U.S. FOOD & DRUG ADMINISTRATION

BIOSAFETY & BIOSECURITY FRAMEWORK




OFFICE OF

Laboratory Science and Safety

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U.S. Food and Drug Administration Framework for Biosafety and Biosecurity

March 3, 2017

STATEMENT OF OVERARCHING PURPOSE

Background

The Office of Laboratory Science and Safety (OLSS) was established by the Food and Drug Administration (FDA) in 2016 to provide executive leadership, oversight, and coordination of laboratory science and safety policies and operation in conjunction with the FDA-wide Environment, Health, and Safety (EH&S) program. Among other important tasks to support FDA with this critical mission, the OLSS Director is charged with the following objectives:

- Serve as the Designated Agency Safety and Health Official (DASHO) and as the Agency's Senior Laboratory Scientific Advisor to ensure that the laboratory workforce is able to conduct mission-critical science appropriately, safely, and effectively.
- Provide oversight and monitoring for FDA's EH&S program, which includes ensuring that the Agency is in compliance with internal policies and federal, state, and local regulatory standards and requirements.
- Provide executive leadership and responsibility in the area of laboratory science, laboratory security, and employee safety and health at FDA locations throughout the United States and globally, which includes consistent and standardized laboratory safety and biosecurity policies and procedures in coordination with the Centers and Office of Regulatory Affairs (ORA).
- Serve as the FDA's single point of accountability for the Agency's overall implementation of policies and procedures, and oversight for all employee safety and health operations and activities.
- Implement a robust laboratory quality management program for FDA to ensure that Agency-derived data and results are of the highest integrity and quality in support of our regulatory and public health mission.
- Serve as the Agency's liaison to the Department of Health and Human Services (DHHS) operating and staff divisions, DHHS Office of Inspector General, U.S. Government Accountability Office, other federal agencies, the scientific community, and other stakeholders as related to laboratory science, safety, and security.

Purpose

The DHHS Coordinating Framework for Biosafety and Biosecurity ("Coordinating Framework") was issued on June 17, 2016, to coordinate strategic planning efforts and to

identify 12 key elements for biosafety and biosecurity across DHHS and requires an Agency response.

The OLSS has developed this document in response to the Coordinating Framework to outline the relevant plans, policies, and procedures currently in place to support the 12 elements identified in the Coordinating Framework to address biosafety and biosecurity at FDA.

As directed by the Coordinating Framework, this document will be reviewed and revised every three years, or as needed, to address the changing needs of the Agency and to address new federal, state, and local regulatory standards and requirements.

Mission Statement

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is responsible for advancing public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

FDA is responsible for regulating the manufacturing, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors.

FDA plays a significant role in the Nation's counterterrorism and crisis management capability related to food, drugs, and the public health. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Vision Statement

FDA envisions a comprehensive biosafety and biosecurity program and the application of best principles and practices within the Agency applied in a manner that protects the safety and health of laboratory personnel, public health, and the environment while fostering progress in the life sciences.

Values Statement

Accountability: As responsible stewards of the life sciences enterprise, the Agency's staff is fully committed to providing quality services to improve and promote public health. The Agency supports the conduct of research and life sciences activities based on sound science and rigorous adherence to best biosafety and biosecurity standards and practices to protect the public and achieve the established public health goals.

Collaboration: The Agency's staff shares a common goal and purpose in enhancing biosafety and biosecurity and works cooperatively and efficiently to achieve shared goals across all agencies. Coordination, collaboration, and partnerships are essential to achieving this shared vision.

Guiding Principles

Life sciences activities (e.g., research, diagnostic, and clinical activities) using hazardous biological agents and toxins (HBATs), which include pathogens and toxins that require safe practices or containment facilities, are vital for enhancing and promoting public health.

Biosafety and biosecurity is an important element to the safe and secure conduct of research without creating undue impediments to scientific progress. Oversight within the Agency is key to biosafety and biosecurity. Personnel, processes, and procedures are the foundations of an effective and comprehensive approach to biosafety and biocontainment. Rigorous adherence to biosafety and biosecurity standards and practices by all individuals within FDA involved in laboratory activities is essential to protecting laboratory personnel, public health, and the environment. At the same time, it is critical that oversight measures allow laboratory activities to proceed in a manner that provides sufficient flexibility so that new challenges to public health, or emergency situations, can be addressed quickly and effectively.

Transparency and accountability are critical components of laboratory science, biosafety, and biosecurity activities. Effective outreach and communication with the FDA scientific community and the public are important in achieving transparency and accountability.

