

<p><b>Volume III</b>  <b>Other Laboratory Operations</b>  Section 1 – Environmental Health &amp; Safety</p>	<p align="center"><b>ORA LABORATORY MANUAL</b></p> <p align="center">FDA Office of Regulatory Affairs  Division of Field Science</p>	<p>DOCUMENT NO.: III-03  VERSION NO.: 1.3  Final  EFFECTIVE DATE:  4/19/04  Revised:  01-18-12</p>
<p align="center"><b>Section 1                      Environmental Health &amp; Safety                      Section 1</b></p>		

## Contents

- 1.1            **Introduction**
- 1.2            **Laboratory Safety**
  - 1.2.1            Hazard Evaluation and Control
    - 1.2.1.1            Physical Hazards
    - 1.2.1.2            Chemical Hazards
    - 1.2.1.3            Biological Hazards
    - 1.2.1.4            Radiological Hazards
    - 1.2.1.5            Respiratory Hazards
  - 1.2.2            General Safety Guidelines
- 1.3            **Emergency Response**
- 1.4            **Environmental Health**
- 1.5            **Environmental Health & Safety Audit**
- 1.6            **Investigations Branch Activities & Safety**
- 1.7            **ORA Environmental Health & Safety References**
  - 1.7.1            FDA Staff Manual Guide
  - 1.7.2            National Level References
  - 1.7.3            Local References
- 1.8            **Document Change History**

## 1.1 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.

## 1.2 Laboratory Safety

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

- employee health,
- physical safety,
- work environment,
- FDA property, and,
- our neighbors.

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).

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.

Risk assessment includes the following:

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

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

## 1.2.1 Hazard Evaluation and Control

Hazard control and hazard evaluation provides a safe working environment.

The three basic procedures to control hazards are the following:

- administrative controls,
- engineering controls, and,
- personal protective equipment.

However, nothing replaces good work practices for ensuring the safest work environment possible.

Administrative controls are changes 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. Engineering controls eliminate or reduce exposure to a chemical or physical hazard through the use or substitution of engineered machinery or equipment. Examples include self-capping syringe needles, ventilation systems such as a fume hood, sound-dampening materials to reduce noise levels, safety interlocks, and radiation shielding. Administrative and engineering controls are the preferred method of hazard mitigation as they reduce or remove the hazards, and provide protection in the event of an error in work practices. The use of PPE is the least desirable way to control hazards. PPE only reduces exposure to the hazard; the hazard is still present. PPE can fail during use and only offer temporary protection. It is critical the proper PPE is assigned for the hazard. PPE also has certain physical limitations in use and can even cause injury to the user if not used properly.

Supervisors and employees analyze the significance of potential hazards associated with laboratory operations through risk analysis or hazard evaluation. Proactive safety protocols prepared for new projects or very hazardous methods can systematically identify the risks and plan what steps can be taken to mitigate the risks.

Hazard evaluation includes such factors as the following:

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

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

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.

### **1.2.1.1 Physical Hazards**

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 20 CFR, Part 1910.

Potential physical hazards in the workplace include the following:

- extreme hot and cold temperatures,
- noise,
- electricity,
- sharps, and
- electric and magnetic fields (EMF).

Other physical hazards include

- injuries from slips, trips, and falls,
- cuts,
- falling and other moving objects,
- dusty environments, and
- poor ergonomic work practices.

In the Laboratory Standard, OSHA defines physical hazards to mean a chemical that is the following:

- combustible liquid,
- compressed gas,
- explosive,
- flammable,
- organic peroxide,
- oxidizer,
- pyrophoric,
- unstable (reactive), or

- water reactive.

Engineering controls, meaning the source of the hazard is modified by a permanent solution, mitigate most physical hazards. 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.

Physical hazards are the number one cause of laboratory accidents. Improper lifting techniques, slips, trips and falls, and cuts make up the vast majority of laboratory accidents. Proper housekeeping, paying attention to office and laboratory surroundings, and other good working practices can minimize all of these accidents.

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 (2000 Edition). The NFPA covers issues with flammability in NFPA 30 Flammable and Combustible Liquids Code, and compressed gases in portable cylinders in NFPA 55.

### **1.2.1.2 Chemical Hazards**

Chemical hazards can enter and harm the body by four main routes:

- Absorption through the skin;
- Inhalation;
- Injection; and
- Ingestion.

Chemical hazards cause harm in seven different ways:

- Catching fire;
- Explosive or reactive;
- Corrosive;
- Irritant;
- Causing chronic organ damage over time;
- Causing an allergic reaction; and
- Causing genetic or reproductive harm.

