

2.3.2. Fire

A. Be aware of the nearest fire exits. In the event of a fire, alert others to the situation.

B. Trained, authorized personnel only use fire extinguishers, provided in the laboratory. Use of a fire extinguisher is voluntary, and should only be used if the fire can be contained safely otherwise evacuate immediately.

C. If someone is injured, assess the situation; assist if possible.

D. Immediately leave the area, close the doors, and leave by the nearest exit. Refer to your Occupant Emergency Plan for guidance on contact information. Follow the laboratory's evacuation plan. Follow any special procedures in the laboratory's evacuation plan (e.g. some facilities arrange for supervisors to meet with their group outside to account for any potential missing employees).

E. Fire drills should be held at least annually.

2.3.3. Chemical and biological spill kits

Be familiar with chemical and biological spill kits contents and their procedures for cleaning up spills. Be familiar with your labs spill clean-up procedures located in your lab's chemical hygiene plan and biosafety manual. If you have any questions, contact the Industrial Hygienist.

2.4. Environmental Health (EH)

A. Executive Order 13148, Greening the Government through Leadership in Environmental Management, requires federal agencies to develop environmental programs, policies, and procedures to ensure compliance with federal law.

B. The FDA Office of Laboratory Safety and Science (OLSS) schedules Environmental Audits periodically depending on laboratory size. Smaller ORA laboratories will be audited every five years while larger laboratories will be audited every three years. These audits will assure labs are complying with both federal and state regulations.

C. ORA laboratories can ensure they comply with environmental regulations by keeping abreast with changes in environmental regulations, performing inspections as needed, recording these inspections and maintaining proper records. These records include, but not limited to, the following: TSDF signed hazardous waste manifests, central waste accumulation inspection forms and having permits (air, water) available. Other areas to consider are complete training records

and proper documented review of laboratory Chemical Hygiene and Respirator Program Plans.

D. The Immediate Office - Office of Business and Safety Operations (IO-OBSO) has developed an environmental audit tool which assists laboratories in organizing their programs. The tool encourages laboratories to create one location or binder for all required environmental information for their site. Contact your lab's industrial hygienist for more information about environmental programs or the audit tool.

2.5. Environmental Health & Safety Audit

A. Laboratories in ORA are inspected under the Administrative Quality Assurance Plan program (AQAP). Items that are inspected and evaluated during this inspection may include:

1. Environmental (e.g. temperature, lighting, noise, tripping hazards, stable shelving, and odors);
2. Housekeeping (e.g. neat storage areas, clear aisles, safe storage, trash disposal);
3. Fire safety (e.g. emergency evacuation plan, emergency lights, clearance of combustibles from open flames and hot equipment);
4. Electrical (e.g. switch cover plates used, no power cord frays, permanent wiring used, GFCI used in wet areas, circuit breakers identified);
5. General laboratory safety (e.g. no food or drink in the laboratory, proper storage of chemicals, proper facility for solvent storage, no excess chemicals, certified hoods and Biosafety Cabinets, proper use of hoods, labels on chemicals and refrigerators, hazard signage on laboratory doors, proper management of carcinogens, peroxide labels used, no mercury contamination, pipetting devices used, equipment is grounded, equipment operated under pressure inspected, glass under pressure taped) ;
6. Compressed Gas Safety (e.g. gas cylinders are labeled, secured, properly transported, and properly stored, correct regulators used);
7. Protective Equipment (e.g. laboratory coats, safety glasses, goggles, face shields, gloves, closed toe shoes, respirators, flushed eyewashes and safety showers, maintained first aid kits)
8. Radiation Safety (e.g. radiation safety plan and radiation safety officer, proper signage, spill kits, film badges used); and

9. Waste management, including infectious, hazardous, select agent, radioactive, recycled, and universal wastes(e.g. regulated wastes properly managed, labeled, proper disposition and documentation)

2.6. Investigations Branch Activities & Safety

Analysts may be involved with activities traditionally associated with the Investigations Branch. These duties include, but are not limited to investigations, wharf exams, inspections, sample collections, and recall checks. The exposure the analysts receive related to these duties may be different from those found in the laboratory. Prior to starting the assignment, review the duties and the expected hazards with the supervisor, Industrial Hygienist, or the lead investigator. Refer to the 'Investigations Operations Manual' (IOM) for further safety guidance related to these duties. A copy of the IOM can be viewed by contacting the local Investigations Branch or on-line at: http://www.fda.gov/ICECI/Inspections/IOM/default.htm