Periodic evaluations are essential to enhancing biosafety and biosecurity programs. Periodic and thorough evaluation of all components of laboratory biosafety and biosecurity systems within the Agency allows for continual improvement in laboratory biosecurity and biosafety practices. The process of enhancing biosafety and biosecurity should continue to evolve.

Goals Statement

The goal is to enhance biosafety and biosecurity practices in FDA laboratory facilities that conduct scientific research and related activities involving HBATs so as to create a safe working environment for all employees.

STRATEGIC PLAN AND IMPLEMENTATION OF A NEW BUSINESS MODEL

The OLSS is currently in the process of developing a Strategic Plan for fiscal years 2017 to 2022, part of which is this framework. The plan will document the vision, mission, goals, and objectives of OLSS and place them in the context of FDA's broader mission. It will describe the principles by which the OLSS will operate and the strategies OLSS will employ to achieve the mission. In addition to developing the Strategic Plan, OLSS is focused on collecting the data needed to develop a new operating model based on the recommendations of the External Laboratory Safety Workgroup (ELSW), Advisory Committee to the Director of the Centers for Disease Control and Prevention (CDC).

Developing the Strategic Plan first requires data collection from stakeholders. The OLSS is conducting stakeholder interviews to understand the needs of the FDA Centers and Offices, and to learn what barriers might exist for implementing and supporting a centralized biosafety and biosecurity program, among other programs. The FDA laboratories are diverse in their scientific and regulatory needs and operating style. The OLSS Strategic Plan will reflect the needs of each lab, as well as the needs of the Agency as a whole. The OLSS is taking the steps outlined in Figure 1 to develop the Strategic Plan, operating model, and implementation plan for strengthing quality, safety and laboratory security at FDA.

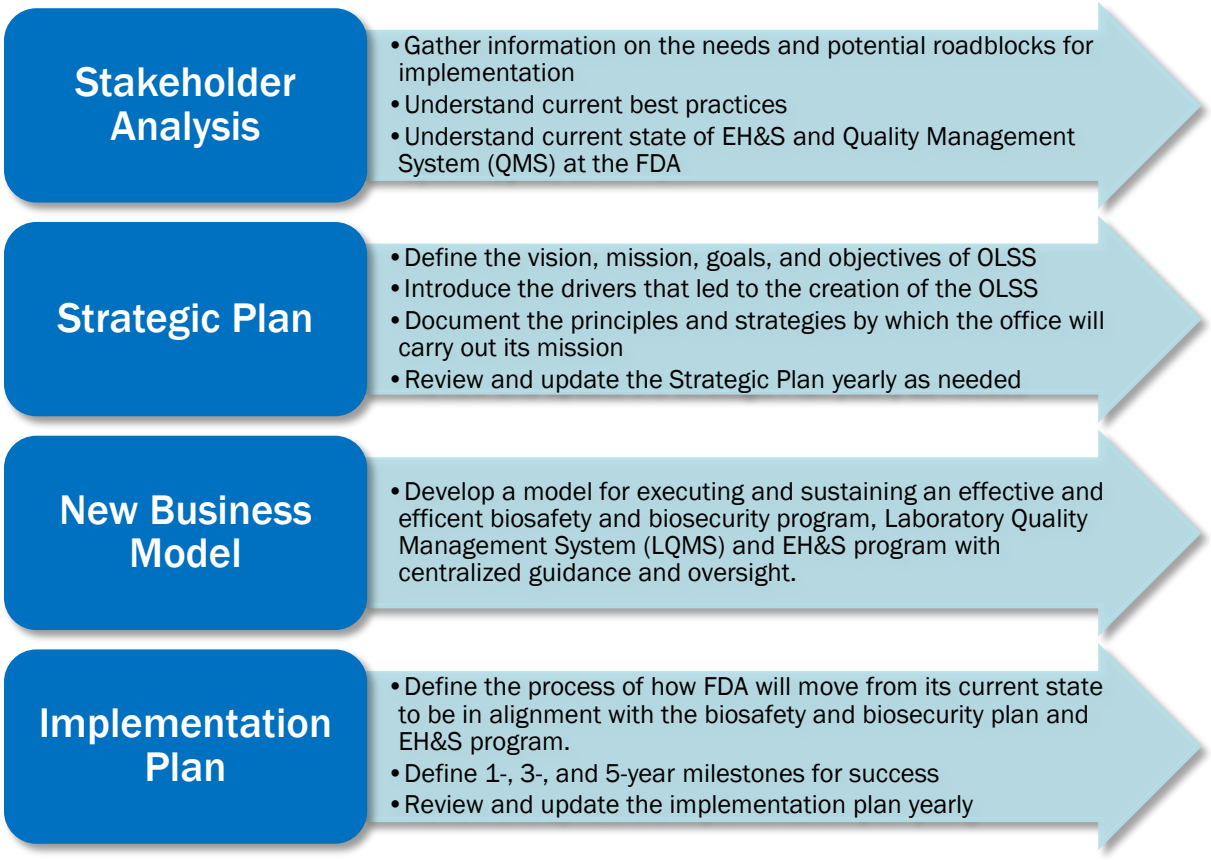

Figure 1: Steps for Developing the Implementation Plan

The OLSS will take the steps outlined above to develop an implementation plan that will allow OLSS to develop an operating framework.

