U.S. FOOD & DRUG ADMINISTRATION

2017-2022 OPERATING MODEL

OFFICE OF LABORATORY SCIENCE AND SAFETY

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MESSAGE FROM THE DIRECTOR

The FDA is dedicated to protecting its employees and the American public while pursuing its fundamental mission of promoting and protecting public health. One of the Agency's highest priorities to support this mission is producing high-quality laboratory data while ensuring a safe and secure workplace for all of our employees.

The Office of Laboratory Science and Safety (OLSS) is dedicated to supporting FDA's mission through a set of goals and objectives as defined in our Strategic Plan. Within this plan, we describe the value of a centralized organization that will generate opportunities for shared best practices, streamlined training, efficient communication among FDA laboratories, and promote a culture of responsibility and safety. We also acknowledge the critical importance of collaboration; we will require significant commitment, engagement, participation and support from leadership and staff across the Agency to accomplish our goals and objectives.

Segaran Pillai, Ph.D.
Director, Office of Laboratory Science and Safety

This Operating Model is the second of several programmatic documents that outline how we will operate internally and interact with stakeholders to accomplish our goals and objectives. It is through continual engagement and establishment of collaborative partnerships across FDA and with other agencies that OLSS can help ensure strategic growth and effective management of our laboratory science and safety programs. The collaboration and commitment of the Centers/ORA staff and leadership is fundamental to the success of our Office as we strive to help advance FDA's public health mission.

We look forward to working collaboratively towards our shared goals and fulfilling the Agency's vital mission by embracing best practices for laboratory science and safety.

Segaran Pillai, Ph.D.
Director, Office of Laboratory Science and Safety

Office of Laboratory Science and Safety (OLSS) 2017–2022 Operating Model

October 13, 2017

EXECUTIVE SUMMARY

The Operating Model (OM) is the framework for how the Office of Laboratory Science and Safety (OLSS) will operate, interact, collaborate and coordinate in partnership with its stakeholders, and deliver value to its customers. It outlines the key programmatic and operational functions that OLSS will engage in to accomplish the goals and objectives, as outlined in the OLSS Strategic Plan.[1]

The OM provides a basis for the establishment of OLSS and the Office's overarching vision, mission, and guiding principles as the foundation for the actions OLSS will perform to achieve its goals. The OM reflects the newly established organizational structure and authorities that will help carry out the Office's activities; it highlights the role that the Director of OLSS will play in providing executive leadership and oversight, and serving as the Agency's single point of accountability. Additionally, the OM details the key functions of the Office (i.e., program management; laboratory quality, laboratory security, and Agency-wide safety services; communication; training; building relations; and fostering a culture of responsibility and safety) and the relationships that it will establish with internal and external stakeholders to help achieve a desired future state focused on best laboratory science; laboratory security; and Agency-wide environment, health, and safety programs.

ACRONYMS

Acronym	Definition
ACD	Advisory Committee to the Director (of the Centers for Disease Control and Prevention)
ACRA	Associate Commissioner for Regulatory Affairs
APHIS	Animal and Plant Health Inspection Service
ARO	Alternate Responsible Officials
ATTF	Anti-Terrorism Task Force
BBPECP	Bloodborne Pathogen Exposure Control Plan
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSAT	Biological Select Agents and Toxins
BSL	Biosafety Level
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CITI	Collaborative Institutional Training Initiative
CJIS	Criminal Justice Information Services
DASHO	Designated Agency Safety and Health Official
DEA	Drug Enforcement Administration
DOT	Department of Transportation
DSAT	Division of Select Agents and Toxins
ECRS	Embracing a Culture of Responsibility and Safety
ELSW	External Laboratory Safety Workgroup (of the ACD)
EMR	Electronic Medical Record
EPA	Environmental Protection Agency
ESEM	Employee Safety and Environmental Management
ESHC	Environmental Safety and Health Council
FBI	Federal Bureau of Investigation
FDA	Food and Drug Administration
FESAP	Federal Experts Security Advisory Panel
FTAC	Fast Track Action Committee
G&A	General & Administrative
GAO	Government Accountability Office
GSA	General Services Administration
HBAT	Hazardous Biological Agents and Toxins
HHS	Health & Human Services
IACUC	Institutional Animal Care and Use Committee
IBC	Institutional Biosafety Committee
IPC	Interagency Policy Committee
ISATTAC	Intragovernmental Select Agents and Toxins Technical Advisory Committee
LPT	Laboratory Profile Tool
LQMS	Laboratory Quality Management System
LQMSWG	Laboratory Quality Management System Working Group
LSPPW	Laboratory Safety Practices and Policies Workgroup

Acronym	Definition
LSSC	Laboratory Science and Safety Council
MAG	Management Advisory Group
MC	Management Council
NCR	National Capital Region
NESHC	National Environmental Safety and Health Committee
NIH	National Institutes of Health
NRC	Nuclear Regulatory Commission
NSC	National Security Council
OC	Office of the Commissioner
OCS	Office of Chief Scientist
OEA	Office of External Affairs
OEO	Office of Emergency Operations
OFEMS	Offices of Facilities, Engineering, and Mission Support Services
OHS	Occupational Health Services
OIG	Office of Inspector General
OLSS	Office of Laboratory Science and Safety
OO	Office of Operations
OPDIVS	Operating Divisions
ORA	Office of Regulatory Affairs
OSEM	Office of Security and Emergency Management
OSHA	Occupational Safety and Health Administration
OSHO	Occupational Safety and Health Officer
OSTP	Office of Science and Technology Policy
PD	Position Description
PHS	Public Health Service
PII	Personally Identifiable Information
PMAP	Performance Management Appraisal Program
RDT&E	Research Development Test & Evaluation
RO	Responsible Officials
RSC	Radiation Safety Committee
SIPS	Safety, Inventory, and Protocols System (HealthRx)
SMG	Staff Manual Guide
SOP	Standard Operating Procedures
SRA	Security Risk Assessment
USDA	United States Department of Agriculture
WO	White Oak
WH	White House