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 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 for the TWA in the Limits for Air Contaminants Table (Table Z-1) in 29 CFR 1910.1000.

One of the easiest ways to gather information about the chemical hazards of a compound is to read the *Material Safety Data Sheet (MSDS)*. No employer may allow the use, handling, or storage of a controlled hazardous product in a workplace unless the product carries a label, a material safety data sheet, and the worker has received the training and information to carry out the work entrusted to him safely. Every laboratory is required to have a MSDS library containing an MSDS sheet for every chemical in their inventory. Additionally the MSDSs 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>.

Contact your Chemical Hygiene Officer or supervisor to find the location for MSDS's in your laboratory and how to use them.

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

### **1.2.1.3 Biological Hazards**

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.

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).

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

- *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)
- *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>
- <http://www.absa.org/resources>
- <http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm>

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.

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.

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

Some biological hazards can be mitigated by the use of 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.

#### **1.2.1.4 Radiological Hazards**

ORA laboratories have limited use of radiological materials. The most common use of ionizing radiation is the sealed Nickel-63(Ni-63) detector in gas chromatographs. This radiological source is 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.

Several ORA laboratories actively work with radiolabeled Phosphorous-32 (P-32) for microbiological probe work, and tritium in the Charm procedure in the analysis of chloramphenicol.

Every Laboratory with radiological sources has a Radiation Safety Program and is registered with the Nuclear Regulatory Commission. Any one who may be exposed to ionizing radiation is fitted with dosimeter badges to record any exposures. Training is provided annually. Other requirements are expressed in the ORA radiation license and in 10 CFR Parts 1-199.

Contact your Radiation Safety Officer (RSO) for more information about radiological hazards. The ORA radiation program is managed through the WEAC facility. All ORA facilities are listed on the WEAC radiation license and the WEAC RSO serves as the lead radiation officer for all other facilities. Any new program involving radiation should be coordinated through WEAC to ensure the work is permitted on the license.

#### **1.2.1.5 Respiratory Hazards**

There are three types of respiratory hazards:

- Oxygen-deficient air;
- Particulate contaminants; and
- Gas and vapor contaminants.

In the laboratory, particulate, gas, and vapor contaminants are the most probable. The most preferred way of dealing with these hazards is through engineering controls, as these will remove or mitigate the hazard. The ORA laboratories use the following ventilation controls:



- Use of directional airflow in the rooms;
- Frequent air exchanges in the rooms;
- Use of chemical hoods;
- Biosafety cabinets; and
- Weighing hoods

Use the hood often 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:

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

Hoods are certified annually.

Other ways to mitigate respiratory hazards include the following:

- use of vacuum systems near dust producing operations,
- higher number of air exchanges in laboratories than in normal office settings, and
- non recycled laboratory air through office portions of the building

The following cases may warrant the use of respirators. 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 small. An employee may want additional protection even though the respiratory hazard has been mitigated to levels considered safe by OSHA or other governing bodies. Any use of a respirator requires that the laboratory have a Respiratory Protection Program as defined by 29 CFR 1910.134. Care is taken to assign the employee a respirator designed to control his particular potential exposure. Under the OSHA Respiratory program, the employee must be medically fit to wear a respirator, trained about the hazard, instructed how to use a respirator, and fit-tested.

Respirators are commonly used in the laboratory for dust control in grinding operations. Typical respirators 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 CHO for more information on respiratory hazards and their mitigation.

## 1.2.2 General Safety Guidelines

The “Laboratory Standard,” 29 CFR 1910.1450, requires a Chemical Hygiene Program and designated Chemical Hygiene Officer. The basic tenets of safe laboratory work will be found in your local Chemical Hygiene Program.

General safety guidelines and rules include, but are not limited to the following:

- Never work alone in the laboratory
- Never mouth-pipette
- Wear safety glasses or goggles at all times in the laboratory
- Practice personal hygiene rules, (e.g. wash hands before leaving the laboratory)
- No eating or drinking in the laboratory
- Use personal protective equipment (PPE)
  - Do not wear laboratory coats outside the laboratory area
  - Wear closed toe, sturdy shoes
- Practice good housekeeping techniques
  - Keep walkways clear
  - Label and date all containers

See the Chemical Hygiene Plan for guidance identified for the local laboratory.

## 1.3 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. Requirements for emergency evacuations can be found in the NFPA Life Safety Code and OSHA 29 CFR 1910.38.

### Emergency Preparedness

1. Know laboratory policies and procedures.  
Read the laboratory’s chemical plan and evacuation 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 MSDS

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 chemical hygiene officer.

2. 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 a supervisor or a co-worker for assistance.

3. 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.