ELEMENTS OF BIOSAFETY AND BIOSECURITY PLAN

Defining a Culture of Responsibility

The internal mission of FDA involves fostering a safe and healthy workplace. FDA recognizes that a basic tenet of this framework for biosafety and biosecurity is that all Agency personnel who work in, oversee, support, or manage laboratories understand and demonstrate a "culture of responsibility." A culture of responsibility exists when each individual accepts personal accountability, ownership, commitment, and responsibility to contribute to a safe and secure working environment. Responsible conduct in the life sciences is characterized

by accountability and compliance with applicable laws, regulations, policies, and procedures.[1]

It is fundamental to the implementation of the culture of responsibility that individuals throughout the organization are responsible, in some capacity, to conduct a risk assessment associated with their work. This assessment will ensure that appropriate measures are in place for risk mitigation and for the safe and secure handling of HBATs and other hazardous materials. This pertains to individuals at all levels within the Agency and to activities that directly or indirectly involve working with HBATs. This also applies to managerial responsibilities and commitments to ensure that resources are made available to sustain this culture of responsibility.

FDA is committed to a culture of responsibility and safety in the workplace. This may involve promoting conscientious laboratory practices and creating a culture that not only values—but that diligently practices—laboratory biosafety and biosecurity. Such a culture provides a more positive, productive, and safe work environment for everyone and the opportunity to leverage and utilize the best safety practices across the Agency.

FDA will continue to review and revise existing EH&S programs that improve the culture of responsibility and best safety practices. This will also require a change in understanding and perception of EH&S policies and practices. The EH&S program must also be understood to be a substantial component of each individual's personal responsibility.

To fully define the new culture of responsibility for safety and quality, the Agency realizes that this cultural change starts at the highest levels of the organization. The FDA created OLSS, in part, to reflect the magnitude of this change, to direct all organizational change related to EH&S, and to lead the effort. Initial efforts will be focused on incident reporting, employee onboarding and exit responsibilities, HBAT inventory control, implementing a laboratory biosafety and security risk assessment framework, and occupational health.

Policies and Procedures

Staff Manual Guide (SMG) 2130.8: HBAT Biosecurity and Inventory Control: The purpose of this SMG is to establish policies and responsibilities for the biosecurity and inventory control of HBATs used or stored in FDA laboratories. This SMG also establishes a survey process for HBAT storage areas, inventories, and transfers, as well as procedures for discrepancy reporting and remediation. This SMG fosters a culture of responsibility by requiring that FDA employees account for laboratory personnel turnover and changes, and properly inactivate and dispose of HBATs that are not assigned to a current qualified FDA employee.

Incident reporting procedure: This describes how all accidents, injuries, near misses, and potential exposures should be reported to OLSS through the Occupational Safety and Health Official (OSHO). Unsafe practices that may result in injury and/or damage to property can

[1] See Appendix A for more information about legal requirements applicable to biosafety and biosecurity.

also be reported anonymously through the FDA reporting hotline or website to promote a safe and healthy environment at FDA.

Governance and Organizational Structure

Appropriate governance for the conduct of research within FDA supports effective strategies for oversight of biosafety and biosecurity practices and helps address compliance with biosafety and biosecurity standards in FDA laboratory facilities. An effective governance and organizational structure includes specific elements necessary to empower FDA leadership, managers, supervisors, and laboratory workers to implement best practices in biosafety and biosecurity.