INTRODUCTION

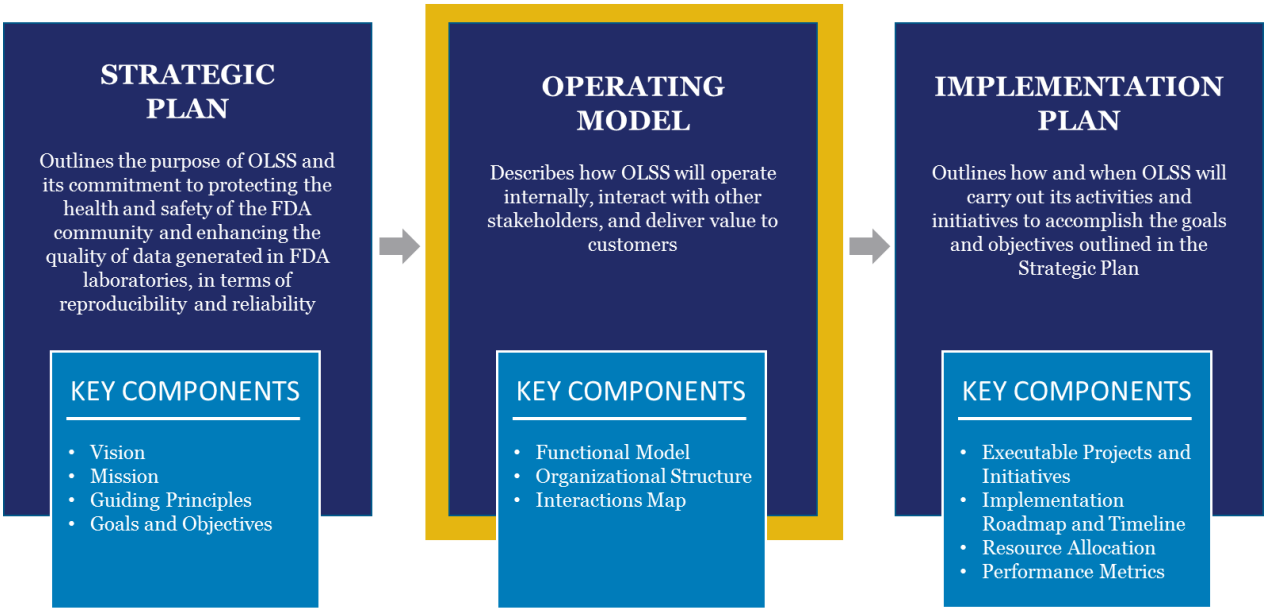
Purpose of the Operating Model

The Office of Laboratory Science and Safety (OLSS) Operating Model (OM) describes how the organization will operate internally, interact with stakeholders, and deliver value to customers. Specifically, the OM defines the following items:

- The 3–5 year ideal future state necessary to achieve OLSS' strategic goals and objectives
- OLSS' key functions, roles, and responsibilities
- The organizational structure and authorities of the Office
- The execution of OLSS' strategy through new or improved standards, processes, tools, and capabilities

Figure 1 highlights the Operating Model as a key component of the future state development process; it uses the Strategic Plan as the foundation to outline the model within which the Office will operate, and provides the baseline for the Implementation Plan that will define all the projects and initiatives needed to accomplish the goals and objectives established in the Strategic Plan.

Figure 1: Key Components for Future State Development



The OLSS Strategic Plan

In January 2017, OLSS released its Strategic Plan. The Office is set up in accordance with this Operating Model to realize its strategic goals and objectives. The following

section provides an overview of OLSS' vision, mission, goals, and guiding principles. For a more detailed discussion of these topics, please refer to the OLSS Strategic Plan.[1]

Vision

FDA serves as a model of excellence for its robust and integrated laboratory science; laboratory security; and Agency-wide environment, health, and safety programs.

Mission

The mission of OLSS is to:

- Ensure FDA's laboratories and workplaces are operated in a safe and secure manner to protect employees, the surrounding communities, and the environment
- Research and disseminate innovative ideas and validated methods for safe and secure laboratory practices
- Support high-quality (i.e., accurate, reliable, and timely) FDA laboratory results
- Promote a culture of shared responsibility and safety

Guiding Principles

OLSS' Strategic Plan describes the following high-level principles and strategies to carry out its mission.

Culture of Responsibility and Safety

Workplaces are safest and laboratory results are of highest quality when FDA employees and leadership share common beliefs, values, and norms about safety and quality and take responsibility for their own roles in these fundamental practices.

Collaborative Development

The OLSS mission will be accomplished through collaborative development and implementation of its programs. The only chance of success will be through partnerships, flexibility, and a spirit of service to FDA employees, leaders, Offices, and Centers.

Transparent Operations

OLSS will operate with transparent processes and communications. For example, when permissible, policies and manuals will be published to FDA's public website, and incident investigations and mitigations will be made public and represented anonymously.

Evidence-Based Practice

Evidence-based practices will be used whenever possible, including organizational theory, laboratory operations, and behavioral change. To the extent practical, OLSS will empirically evaluate the outcomes of its programs and initiatives, and will shift resources toward programs or initiatives that need the most assistance or attention.

OLSS' Goals

OLSS' seven goals encompass workplace health and safety, laboratory safety, laboratory security, laboratory quality, efficiency, applied research, and culture of responsibility and safety:

1. Minimize risks to employee health and safety attributable to the FDA workplace, outside of laboratory activities.
2. Minimize risk to employee health and safety attributable to laboratory activities.
3. Ensure appropriate security and procedural safeguards are implemented in laboratories with biological, chemical, radiological, and other hazardous materials.
4. Protect and preserve the quality—including accuracy, reliability, reproducibility, and timeliness—of laboratory results and data.
5. Increase efficiency related to laboratory science; laboratory security; and Agency-wide environment, health, and safety.
6. Conduct a program of applied research to generate evidence for best laboratory science and safety practices.
7. Reinforce and promote the Agency-wide culture of responsibility and safety.

The Establishment of OLSS

OLSS was created in the wake of a series of safety-related events both internal and external to the Food and Drug Administration (FDA). The Office was established with concurrence from Congress in February 2017, after a series of earlier steps:

- In July 2014, FDA established the Laboratory Safety Practices and Policies Workgroup (LSPPW). The LSPPW evolved into the Laboratory Science and Safety Council (LSSC) to serve as an advisory body for OLSS operations.
- In August 2014, the White House (WH) urged all federal departments and agencies that possess, use, or transfer select agents and toxins that could pose a significant threat to public health to conduct a "safety stand-down" to inventory all of their laboratories.
- In July 2015, the External Laboratory Safety Workgroup (ELSW) presented its report titled *Recommendations of the Advisory Committee to the Director (ACD), CDC, Concerning Laboratory Safety at the Food and Drug Administration* to the ACD.
- In October 2016, the Former FDA Commissioner, Dr. Robert Califf, formally announced the establishment of the Office of Laboratory Science and Safety (OLSS).
- In January 2017, OLSS released the first version of the 2017–2022 OLSS Strategic Plan.

In response to these external and internal developments, FDA leadership took the opportunity to establish the Office in October 2015 as the central point of accountability for laboratory science; laboratory security; and Agency-wide environment, health, and safety. The Commissioner* publicly declared to the FDA community his mandate that the Director of OLSS would shoulder the following responsibilities[1]:

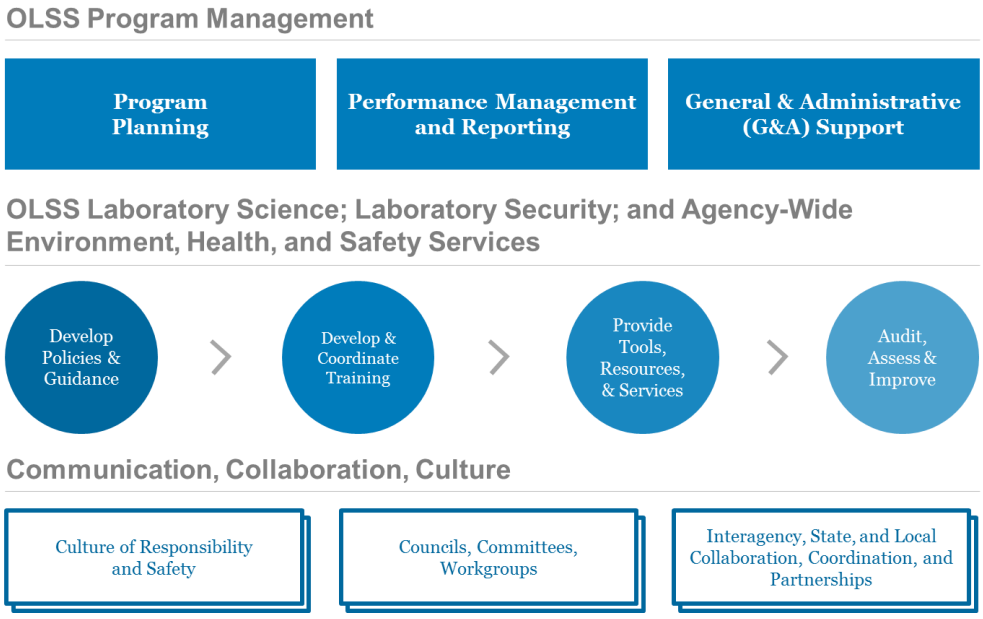
- **Serve as the Designated Agency Safety and Health Official (DASHO)** and as the Agency's Senior Laboratory Scientific Advisor to ensure that the laboratory workforce is able to conduct mission-critical science safely and effectively.
- **Provide executive leadership** in the area of laboratory science and employee safety and health, which includes centralizing and standardizing laboratory safety and laboratory security policies and practices across the Agency.
- **Provide oversight and monitoring** for FDA's safety program, which includes routine and ad-hoc inspections to evaluate laboratory safety standards and ensuring that the Agency is in compliance with federal, state, and local regulatory standards and requirements.
- **Serve as the Agency's single point of accountability** for implementation of policies and procedures, and for oversight for all employee safety and health operations and activities.
- **Serve as the Agency liaison** with respect to employee and laboratory safety to HHS Operating Divisions (OPDIVS) and components of HHS, other federal agencies, and the scientific community.
- **Develop and implement a robust Laboratory Quality Management System** (LQMS) for FDA to ensure that the integrity and quality of data and results support FDA's regulatory mission.
- **Conduct and fund appropriate applied research** to enhance laboratory science, laboratory security, and Agency-wide safety.

** The outlined list of responsibilities is pulled directly from the Strategic Plan and the Letter from the Commissioner.*

OVERVIEW OF OLSS KEY FUNCTIONS

The OLSS functional model presented in Figure 2 highlights the enduring functions that OLSS will establish to run a successful program. The model allows for clear communication of the functions that the Office will be responsible for and the essential Program Management, services (e.g., developing policies, training, assessments, etc.), and collaboration elements critical for OLSS to be successful.

Figure 2: OLSS Functional Model



A number of activities are currently underway or in planning, and these will be presented within the context of the model later in the document to provide information on what will fall under each of the functions. The model will also be used to guide activities related to budget, personnel, projects, contracts, collaborations, and communications. Additionally, it will outline OLSS' key internal program management activities; describe laboratory science*; laboratory security; and Agency-wide environment, health, and safety services; and highlight communications, collaborations, coordination, and partnerships. It also reflects the Employee Safety and Environmental Management (ESEM) staff realignment to OLSS.

Tables 1–10 list the range of activities OLSS will pursue as part of its program management, services, and communication and collaboration strategy. The information presented is not exhaustive of all OLSS activities, but rather a summary to provide context and understanding of past, present, and future activities within the functional

Laboratory science refers to the implementation of a robust LQMS across the Agency.

model. A more exhaustive list of activities will be outlined in the Cost Allocation Model-Activity Catalog and will be tracked and managed through the Implementation Plan.

OLSS Program Management

Program Planning

The goal of program planning is to coordinate and sequence the functions and activities of the Office so it can manage strategically. See Table 1 for a summary list of these activities.

Table 1: Summary of OLSS Program Planning Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Ensured Centers/ORA's adherence to Agency-wide policies and procedures • Established staff manual guides (SMGs[2,3]) • Continued to foster a culture of responsibility and safety • Developed Agency-wide Laboratory Quality Management System Working Group (LQMSWG) Charter	• Manage budget • Develop the Operating Model • Develop "Embracing a Culture of Responsibility and Safety (ECRS)" initiative—Tactical Plan • Revise OLSS Organizational Chart • Develop Agency-wide inventory control and management system • Establish Agency-wide policies	• Develop the Implementation Plan • Establish Applied Research Program to enhance laboratory safety and security • Develop a strategic path for understanding and policy implementation with respect to an Agency-wide LQMS • Develop Agency-wide inventory control and management system

Performance Management and Reporting

A strong performance management and reporting system will allow OLSS to assess the impact of the Office's actions, identify metrics to track results, and ensure that its goals and objectives have been achieved. See Table 2 for a summary list of these activities.

Table 2: Summary of OLSS Performance Management and Reporting Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Supported data calls from oversight bodies • Performed annual employee reviews (PMAPs) • Prepared and disseminated reports (e.g., safety incidents report, responses) to external stakeholders (e.g., WH, Health & Human Services [HHS], Congress, regulatory bodies, interagency partners, etc.)	• Prepare OLSS Annual Report • Measure Office performance • Submit FDA Annual Report to HHS • Complete FDA Environmental Compliance audits • Disseminate FDA accident report CY16, redacted as appropriate, (e.g., safety incidents report, responses) to external stakeholders (e.g., WH, HHS, Congress, regulatory bodies, interagency partners, etc.)	• Reduce data calls through real-time data collection • Perform and report on laboratory inspections or audits starting in FY18

General and Administrative Support

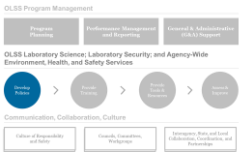
OLSS will require general and administrative support in conjunction with all other program management activities. See Table 3 for a summary list of these activities.

Table 3: Summary of OLSS General and Administrative Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• N/A	• Provide OLSS staff G&A support (e.g., travel, supplies, asset inventory) • Manage OLSS contracts (e.g., analyze and readjust language in the existing Federal Occupational Health (FOH) contract to ensure OLSS has proper oversight for employee health; manage personnel files for the Occupational Health and Safety Officer (OSHO) • Develop meeting minutes • Develop and maintain the Rewards and Recognition Program	• Maintain Performance Management Appraisal Programs (PMAPs), establish competency levels, and maintain/update staff Position Descriptions (PDs) for Agency safety staff • Provide training course enhancement opportunities; track time and attendance • Hire Personnel and Budget SMEs, and outline HR rules for the organization • Ensure protection of Personally Identifiable Information (PII)

OLSS Laboratory Science; Laboratory Security; and Agency-Wide Environment, Health, and Safety Services

Develop Policies and Guidance



The Agency aims to meet a set of consensus-driven baseline standards for safety at its workplaces and high-quality operation of its laboratories. Table 4 lists the activities OLSS will pursue to lead the development of these standards and establish corresponding Agency policies and guidance where appropriate.