2.7. ORA Environmental Health & Safety References

2.7.1. FDA Staff Manual Guide

ORA's EHS policies reside in the FDA Staff Manual Guide 2130.1. The Staff Manual Guide sets forth the Food and Drug Administration's authority, policy, scope, and assignment of responsibility towards the establishment and management of a comprehensive safety and occupational health program. The link to the Staff Manual Guide is: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm

2.7.2. National Level References

The following references are promulgated at the National level. They provide general safety information:

1. The NTEU Collective Bargaining Agreement, Article 50: Health and Safety
2. FDA Intranet Safety web site: https://intranet.hhs.gov/manual/consolidated-collective-bargaining-agreement

2.7.3. Local References

The Chemical Hygiene Program describes your laboratories specific policies, procedures, equipment, personal protective equipment and work practices that protect lab staff from health hazards presented hazardous chemicals used in your laboratory.

The Hazardous Waste Program is written specifically for your laboratory and needs to comply with all federal and state environmental regulations. Laboratory waste amounts determine if your facility is considered a very small, small or large quantity generator of hazardous waste. Laboratories will need to keep monthly waste generation logs to determine which category they belong.

The following plans are also required and are written as sit-specific: evacuation and occupant emergency plan, as well as the BioSafety Manual:

2.7.3.1. Radiation Safety Program

A. All field laboratories that have radioactive sources on-site have this program. Sources of radiation typically found in ORA field laboratories include tritium, used in shellfish toxin research, and Nickel-63, used in some laboratory instruments.

B. Regulations regarding radiological hazards in the work place include:

1. 10CFR19: Notices, instructions, reports to workers, inspections.
2. 10CFR20: Standards for protection against radiation.
3. 10CFR21: Reporting of defects and non-compliance.
4. 10CFR71: Packaging and transportation of radioactive materials
5. NRC Reg Guide 8.36: Radiation Dose to Embryo/Fetus.

2.7.3.2. Department of Transportation (DOT) Shipment of Dangerous Goods

As mandated by DOT, the shipment of microbiological slants and hazardous chemicals requires detailed packaging and labeling. The laboratory may have a work instruction or standard procedure devoted to these requirements.

2.7.3.3. Bloodborne Pathogens Program

Although few FDA Field laboratories require this program, the bloodborne pathogens program is followed when the laboratory analyzes products that have been inside a human body, (e.g. ex-planted medical devices or pills that were ingested then expelled, or been in contact with bodily fluids such as blood, saliva, or vomitus), pharmaceuticals that may contain constituents derived from blood products, or sample analyses that use blood products in their analyses (e.g. invitro-diagnostics). Analysts receive bloodborne pathogen training and are able to handle these samples safely prior to analyzing samples in this program area.

2.7.3.4. Institutional Animal Care and Use Committee (IACUC) and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) Program

Few FDA laboratories have this program. Only those FDA AAALAC laboratories with IACUC approved protocols may perform animal testing.

2.7.3.5. Select Agent Program

Any ORA laboratory working with select agents regulated by CDC should have this program in place. The laboratory must be registered with CDC to transfer any select agents listed in their regulations in 42 CFR 72.6. CDC inspects facilities to ensure the facilities are capable of handling these organisms. All receipts, transfers, and disposals of agents are documented on their EA101 form.

3. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.3	R	02/06/2012	LMEB	LMEB
1.4	R	01/29/2013	LMEB	LMEB
02	R	08/13/2019	LMEB	LMEB

* - D: Draft, I: Initial, R: Revision

4. Change History

Revision #	Change
1.3	1.1.1 – section deleted 1.2.1 – added administrative and engineering controls definition to fourth paragraph 1.2.1.1 – added OSHA 29CFR, Part 1910 1.6 – updated IOM weblink 1.7.1 – updated SMB weblink 1.7.2 – updated NTEU CBA weblink 1.7.3 – updated IOM reference and weblink 1.8 – added section
1.4	Header – Division of Field Science changed to Office of Regulatory Science
1.5	Deleted References
02	Extensive content revisions made by the ORS Safety staff. Formatting was also revised to improve layout of the document.

5. Attachments

None