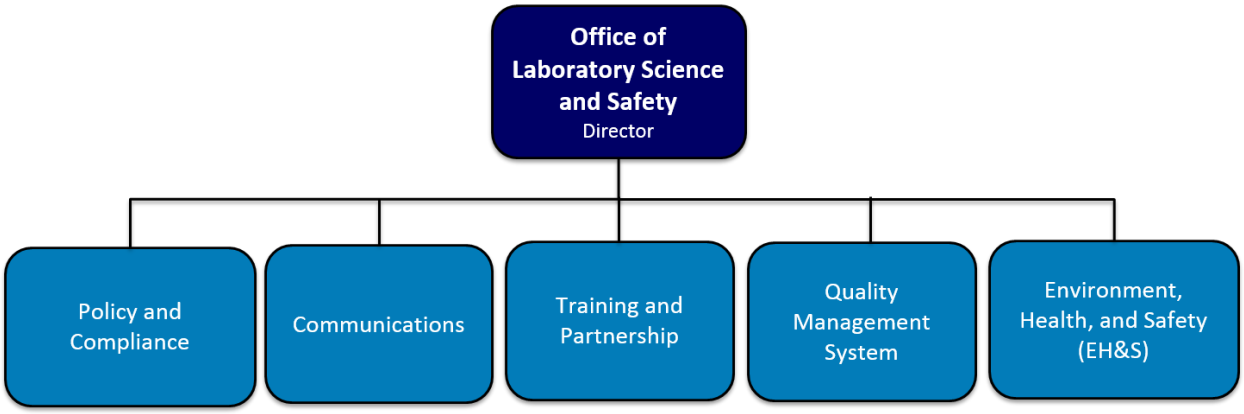

Figure 2: Conceptual OLSS Office Structure

This conceptual organization of OLSS to ensure that the EH&S program, including biosafety and biosecurity, is coordinated across FDA.

Below is the summary of the committees/boards, and their responsibilities, that support the biosafety framework at the FDA.

- **Institutional Biosafety Committees (IBCs)** promote the safe use of biohazardous materials in FDA laboratories and facilitate compliance with applicable federal, state, and local regulations and guidelines and Agency policy. They are responsible for reviewing, approving, and providing safety oversight to projects involving recombinant DNA research in accordance with FDA policy as well as the responsibilities defined in Section IV B-1 of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant Deoxyribonucleic Acid (rDNA) Molecules and in Section IV of the NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules (rsNAM). At FDA, IBCs also review protocols that involve HBATs in BSL-2 or higher environments.
- **Environment, Safety, and Health Council (ESHC)** coordinates Agency safety programs to provide a safe and healthy place of employment. It serves as a forum to share and support outreach efforts of ESEM and the Center/ORA Safety Programs. The ESHC primarily:
    - Manages and supports safety programs to enhance the effectiveness of the Agency in accomplishing its mission

  - Creates the expertise, information, and tools needed to provide the highest practical degree of safety, health, and environmental compliance by all FDA employees
  - Minimizes risks of accidents, injuries, or illnesses; minimizes losses in property damage; and ensures compliance with applicable federal, state, and local regulations

- Each Center using animals for laboratory research participates in an **Institutional Animal Care and Use Committee (IACUC).** These committees review research protocols and conduct evaluations of the Center's animal care and use program, which includes the results of inspections of these facilities, which are required by law.
- The **Center Safety Committees** monitor and support the campus EH&S programs. The committees assist in ensuring an open channel of communication between employees and management, including the OLSS.
- The **Laboratory Safety and Security Council (LSSC)** provides ongoing coordination of FDA's policies, best practices, and procedures related to laboratory science, safety, security, and other related issues. The LSSC oversees Agency activities for managing all potentially hazardous materials in the Agency's possession, including chemicals, radioactive materials, and HBATs, in alignment with evolving DHHS and federal policies.

OLSS will form committees/task forces/working groups on laboratory science and safety, as needed, to ensure proper review of new guidance and dissemination of information to the Centers and Offices.

Organizational Structure

FDA has developed an operating structure that ensures the Director for OLSS reports directly to the Commissioner (Figure 3). The Employee Safety and Environmental Management Office has been realigned under the umbrella of the OLSS for effective coordination of all safety activities. This realignment makes OLSS the point of accountability for all EH&S, laboratory science, safety, and security. This reorganization will ensure that EH&S is a top priority as the elements of the program are put into place.