Table 4: Summary of OLSS Policies Development Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Developed SMG2130.8: Hazardous Biological Agents and Toxins (HBATs) • Developed SMG1410.63: Ensurance of Compliance of FDA Laboratory Science and Safety and Environmental Health and Safety Programs • Developed policy regarding emerging infectious diseases (e.g., Zika) • Attended the Center for Biologics Evaluation and Research (CBER) BSL-3 Table-top drill/exercise • Continued to maintain the Annual Attestation Forms • Updated the Institutional Biosafety Committee (IBC) charter • Issued a process for minors visiting or interning in the laboratories • Issued a process for the on-boarding and off-boarding new laboratory emnployees.	• Develop Laboratory Quality Management System Policy and Framework • Develop and maintain policies and SMGs • Provide consultation in establishing and maintaining Standard Operating Procedures (SOPs) • Establish and maintain emergency action plans • Establish and maintain library of procedures and documents • Standardize provision of OHS across the agency • Develop international travel health and safety recommendations • Enhance Environmental Compliance Program • Developing robust information system to facilitate IBC Review	• Develop pre-employment fitness standards and require periodic exams for employees engaged in special occupations • Evaluate manpower needed to implement the OLSS Strategic Plan for the Agency • Develop and maintain purchasing- and inventory-related policies (e.g., guidance/checklist/guidelines for reagents and consumables management, selection and evaluation of providers, procurement, stock management and inventory, referrals and subcontracting) • Model process management/control policy after ORA internal policy • Provide guidance to the laboratories to ensure the same level of safety personnel across Centers/Offices; ensure the authorization chain is somewhat similar, even if they have different titles • Establish policies that govern industrial hygiene at the Agency • Create sharps disposal policy program for non-lab sharps • Coordinate responses to future Congressional inquiries and requests Coordinate with the Office of Inspector General (OIG) and the Government Accountability Office (GAO) reviews and responses

Develop and Coordinate Training

Table 5 lists the current and planned activities for establishing Agency-wide training on safety policies and best practices that will support OLSS' effort to mitigate exposure and risks from laboratory hazards and minimize risk to employee health and safety. Agency-wide environmental compliance training to adhere to federal, state, and local requirements is also listed in Table 5.

Table 5: Summary of OLSS Training-Related Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Established Collaborative Institutional Training Initiative (CITI) biosafety training module contract • Developed and conducted environmental training • Established training requirements for environmental auditors • • Developed Bloodborne Pathogens Exposure Control Plan [BBPECP]	• Manage CITI biosafety training modules • Manage Office/supervisor training specific to FDA • Develop international travel briefings based on policy • Provide training on the Environmental Compliance Program • Access to existing classes from the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) • Better utilization of FDA University. • Develop training aligned with laboratory safety manual content • Provide central training administration (e.g., manage training certifications and documentation maintained across Learning Management Centers) • Participate in Lab emergency preparedness drills/exercises for BSL-3 and select agent labs • Develop and maintain safety and security manuals • Determine training needs for FDA laboratory personnel	• Develop/update training modules addressing Agency and site-specific safety needs • Provide internal periodic training to OLSS staff members (e.g., embed staff inside the laboratories) • Coordinate Agency-wide health and safety training programs (e.g., radiation, biological, lab operations, ergonomic, Individual Development Plans) • Develop and participate in emergency response exercises • Present EHS portion of the New Employee Orientation •

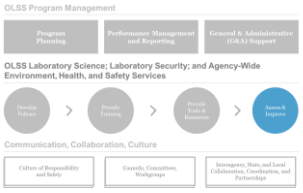
Provide Tools, Resources, and Services

OLSS will provide scientists and researchers with tools and resources to support and help maintain high-quality laboratory science, laboratory security, and Agency-wide safety programs and activities. See Table 6 for a summary list of activities.

Table 6: Summary of OLSS Tools- and Resource-Related Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Provided HBAT inventory template • Piloted the incident reporting form, process, and database (HealthRx) • Piloted on/off-boarding checklists • Piloted Electronic Medical Record System (EMR) for vaccination records • Supported Public Health Service (PHS) organized Influenza vaccination campaign in the National Capital Region (NCR) • Managed decontamination/ decommissioning of FDA facilities • Coordinated emergency evacuation drill activities that minimize disruptions to research • Provided tools and resources for improved recycling of non- contaminated laboratory plastics	• Provide records management (e.g., incident reporting, inventory management) • Implement on/off-boarding checklists • Develop and implement Safety, Inventory, and Protocols System (SIPS) including EMR • Manage laboratory information, licenses held by individual labs (e.g., Nuclear Regulatory Commission [NRC], Anti-Terrorism Task Force [ATTF], Drug Enforcement Administration [DEA], etc.), and waste management contract • Establish FDA OSHO's Reporting Structure • Develop and centralize the incident reporting process • Establish performance measures to assess performance and progress against the Office's goals and objectives • Provide evaluation of occupational injuries/illness across the Agency • Provide tool to categorize, and manage inventory • Provide tools and resources to support the Environmental Compliance Program • Provide tools and resources for improved recycling and reuse of office supplies • Developing robust information system to facilitate IBC Review • Provide industrial hygiene services to the Agency	• Develop a risk assessment framework • Develop risk assessments checklists • Implement and develop a common understanding with respect to an Agency-wide LQMS • Explore cost efficiencies for equipment maintenance and calibration; manage standard questionnaire form to capture certification dates • Establish standard Agency and OLSS processes (e.g., incident reporting; corrective action; on/off-boarding of staff; etc • Manage SIPS/EMR • Provide international travel risk communication to travelers • Manage Agency-wide hearing and vision protection program • Establish a robust Return to Work Program to facilitate an employee's return to work in some capacity as soon as they are able after an illness or injury • Develop Enterprise Content Management (ECM) repository • Establish protocol/triaging methods for incoming customer complaints, suggestions, and ideas • Contribute to wellness programs

Audit, Assess, and Improve



When feasible, OLSS will offer the tools and resources needed to support, assess, and conduct periodic audits to ensure compliance with laboratory science; laboratory security; and Agency-wide environment, health, and safety policies across the Agency and to continuously identify non-compliance, dificiencies, gaps and resource needs. See Table 7 for a summary list of activities.