## Fire

Be aware of the nearest fire exits. In the event of a fire, alert others to the situation. Trained, authorized personnel only use fire extinguishers, provided in the laboratory. If someone is injured, assess the situation; assist if possible. Immediately leave the area, close the doors, and leave by the nearest exit. Alert responsible fire commanders if anyone is still inside the building. 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). Fire drills should be held at least annually.

## Chemical, biological, and radiological spill kits

Be familiar with chemical, biological, and radiological spill kits contents and their procedures for cleaning-up spills. Document the spill, the personnel exposed during the incident, and the clean-up procedure. Chemical spill clean-up procedures depend upon the type and amount of the chemical spilled. Acid and base spills can be neutralized, rendering them non-hazardous, while solvent and toxic chemical spills need to be absorbed and disposed as hazardous waste. Biological spills can be cleaned-up and disinfected with the use of chlorinated gel absorbents.

## 1.4 Environmental Health (EH)

Environmental health comprises aspects of human health, including quality of life, that are determined by interactions with physical, chemical, biological, and social factors in the environment. It also refers to the theory and practice of assessing, correcting, controlling and

preventing those factors in the environment that may adversely affect the health of present and future generations. (from the Pew Environmental Health Commission).

Chemical releases into the environment can have an adverse effect on human health and may result in human disease, not to mention the remainder of the environment. Many of the chemicals ORA uses can have an adverse environmental effect. Two sources of pollution from the laboratories are air contamination from building exhausts and waste disposal. Laboratory exhaust is not uniformly regulated, but waste disposal is closely regulated.

Hazardous substances are used every day in the laboratory. The previous safety sections describe some of the programs designed to mitigate the hazards associated with the use of hazardous substances. What about when we are done working? The left-over chemicals, reagents, media are disposed in accordance with the various regulations designed to protect our environment from hazardous waste.

The Environmental Protection Agency is the Federal Agency most responsible for promulgating laws designed to protect the environment. Occupational Safety and Health Administration (OSHA) and the Department of Transportation (DOT) have also promulgated regulations regarding environmental health as it applies to our laboratories. Applicable EH regulations include, but are not limited to the following:

- Code of Federal Regulations (CFR)-40 Parts 260 – 300, Protection of Environment
- EPA Resource Conservation and Recovery Act , CFR40, Parts 124, 260-268, 270-272,280.
- EPA Toxic Substances Control Act , applicable regulations in Title 40, CFR, Parts 700-763, 790-799.
- Clean Air Act (EPA), applicable regulations in Title 49, Code of Federal Regulations (CFR), Parts 25, 50-53, 60-61.
- Clean Water Act (EPA), applicable regulations in Title 49, CFR, Parts 25, 104-117, 129, 131, 135-136.
- Comprehensive Environmental Response, Compensation, and Liability Act (EPA), applicable regulations in Title 40, CFR, Parts 700-763, 790-799.
- Occupational Safety and Health Act (OSHA), applicable regulations in Title 29, CFR, Part 1910.
- Hazardous Materials Transportation Act (DOT), applicable regulations in Title 49, CFR, Parts 172-177.

The State, County or Public Utility District will likely have additional requirements for proper waste disposal. The local Hazardous Waste Manager has a hazardous waste program document providing guidance on proper waste disposal through detailed step-by step instructions.

The term hazardous waste is defined as any solid, liquid, semi-solid, or contained gaseous waste, which, because of its quantity, concentration, or physical, chemical, or infectious characteristics may:

- Cause or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness, and
- Pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of, or otherwise managed.

Hazardous waste results from the conduct of research and analytical testing, unused or out of date hazardous chemicals and their containers, samples, empty containers that previously held a toxic chemical, batteries, waste oils, TLC plates and packed columns, asbestos, mercury, items contaminated with hazardous chemicals, and material generated during spill clean-up operations. Prior to disposal, one must stop to determine if any waste generated is hazardous.

Definitions, critical in interpreting the waste regulations and understanding how to manage the waste on-site, can be found in 40 CFR 261 Subparts C and D. It is imperative everyone understands what chemicals are listed on EPA's "P" list; these wastes are segregated from other waste streams. Chemicals listed on EPA's "P" list of acute hazardous wastes are more highly regulated and call for additional management and expense.

Contact the Hazardous Waste Manager and the local Hazardous Waste Management Plan for any question regarding waste prior to disposal (e.g. determining if waste is hazardous). Annual hazardous waste training should be given for all waste generators.