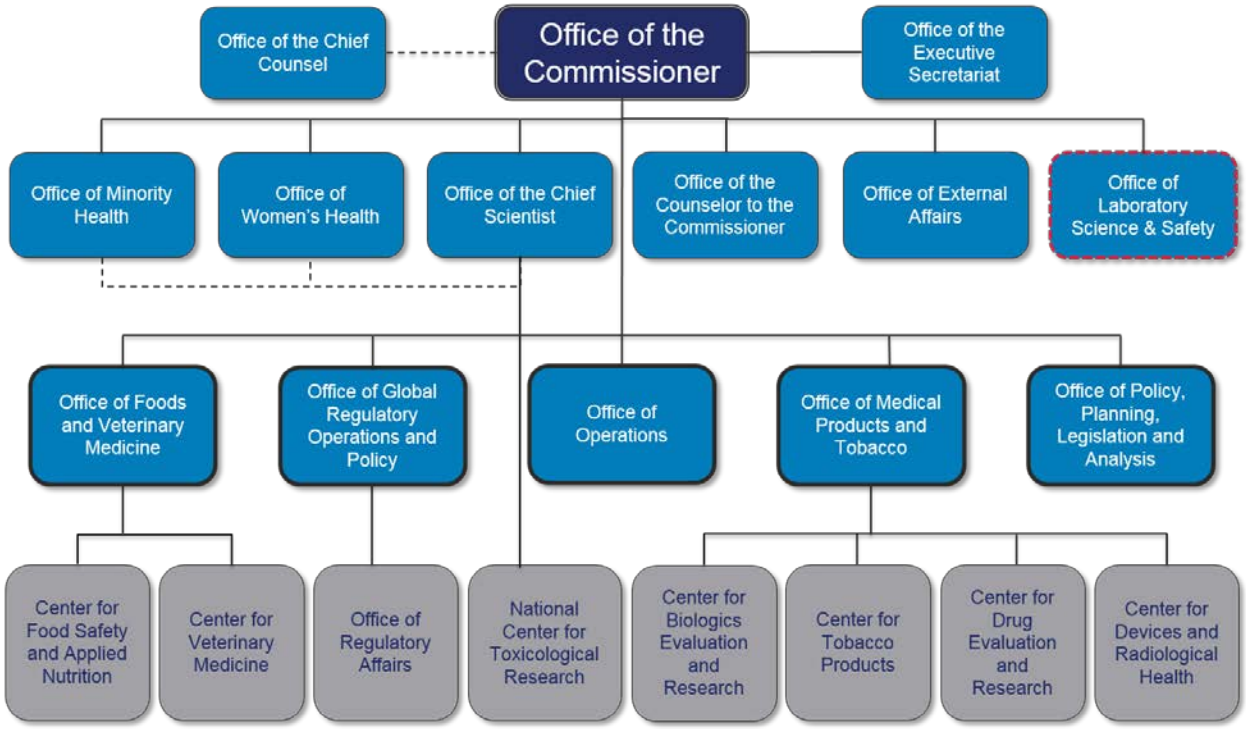

Figure 3: FDA Organizational Structure

OLSS *is responsible for providing leadership, oversight, and coordination of laboratory policies and operation and Agency-wide safety management activities. OLSS ensures that FDA implements best laboratory practices, policies, procedures, management, training, and a robust Laboratory Quality Management System to support laboratory science, security, and safety across FDA. OLSS also promotes the highest practical degree of safety, health, and environmental compliance for all FDA employees. Together with FDA Center safety programs, OLSS works to minimize risks of accidents, injuries, or illnesses; minimize property loss or damage; and maintain compliance with all applicable federal, state, and local laws, standards, and regulations.*

Biosafety Infrastructure

Biosafety involves the application of best laboratory practices and procedures, laboratory facilities, safety equipment, and relevant occupational health programs when working with potentially infectious microorganisms and other biohazards. The FDA recognizes the importance of effective and comprehensive biosafety oversight and the application of principles and practices within the Agency implemented in a manner that protects laboratory personnel, public health, and the environment while fostering progress in the life sciences.

The following organizations work to support biosafety infrastructure at FDA:

- LSSC
- IBC
- ESHC
- IACUC

- Center ESH Committees

Agency-wide Manual and Plans: A laboratory biosafety manual is currently being developed by OLSS to standardize and promote the best laboratory safety and security practices in a consistent manner across the Agency. This manual will describe the common processes, equipment, structure, and other attributes that ensure work with HBATs is performed to the highest standards of safety to protect the individual, organization, and the community. This manual will address biosafety level (BSL)-1 and BSL-2 activities. BSL-3 activities will be covered in a separate dedicated manual. This manual will include common procedures for risk assessment of biological materials, personal protective equipment, primary containment, spill response, waste management, and procedures to report incidents, accidents, near misses, and laboratory-acquired infections, training, and other issues or concerns associated with laboratory safety and security.

Physical Infrastructure for Biosecurity

Physical security includes the physical barriers, such as key-coded locks on laboratory doors or refrigerators and other methods used to keep unauthorized personnel out of laboratories or from gaining unrestricted access to HBATs. FDA recognizes the importance of an effective and comprehensive laboratory biosecurity program.