Table 7: Summary of OLSS Assessment- and Improvement-Related Activities

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Conducted annual radiation safety program audit • Provided medical surveillance physicals for laboratorians • Developed and implemented FDA environmental audit program • • Conducted site visits to ORA, CDER, and CFSAN field laboratories	• Develop/provide laboratory safety assessment tools and resources; leverage proficiency checklist • Develop and utilize the Laboratory Profile Tool (LPT) as a self-assessment tool for laboratory safety and quality management • Conduct on-site reviews, workplace evaluations, and walkthroughs of FDA laboratories • Conduct environmental assessments and implement remediation plans • Maintain Agency Laboratory Annual Reports • Develop and utilize the Organizational Profile Tool (OPT) as a questionnaire for stakeholder analysis • Contribute to PMAP for OSHOs • Conduct environmental and radiation safety audits • Assess and improve the Environmental Compliance Program • Develop laboratory audit program	• Conduct Occupational Safety and Health Administration (OSHA) compliance assessments • Coordinate mitigation strategies • Investigate root cause of incidents to identify systemic issues • Provide routine inspection or audit services • Support drafting/ implementing a Corrective Action Plan • Maintain central incident reporting database • Conduct employee surveys to measure effectiveness of programs and needs • Conduct assessments of all available validation methods and decide on the best method through consensus • Conduct annual OLSS self-assessment •

OLSS Communication, Collaboration, and Culture

Establish a Culture of Responsibility and Safety

One of OLSS' key guiding principles is to establish and promote an Agency-wide culture of responsibility and safety in order to create the bestworking environment focused on emphasizing safety, laboratory security, and responsible conduct to minimize risks to employee health and safety. See Table 8 for a summary

list of activities in support of this effort.

Table 8: Summary of OLSS Activities Related to Responsibility and Safety Culture

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Developed monthly e-Newsletters • Adopted, through the Radiation Safety Program, the Nuclear Regulatory Commission Policy Statement on Safety Culture as a guiding principle for radiation safety • Developed 1-2-3 emergency procedures digital signs displayed in the NCR (August 2016) • Promoted influenza vaccination campaign • 1-2-3 emergency signs in labs	• Establish communication standards and best practices • Develop and implement FDA OLSS Ambassador Program • Provide recommendations to improve culture of responsibility and safety • Develop communication methods to promote culture of responsibility and safety • Communicate environmental regulation/policy updates and changes to the Agency • Maintain communications with stakeholder groups • Develop and implement the OLSS Awards and Recognition Program	• Conduct safety and lab security communication campaigns • Establish and implement an OSHO residency program for rotation within OLSS to explore opportunities for collaboration, establishing the best program at FDA, and to promote career enhancement • Conduct organizational analysis to determine the OSHO's reporting structure to offer the best program at FDA • Updating WO waste poster • Update FDA recycling program/policy • Develop FDA foundational safety training program for integration into New Employee Orientation, as appropriate

Engage with Councils, Committees, and Working Groups

OLSS will collaborate with internal stakeholders to better understand the current state environment, establish communication standards and best practices, and continue to promote a culture of responsibility and safety. See Table 9 for a summary list of activities.

Table 9: Summary of OLSS Activities Related to Councils, Committees, and Workgroups Engagement

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Adopted the ELSW recommendations and related goals • Participated in the Subcommittee on National Security Laboratory RDT&E Facilities & Infrastructure • Participate in Incident Readiness Response WG	• Provide briefings to Center Directors, Executive Officers, and the Commissioner • Support/oversee multiple councils, working groups, and committees (e.g., LSSC; LQMSWG; Workplace Council; ESHC; IBC,) • Participate in International Travel Health and Safety Workgroup	• Support/oversee other committees and councils (e.g., IACUC, RSC, WO Safety Committee, Safety Training Committee, Lab Staff Forum)

Legend:
IACUC: Institutional Animal Care and Use Committee; RDT&E: Research Development Test & Evaluation; RSC: Radiation Safety Committee; WO: White Oak

Develop and Maintain Interagency, State, and Local Collaboration, Coordination, and Partnerships

OLSS will engage in collaborative partnerships across FDA and other agencies to ensure effective management of laboratory science and safety programs. Growing strategic alliances with our partners across FDA laboratories, other federal agencies, and the private industry is key to accomplishing the Office's mission. See Table 10 for a summary list of activities.

Table 10: Summary of OLSS Activities Related to the Development and Maintenance of Interagency, State, and Local Collaboration, Coordination, and Partnerships

OLSS-Accomplished Activities	Activities Currently Underway	Future Activities
• Participated in ongoing inter-agency and partnerships workgroups (international traveler health and safety, FESAP 2.8) • Assisted CDC with their environmental audit program • Provided environmental training to HHS, NIH, and CDC personnel • Maintained GAO engagements • Attended Congressional hearings • Participated in the Committee on Homeland and National Security	• Contribute to interagency planning (e.g., radiological emergencies) • Contribute to BMBL • Contribute to HHS Fast Track • Contribute to WH IPCs • Liaise with other agencies (e.g., CDC, NIH) • Liaise with GSA to ensure FDA sustainability and recycling goals are met as tenants of GSA property • Lead the CDC/DSAT, USDA/APHIS Biannual Select Agent Review process • Lead the CDC toxin evaluation and exclusion limits determination • Establish Private/Public Partnership with Biosciences Roundtable on solving issues regarding recycling in the labs • Contribute to the HHS Biosafety and Biosecurity Coordinating Council • Participate in CDC ISATTAC • Support USDA/APHIS ISATTAC • Participate in NSC BSAT IPC • Participate in HHS FESAP meeting • Co-Chair OSTP FTAC meetings • Participate in House Oversight and Government Reform Committee Hearing • Participate in OSTP-led dual research of concern meetings	• Host Fellows on learning assignments as a mentoring initiative partnering with NIH and CDC

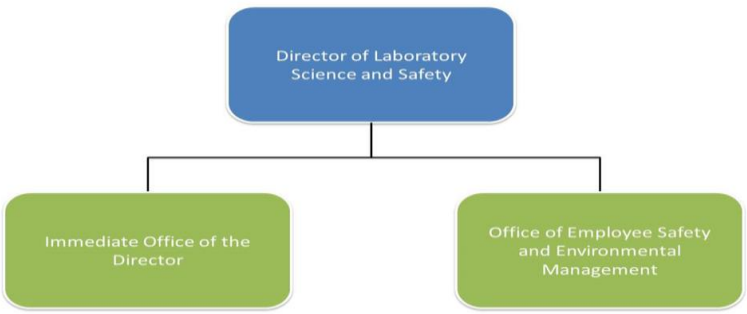
Legend:
APHIS: Animal and Plant Health Inspection Service; BMBL: Biosafety in Microbiological and Biomedical Laboratories; BSAT: Biological Select Agents and Toxins; DSAT: Division of Select Agents and Toxins; ESHC: Environmental Safety and Health Council; FESAP: Federal Experts Security Advisory Panel; FTAC: Fast Track Action Committee; GSA: General Services Administration; IPC: Interagency Policy Committee; ISATTAC: Intragovernmental Select Agents and Toxins Technical Advisory Committee; NSC: National Security Council; OSTP: Office of Science and Technology Policy; USDA: United States Department of Agriculture

OLSS ORGANIZATIONAL STRUCTURE AND AUTHORITIES

Organizational Structure

OLSS is situated directly under the Office of the Commissioner. The Office's Organizational Structure, shown in Figure 3, is currently under development. This organizational structure is a temporary holding point for the teams that exist within OLSS, until the Office has a base appropriation. Because OLSS is a new entity with an evolving mission and goals, changes and adaptations will likely be necessary.