## **1.5 Environmental Health & Safety Audit**

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

- Environmental (e.g. temperature, lighting, noise, tripping hazards, stable shelving, and odors);
- Housekeeping (e.g. neat storage areas, clear aisles, safe storage, trash disposal);
- Fire safety (e.g. emergency evacuation plan, emergency lights, clearance of combustibles from open flames and hot equipment);

- Electrical (e.g. switch cover plates used, no power cord frays, permanent wiring used, GFCI used in wet areas, circuit breakers identified);
- 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) ;
- Compressed Gas Safety (e.g. gas cylinders are labeled, secured, properly transported, and properly stored, correct regulators used);
- 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)
- Radiation Safety (e.g. radiation safety plan and radiation safety officer, proper signage, spill kits, film badges used); and
- Waste management, including infectious, hazardous, select agent, radioactive, recycled, and universal wastes(e.g. regulated wastes properly managed, labeled, proper disposition and documentation)

## **1.6 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, CHO, 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>

## **1.7 ORA Environmental Health & Safety References**

### **1.7.1 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>

## 1.7.2 National Level References

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

The NTEU Collective Bargaining Agreement, Article 47: Health and Safety  
FDA Intranet Safety web site:  
<http://inside.fda.gov:9003/EmployeeResources/NationalTreasuryEmployeesUnion/GeneralInformation/ucm231259.htm>

## 1.7.3 Local References

The following references are created by each laboratory for internal use. These references help ensure compliance with various Federal regulations and ORA mandated programs. They are prescriptive in nature, stating steps and guidelines for ensuring compliance. These are the documents for reference and use on a regular basis.

Each laboratory will have documents that cover the described areas; the actual name of the documents may vary from those shown below. In some cases, the documents listed may be sub-components of another reference as well as additional EHS references. Everyone is responsible for following the procedures outlined in the laboratory's version of the following references.

Each laboratory's EHS documents include, but are not limited to the following:

- **Chemical Hygiene Program**  
This document helps provide compliance with the 'Lab Standard', 29 CFR 1910.1450. Information in this document covers general laboratory safety, chemical hazards, personal protective equipment (PPE), safety equipment certification programs, special SOPs for highly hazardous work, safety responsibilities for various personnel, procedures following exposure to a chemical, and other occupational health topics. Every ORA Field Laboratory should have this reference.
- **Hazardous Waste Management Program**  
This document helps provide compliance with various Environmental Protection Agency regulations. The document provides detailed instruction for the safe disposal

of laboratory reagents and hazardous substances. Every ORA Field Laboratory should have this reference.

- **Evacuation Plan**  
This document outlines the steps taken when evacuating the building during an emergency. If the laboratory is co-located with a District Office or other tenants in a common building, this document may cover all tenants and therefore will not be particular to the laboratory. Every ORA Field Laboratory should have this reference. (This plan may be combined with the Occupant Emergency Plan at some facilities.)
- **Occupant Emergency Plan**  
This document outlines whom to call during an emergency (e.g. building managers, local fire, police, and emergency medical teams). The plan may also provide questions to ask when receiving a telephone bomb threat, or what to do during an earthquake or severe weather. Every ORA Field Laboratory should have this reference.
- **Biosafety Manual**  
This document outlines the measures that ensure safe handling of biological agents. Every ORA Field Laboratory with a Microbiology component should have this reference.
- **Respirator Program**  
This program ensures compliance with 29 CFR 1910.134 - the Respirator Standard. This program covers the use, care, and fitting of respirators. The first choice for protection from respiratory hazards is engineering controls (e.g. fume hoods). However, if the lab decides that it wants or needs to provide the extra protection of respirators the Respirator Standard is followed.
- **Radiation Safety Program**  
All field laboratories that have radioactive sources on-site have this program. Sources of radiation typically found in ORA field laboratories include P-32, used in the microbiology area, and Nickel-63, used in some gas chromatograph detectors.

Regulations regarding radiological hazards in the work place include:

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

- **Blood-borne Pathogen Program**  
Although few FDA Field laboratories have this program, the blood-borne pathogen 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 blood-borne pathogen training and are able to handle these samples safely prior to analyzing samples in this program area.
- **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.
- **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.

#### References:

*Annual refresher on health & safety for hazardous waste site investigation personnel.* (2001). New Brunswick, NJ: University of Medicine and Dentistry of New Jersey - School of Public Health, Office for Public Health Practice, Centers for Education and Training, 317 George Street, Plaza II, 08901-2008

U.S. Food & Drug Administration, Office of Regulatory Affairs, Division of Field Investigations. (current edition). *Investigations operations manual* or the website address, <http://www.fda.gov/ICECI/Inspections/IOM/default.htm>

## 1.8 Document Change History

Version 1.3   Revision   Approved: 02-06-12   Author: LMEB   Approver: LMEB

Version 1.3 changes:

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