The Director of the Office of Security and Emergency Management (OSEM) ensures the overall physical security of FDA campuses. The Level of Protection plans for each FDA campus, interlinked to biosecurity, are guided by the Department of Homeland Security's (DHS) Interagency Security Committee (ISC). Level of Protection plans are formulated in accordance with the DHS ISC recommendations and comprehensive risk assessments that guide the development of countermeasures to mitigate the risk. Each plan identifies key security objectives that aim to prohibit access by unauthorized persons, protect FDA personnel and infrastructure from undesirable events, harden facilities, and mitigate risks to acceptable levels.

BSL-3 and Registered Select Agent Laboratories

Current policies and procedures outline the security measures at FDA into a three-tiered system: the facility, secured laboratories, and secured locations within the laboratory.

The facility is protected by multiple levels of physical security that may include, for example, security guards, card readers, closed-circuit television cameras, locked doors, intrusion detection alarms, access control, and package screening.

The secured laboratory is an area within the facility for which additional physical security is maintained. The OLSS coordinates with the OSEM to address this critical requirement. Access may be restricted by the use of key locks, combination locks, biometric readers, and/or card swipe readers, depending on the level of controlled access required to mitigate security risk.

For some laboratories (e.g., BSL-3), biometric access logs are maintained electronically and visitor logs are maintained manually. Additionally, the entrance and exit of all personnel including authorized personnel is recorded either electronically or manually.

Secured locations are areas within the BSL-2 laboratories that have at least one additional level of physical security. These areas serve as the storage areas for select agents and toxins when not in use. These locations may include storage units or animal cages that contain locking mechanisms. All select agents are to be kept in locked storage units when not in use.

Personnel Reliability and Suitability

In the context of life sciences research, personnel reliability and suitability provide an assurance that individuals with access to dangerous pathogens are trustworthy and reliable. The Agency implements federal requirements to ensure investigations for suitability and access to classified information are adjudicated to determine that personnel are trustworthy, honest, reliable, and loyal to the United States. Individuals working for, or on behalf of, the federal government must be favorably adjudicated. Agency components have implemented reliable methodologies to make decisions using risk-based assessments to ensure that persons with access to HBATs meet a high standard of reliability, are trustworthy, and are physically and mentally competent.

The FDA's Office of Security Operations is responsible for providing leadership and guidance to the Agency for all aspects of physical and personnel security, including suitability and the National Security Information program. Personnel suitability and security involves making sound decisions and taking necessary actions to mitigate risk to the Agency by ensuring FDA's workforce is reliable, trustworthy of good conduct and character, and of complete and unswerving loyalty to the United States. Personnel security and suitability policies and procedures provide a basis to determine a person's suitability to work for, or on behalf of, the government and assess whether a federal employee or contractor should be granted a security clearance.

The FDA implements Personnel Identity Verification (PIV) requirements of the Federal Information Processing Standards (FIPS) 201 and the suitability and security program required by the Office of Personnel Management (OPM) as set forth in "Suitability" (5 Code of Federal Regulations [CFR] Part 731), and "National Security Positions" (5 CFR, Part 732). FDA has implemented Agency-level policies and procedures that govern personnel reliability and suitability for responsible conduct and work with biological agents and other hazards.

Among other policies and procedures, SMG 2130.8 allows for HBATs to be removed from the possession of individuals who repeatedly, and willfully, fail to comply with HBAT biosafety and biosecurity policy.

Inventory Control and Management

Policies for inventory control and management are described in SMG 2130.8 for the storage, shipping, disposal, recordkeeping, and monitoring for HBATs. Material accountability procedures are important in tracking the inventory, storage, use, transfer, and destruction of HBATs. Proper storage, management, and safeguards are in place to prevent the loss, theft, or accidental release of HBATs.

FDA is committed to maintaining a culture of responsibility for the receipt, processing, protection, storage, retention, and disposal of HBATs. Several policies, governance entities,

and improvement initiatives are being established and implemented for specimen and sample management and inventory control. These policies ensure that there is a clear chain of custody for, and accounting of, HBATs at FDA. This policy will be supported with the implementation of the Safety Inventory and Protocol System (SIPS), an enterprise system.

Training and Competencies

The FDA recognizes the importance of training and technical competence for all personnel who work in, oversee, support, or manage FDA laboratory facilities. Putting into practice mechanisms to support the training and technical competence of personnel is critical for maintaining laboratory safety and security in FDA facilities.

The FDA also recognizes that training is integral to promoting a culture of responsibility and security and ensuring compliance with legal and regulatory requirements. Comprehensive online and in-person training programs developed by the FDA and third parties are available to FDA employees. In addition, FDA recognizes that safety training includes information that must be specific and pertinent to each safety program.