Figure 3: Interim FY18 OLSS Organizational Structure (Draft)



Authorities

The functional statements for OLSS were approved by the Secretary of Health and Human Services on September 30, 2016, and became effective on February 11, 2017.[2] The Commissioner of Food and Drugs approved the delegations, via memorandum, on February 23, 2017.[3]

Authority Delegated and to Whom Delegated**

- The following official is the Designated Agency Safety and Health Official (DASHO) for the FDA[3]:
    1. Director, Office of Laboratory Science and Safety (OLSS), Office of the Commissioner (OC).
- The DASHO is authorized under Executive Order 12196, the Occupational Safety and Health Act (the Act) (Public Law 91-596, December 29, 1970 as amended), and 29 C.F.R. 1960 et seq., as amended; and as authorized in the Department of Health and Human Services Assistant Secretary for Administration memorandum of May 17, 2012, to perform the following[3]:
    1. Ensure compliance with the FDA Laboratory Science & Safety and Environmental Health & Safety programs.

2. Stop any work that is deemed unsafe to employees and/or the community or poses an imminent danger as defined in Section 13(a) of the Act.
3. Address items or activities of a non-imminent danger, as defined in the Act.
4. Transfer hazardous materials from personnel that are not acting in compliance with federal, state, and local laws; regulatory standards; and requirements to maintain the safety and security of that hazardous material.
5. Designate safety and health officials, at appropriate levels, with budgets and staffs, to implement the occupational safety and health program.

Redelegation**

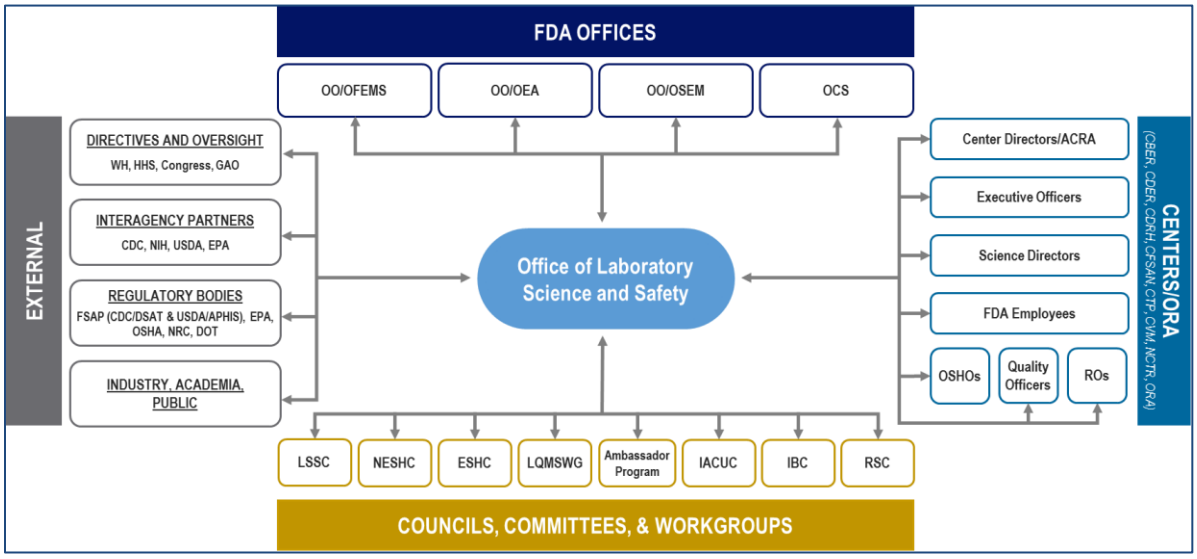
- A. The DASHO may redelegate the following authorities[3]:
    1. Agency-wide management and administration of the occupational safety and health program
    2. Designation of safety and health officials

** *The above authorities are pulled directly from SMGs 1410.63.*

OVERVIEW OF OLSS INTERACTIONS WITH STAKEHOLDERS

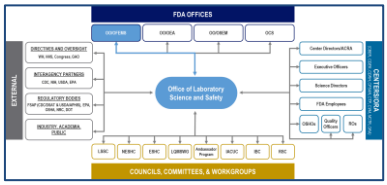
The OLSS interactions map presented in Figure 4 highlights the connections between OLSS and its internal and external stakeholders, including immediate (e.g., laboratory staff and employees) and more distant (e.g., the public, sister institutions, industry) stakeholders. OLSS' roles and responsibilities in relation to each FDA stakeholder group are presented side by side with that group's shared responsibilities and expectations. The information presented is not comprehensive of all duties, but rather a summary of the expected and desired relationships between OLSS and each group. These roles are expected to change and become increasingly well-defined over time as the newly formed Office integrates into the FDA community. Ultimately, staff manual guides will codify the specific authorities, roles, and responsibilities of OLSS and its stakeholder groups. The following subsections further detail each of these stakeholder interactions.

Figure 4: OLSS Interactions Map



OLSS and FDA Offices

Office of Operations (OO)/Offices of Facilities, Engineering, and Mission Support Services (OFEMS)

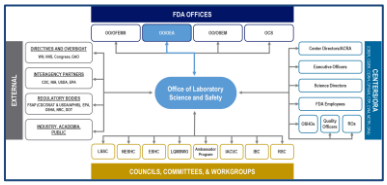


OO/OFEMS is responsible for ensuring a high-quality and safe work environment by providing vital facilities and mission support services.[4] The respective roles and responsibilities of OLSS and OO/OFEMS are outlined in Table 11.

Table 11: OLSS and OO/OFEMS Roles and Responsibilities

Office of Laboratory Science & Safety	Office of Operations/Offices of Facilities, Engineering, and Mission Support Services
• Provide expertise and consultations on lab and building design and renovations • Commission BSL-3 facilities from a biological safety perspective and verify FDA BSL-3 laboratories for compliance to safety guidelines • Provide certifications for ventilation equipment in facilities outside of WO • Establish minimum ventilation requirements for offices. • Ensure laboratories are properly decontaminated following a laboratory move.	• Collaborate with OLSS to optimize the safety and lab specific features (e.g., chemical fume hood, HVAC design, and location of safety showers, etc.) • Collaborate on the design of facilities to ensure safety and efficiency, and ensure that all new facilities/renovations leveraging best practices/guidelines • Collaborate with OLSS to resolve problems related to ventilation, facility design or facility structure • Assist with IAQ investigations • Assist with facility related issues involving slips/trips/falls
Communication Channels: As-needed for facilities development consultation. Regular check-ins while laboratory design or construction is underway, and during BSL-3 laboratory commissioning and annual activities related to re-verification	

OO/Office of External Affairs (OEA)

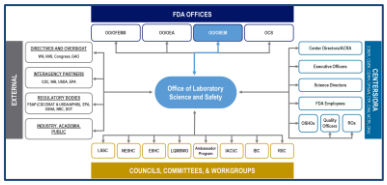


OEA is responsible for serving as the central point of communication and education about the FDA's public health and regulatory activity, including the development, coordination, and leadership of all FDA communication and outreach efforts.[5] The respective roles and responsibilities of OLSS and OEA are outlined in Table 12.

Table 12: OLSS and OO/OEA Roles and Responsibilities

Office of Laboratory Science & Safety	Office of Operations/Office of External Affairs
• Inform OEA of new policies and practices • Inform OEA before posting information on web • Coordinate emergency drills/exercises with OEA	• Collaborate with OLSS when media contacts FDA for comment on OLSS-related issues and during emergency drills/exercises planning/ implementation
Communication Channels: Direct communication/interaction, drill planning meetings	

OO/Office of Security and Emergency Management (OSEM)

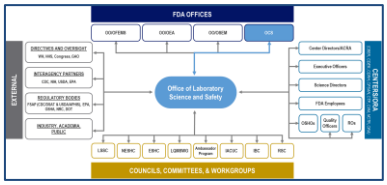


OSEM provides leadership, oversight, and collaboration of the Agency's security and emergency management programs by developing and implementing policies in coordination with internal service providers, HHS service providers, and other federal agency components.[6] The respective roles and responsibilities of OLSS and OO/OSEM are outlined in Table 13.

Table 13: OLSS and OO/OSEM Roles and Responsibilities

Office of Laboratory Science & Safety	Office of Operations/Office of Security and Emergency Management
• Consult for policies and program enhancement • Communicate requirements for laboratory security • Provide emergency preparedness and response coordination with OSEM for involvement of staff for drills and exercises and review of drill reports, as applicable • For high containment and Select Agent labs, maintain updated lists of personnel and share with OSEM • Address personnel reliability and the physical security aspect • Coordinate emergency preparedness initiatives	• Security (facility) • Security (lab, physical security) • Personnel screening/clearance • Facilitate emergency drills with external and internal stakeholders and compile reports • Conduct and document regular drills with security staff to ensure adherence to SOPs and Post Orders
Communication Channels: LSSC, direct interaction, BSL-3 team meetings, drill planning meetings, and other ad hoc meetings as necessary	

Office of the Chief Scientist (OCS)



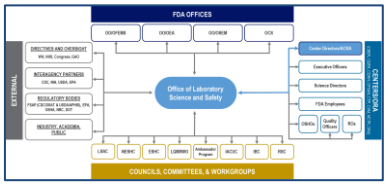
OCS's mission is to provide strategic leadership, coordination, and expertise, supporting scientific excellence, innovation and capacity to achieve FDA's public health mission. OLSS is focused on the quality of laboratory procedures (i.e., the accuracy, reliability, and timeliness of laboratory data). This focus will support and enhance the mission of the OCS. The respective roles and responsibilities of OLSS and OCS are outlined in Table 14.

Table 14: OLSS and OCS Roles and Responsibilities

Office of Laboratory Science & Safety	Office of the Chief Scientist
• Advise Chief Scientist on laboratory safety, security, and quality • Collaborate on a grants program for applied research • Develop Agency-wide laboratory quality policy, training, tools, and assessments for use by laboratory and research scientists as appropriate	• Provide strategic leadership and support for high quality, collaborative, scientific activities that advance regulatory science and address important public health issues centered around evaluation, quality, safety, and effectiveness of FDA regulated products • Provide core scientific leadership and technical expertise, and ensure agency capacity for advanced bioinformatics activities needed to support FDA programs • Serve as an agency and government resource for excellence, methods development, outreach and partnerships in advanced bioinformatics science • Lead agency efforts to protect and enhance scientific integrity, and, where substantive scientific differences of opinion arise and require review at the FDA level, address them through appropriate processes intended to protect both FDA's mission and the integrity of its science
Communication Channels: OLSS program planning documents and briefings, ad hoc meetings as needed	

OLSS and the Centers/ORA

Center Directors/Associate Commissioner for Regulatory Affairs (ACRA)

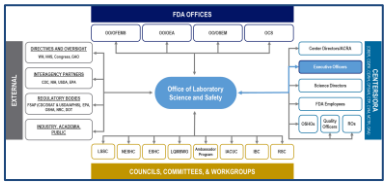


Center Directors and ACRA provide scientific, policy, and managerial leadership and direction, and communicate Agency initiatives and guidance to their respective Centers/ORA and FDA leadership. The respective roles and responsibilities of OLSS and the Center Directors/ACRA are outlined in Table 15.

Table 15: OLSS and Center Directors/ACRA Roles and Responsibilities

Office of Laboratory Science & Safety	Center Directors/ ACRA
• Communicate OLSS initiatives and collaborate • Obtain buy-in for Agency-wide policies and practices	• Ensure and enforce compliance with OLSS policies and procedures • Foster a culture of responsibility and safety • Provide support and resources to address findings from OLSS evaluations
Communication Channels: Direct between the Director of OLSS and Center Directors/ACRA	

Executive Officers

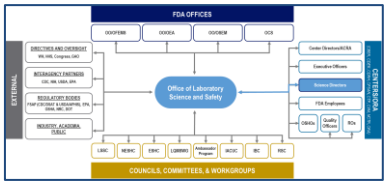


Executive Officers support the Center/ORA directors by providing executive leadership for Center/ORA operations and management. The respective roles and responsibilities for OLSS and the Executive Officers are outlined in Table 16.

Table 16: OLSS and Executive Officers Roles and Responsibilities

Office of Laboratory Science & Safety	Executive Officers
• Communicate OLSS initiatives • Obtain buy-in of Agency-wide policies and practices	• Enforce compliance with OLSS policies and procedures at the Center/ORA level • Foster a culture of responsibility and safety • Provide support and resources to address findings from OLSS evaluations • Contribute to process improvement and application of processes
Communication Channels: Direct between Director of OLSS and executive officers and management council meetings	

Science Directors

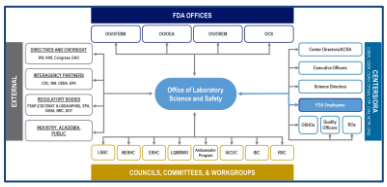


Science Directors offer executive leadership for the Centers/ORA in mission-relevant scientific activities. The respective roles and responsibilities of OLSS and the Science Directors are outlined in Table 17.

Table 17: OLSS and Science Directors Roles and Responsibilities

Office of Laboratory Science & Safety	Science Directors
• Consult with Science Directors to balance mission-critical activities, environmental, and occupational safety and health programs • Provide policies, best practices, and guidance	• Collaborate with OLSS to ensure balance between OLSS policies and procedures and work toward the scientific mission of the Center/ORA • Ensure compliance with regulations and policies • Encourage incident and near-miss reporting • Foster a culture of responsibility and safety • Encourage implementation of best laboratory science and safety practices
Communication Channels: LSSC, document reviews, e-Newsletter, briefings, and annual reports	

FDA Employees and Managers

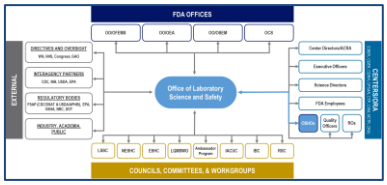


FDA Employees and Managers are responsible for ensuring that analytical activities meet the mission of the Agency, its customers, and regulations. The respective roles and responsibilities for OLSS and the laboratory staff and managers are outlined in Table 18.