The OLSS will provide institutional oversight of laboratory safety training and certification programs to ensure Agency and DHHS standards are met. This oversight will be informed by ongoing collaboration with the LSSC and FDA Centers/Offices and by review/update of the initial Laboratory Safety Training Implementation Plan prepared for FDA University (FDAU) in September 2015.

FDA is actively engaged in identifying and implementing Agency-wide safety training improvements. The development of a comprehensive training program, with role and laboratory discipline specific modules, will be a key component of the implementation plan. FDA will work to identify training gaps and to strengthen the existing training programs. This will ensure relevancy and consistency for best and safe practices across the Agency.

Occupational Safety and Health Program Processes

FDA is committed to providing occupational safety and health programs for its employees. It is the responsibility of FDA to comply with safety and health standards issued under Section 6 of the Occupational Safety and Health Act of 1970. To foster a safe work environment, FDA provides the highest practical degree of safety to ensure good health for employees in all FDA activities.

The promotion and employment of safety and health policies, practices, and procedures is the responsibility of each member of the FDA community. Employees are expected to perform their work in a safe manner and to ensure that they do not place themselves, coworkers, visitors, support services personnel, or the general public at risk of injury or illness due to unsafe or unhealthy conditions, actions, or infractions.

It is the policy of the FDA to select operational strategies which accomplish regulatory, research, and public information objectives of the Agency and which foster a safe and healthy environment for all employees and for those communities in which the FDA operates. Safe working environments are achieved through risk assessments, hazard evaluations, mitigation strategies, and control measures such as engineering design

administrative controls, personal protective equipment, prudent work practices, and training.

Emergency Response Procedures

An incident response plan guides the response to an emergency and includes a set of standard operating procedures (SOPs). FDA recognizes that an incident response plan is a key part of risk management, and that it provides a means of planning for unexpected or unanticipated events. The OSEM develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. OLSS will work with Centers/ORA to develop laboratory emergency response plans.

Plans to address select agents are also an important component of emergency response. Under the provisions of select agent regulations (7 CFR §331.14, 9 CFR §121.14 and 42 CFR §73.14), an entity registered with the Federal Select Agent Program is required to have plans in place in the event of a natural, accidental, and/or man-made disaster. With these provisions, the Federal Select Agent Program can, with reasonable comfort, be assured that the registered entity's select agents and toxins are secured and safeguarded.

The FDA maintains and manages a sustained state of preparedness, response, and emergency management for its internal operations. Therefore, policies, plans, and procedures have been established to ensure effective and efficient responses during emergency events. The FDA conducts tabletop exercises annually, in collaboration with local police, fire, and emergency medical personnel, as applicable. This includes both mock and periodic real-drill responses. The FDA dispatches and maintains radio communications during emergencies/incidents with the OSEM, the security force, and external first responders.

Total Quality Management

Implementation of a sustainable and robust quality management system (QMS) approach to addressing oversight that includes safety and security could improve institutional capacity to address policy and operational issues in safety management, provide a structure for strategic planning for biosafety and biosecurity governance, and contribute to an enhanced culture of safe and responsible conduct among all institutional stakeholders.

The OLSS is evaluating an implementation plan of QMS for all laboratory science operations. In collaboration with the Centers and ORA, a framework for QMS will be developed by leveraging the 12 quality system essentials outlined by the Clinical and Laboratory Standards Institute, as appropriate. The initial focus will be on EH&S, but will be built to include some (or all) of the 12 elements and have the flexibility to reach additional standards for laboratory quality, when appropriate, and QMS standard International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC) 17025, if applicable. In addition, to address the Agency's specific biosafety and biosecurity needs, FDA may incorporate criteria from other OSH-related QMS standards such as Occupation Health and Safety Assessment Series (OHSAS) 18001, American National Standards Institute (ANSI) Z10, or the eventual ISO 45001 (expected for release in late 2017).

Engagement, Collaboration, and Partnership

Strengthening laboratory biosafety and biosecurity is a collaborative process and includes participation and commitment from all stakeholders. The appropriate breadth of collaboration depends on the hazards in use in a particular laboratory. Internal groups supporting collaboration might include human resources, facility engineers, EH&S, biosafety, biosecurity, occupational medicine, risk management, and emergency preparedness personnel. External collaborators might include first responders (e.g., police, fire, and emergency medical personnel, hazardous materials responders), scientific societies, Congress, and the public.

The FDA recognizes the importance of developing channels to foster employee engagement, collaboration, and partnerships with other organizations. Internal engagements, collaborations, and partnerships will develop through councils, committees, and working groups to ensure that FDA policies and procedures are established by leveraging best practices and consensus, as appropriate.

The FDA is seeking to harmonize its EH&S program, including this biosafety and biosecurity framework, with other programs at the CDC, NIH, and similar agencies. This effort is in support of sharing best and standardized practices for consistency across the DHHS agencies.

Communication and Outreach

The FDA promotes communication, outreach, and transparency involving life sciences research. Laboratory security, safety, containment procedures, equipment, and oversight are critical to the communities' acceptance of research in laboratory facilities. FDA recognizes that public education and outreach programs for stakeholders are vital for enhancing trust in the integrity of FDA laboratory facilities.

The strategy is intended to improve how we communicate about laboratory incidents or potential safety issues related to laboratory safety and security, provide updates to policies and programs, and share best practices with internal stakeholders, as well as how we interact with external stakeholders to uphold the Agency's mission to strengthen the culture of responsibility, security, and transparency.

Representative activities of OLSS' communication and outreach strategy for internal and external stakeholders are provided herein.

OLSS will continue to use, and improve upon, a proactive, transparent, collaborative, two-way communications strategy to engage the Agency's laboratory staff and leadership. The goal is to reduce the occupational exposure to hazardous agents and environmental hazards that could lead to injuries and illnesses. OLSS will disseminate Agency-wide policies, procedures, best practices, and organizational structures that clearly outline the roles, responsibilities, and expectations for all employees to drive a culture of responsibility and safety excellence. The OLSS will develop a comprehensive approach to inform employees about the potential hazards or risks to which they might encounter (e.g., reporting laboratory incidents and accidents) to drive increased awareness, enhance a culture of responsibility, and embrace a culture of safety.

Among other strategies, OLSS will regularly engage its stakeholders through email updates such as the OLSS Newsletter to provide important updates related to breaking news; changes in policies, procedures, or best practices; advances in laboratory science and safety; available training opportunities; and other information to promote safety and quality.

The FDA also aims to promote a culture of transparency with the public. As a result, OLSS has established policies and procedures to guide communications with external stakeholders for sharing best practices, notification of program changes, and interaction with the media. The external communications plan intends to ensure timely, high-quality, and effective communication between FDA and external stakeholders to ultimately facilitate effective biosafety and biosecurity measures.

APPENDIX A: FEDERAL REQUIREMENTS APPLICABLE TO BIOSAFETY AND BIOSECURITY

A variety of laws, regulations, policies, and procedures govern biosafety management systems in DHHS laboratory facilities to provide a layered and redundant approach to minimize the risk while working with HBATs.

- The Federal regulations that pertain most directly to biosafety and biosecurity oversight at high containment (BSL-3 and BSL-4) research laboratories are the following:
  - Applicable Occupational Safety and Health Administration (OSHA) regulations (*General Duty Clause, Respiratory Protection Standard, Personal Protective Equipment Standards,* and *Bloodborne Pathogens Standard*)
  - Select Agent Regulations, developed by DHHS and the U.S. Department of Agriculture (USDA)
  - USDA Animal Plant Health Inspection Service (APHIS) permitting regulations
  - HHS Centers for Disease Control and Prevention (CDC) regulations that require a permit for the import of any infectious agent known or suspected to cause disease in humans
  - *Importation of Etiological Agents of Livestock, Poultry, and Other Animal Diseases and Other Materials Derived from Livestock, Poultry, or Other Animals* is regulated by the USDA APHIS
- The Department of Transportation (DOT) regulations that restrict the transportation within the United States of hazardous biological agents unless certain conditions are met.
- The Department of Commerce regulations that restrict the export of hazardous biological agents unless certain conditions are met.
- United States Postal Service regulations that restrict the transportation of infectious substances through USPS mail.
- *Technical Instructions for the Safe Transport of Dangerous Goods by Air* published by International Civil Aviation Organization that applies to the shipment of infectious substances by air and is recognized in the United States.
- Dangerous Goods Regulations by International Air Transport Association (IATA) regulates transporting infectious substances via airlines.

Other federal regulations and regulatory oversight, although ancillary to research on hazardous biological agents, can have an impact on research facilities.

The federal guidelines that pertain generally to research activities in biomedical laboratories include the following:

1. *Biosafety in Microbiological and Biomedical Laboratories* (*BMBL*), fifth edition, a guidance document developed by CDC and NIH
2. *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines)

Other federal agencies also require compliance with the *NIH Guidelines* as a term and condition of their own funding. The U.S. government has also established policies relevant to biosafety and biosecurity (e.g., dual-use research of concern).

More information about federal laws, regulations, guidelines, and policies is available at www.phe.gov/S3.