Table 18: OLSS and FDA Employees and Managers Roles and Responsibilities

Office of Laboratory Science & Safety	FDA Employees and Managers
• Provide policies, procedures, and manuals • Update manuals • Communicate best practices • Provide annual reports • Follow-up on incident reports to ensure a safe environment • Provide training opportunities • Develop and maintain the FDA OLSS Awards and Recognition Program	• Adhere to policies and procedures • Take all appropriate training relevant to the type of hazards in the respective laboratory and work related activities • Coordinate training for new personnel and for staff when new equipment or procedures are introduced • Conduct risk assessment to determine appropriate safety measures, mitigation strategies and consult with Center safety staff for review of protocols and experiments • Update SOPs, as needed • Embrace culture of responsibility and safety • Report incidents and near-misses to local OSHO or to OLSS
Communication Channels: Document review, e-Newsletter, ad hoc meetings as needed	

Occupational Safety and Health Officers (OSHOs)

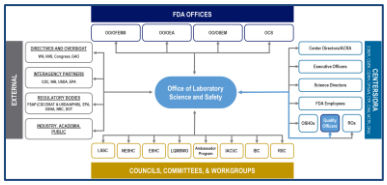


The OSHOs are responsible for contributing to the Agency's mission by providing proactive technical and administrative service to plan, coordinate, and support the implementation of OLSS policies and guidance at the Center level. This will include federal, state, and local occupational safety and health requirements (as appropriate), environmental regulations and additional good-management practices issued by OLSS. The respective roles and responsibilities of OLSS and the OSHOs are outlined in Table 19.

Table 19: OLSS and OSHOs Roles and Responsibilities

Office of Laboratory Science & Safety	Occupational Safety and Health Officers
• Provide Agency policy development and issuance • Coordinate FDA-wide communications • Promote Agency-wide culture of responsibility and safety • Develop Agency-wide training with aspects of local requirements and hazards • Conduct independent annual inspections of laboratories • Provide Safety Engineering Services, OHS, Industrial Hygiene and Hazardous Waste Management Services • Serve as the Agency liaison for external stakeholders (i.e. OIG, GAO, GSA) • Participate in monthly FDA Security Incident Response Meeting • Develop and maintain the Rewards and Recognition Program • Serve as Agency SME to provide EHS assistance to Center OSHOs	• Ensure on-site implementation of Agency policies • Complete incident reports for accidents/injuries/ near-misses with the use of ECOMP, the FDA Incident Reporting Form, and documenting security incidents; responsible for reporting incidents in a timely manner • Conduct annual site surveys • Coordinate local training • Oversee general program implementation at Center facility sites for local safety programs (e.g., AED; Office of Emergency Operations [OEO]; Chemical, Biological, Respiratory Protection Program; Lab Coat Program; BSL-3 Program; and Select Agent Program, as applicable) • Oversee the storage, custody, assignment, and transfer of Hazardous Biological Agents and Toxins (HBATs) (SMG 2130.8) • Oversee or support implementation of Select Agent registration and implementation of a SA Program, if applicable • Provide comments and consultation to IBC, IACUC and RSC as applicable • Ensure environmental compliance • Address findings from OLSS evaluations
Communication Channels: Direct OLSS-OSHO relationships, ESHC meetings, e-Newsletter, and annual reports	

Quality Officers

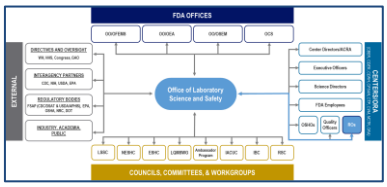


Quality Officers oversee the laboratory quality management system within their respective Centers. The respective roles and responsibilities for OLSS and the Quality Officers are outlined in Table 20.

Table 20: OLSS and Quality Officers' Roles and Responsibilities

Office of Laboratory Science & Safety	Quality Officers
• Develop and implement Agency-wide standards • Collaborate with Quality Officers • Lead and oversee the Agency LQMS initiative • Develop and maintain the Aewards and Recognition Program •	• Implement Center-specific quality programs based on Agency standards • Work with OLSS to develop Agency laboratory quality management standards by participating in the laboratory quality management system working group
Communication Channels: LQMSWG, ad hoc meetings, e-Newsletter	

Responsible Officials (ROs)



An RO is responsible for ensuring that FDA is in compliance with the Select Agent Regulations and serves as the main point of contact for all select agent registration, reporting, and compliance issues, for the specific entity that is registered. Due to the geographic and administrative distribution of SA activities within the Agency, there are multiple ROs within FDA each overseeing their own registration and program needs. The respective roles and responsibilities for OLSS and ROs are outlined in Table 21.

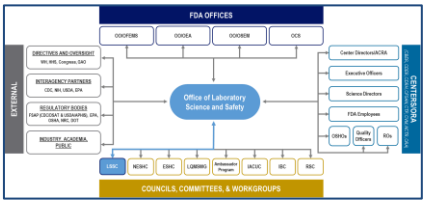
Table 21: OLSS and ROs Roles and Responsibilities

Office of Laboratory Science & Safety	Responsible Officials
• Ensure that sufficient authority is delegated to the RO to speak and act on behalf of the FDA • Assist the RO in their delegated responsibilities, as needed • Conduct investigations and implement appropriate policy and guidance associated with select agent incidents	• Undergo a security risk assessment (SRA) conducted by the Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) and be approved by the FSAP • Be familiar with the select agent regulations to the extent that the RO can ensure that his or her entity is compliant with all of the requirements of the select agent regulations • Ensure compliance with the select agent regulations • Ensure that annual inspections are conducted for each laboratory and all other registered areas where select agents and toxins are stored or used in order to determine compliance with the requirements of the select agent regulations; results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected • Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan • Participate in annual drills of the Incident Response Plan, the Biosafety Manual and the Security Plan • Designate AROs • Notify OLSS immediately about all select agent violations, deficiencies, or incidents

Office of Laboratory Science & Safety	Responsible Officials
Communication Channels: Center Select Agent program meetings (bi-weekly or monthly); BSL-3 Team Meetings (at least monthly to include Security, Facilities, OSHOs and RO/AROs and any SAP Administrators	

OLSS, Councils, Committees, and Workgroups

Laboratory Science and Safety Council (LSSC)

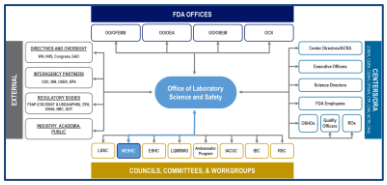


The LSSC is responsible for advising OLSS with respect to FDA's policies, practices, and procedures related to laboratory safety, security, and other related issues, in addition to overseeing Agency activities for managing all potentially hazardous materials in the Agency's possession.[7] The respective roles and responsibilities of OLSS and the LSSC are outlined in Table 22.

Table 22: OLSS and LSSC Roles and Responsibilities

Office of Laboratory Science & Safety	Laboratory Science and Safety Council
• Serve as the FDA's focal point for development of policies and guidance and coordination with internal/external efforts and queries addressing general laboratory science; laboratory security; and Agency-wide environment, health, and safety ¬policies and practices • Draft Agency-wide laboratory science; laboratory security; and Agency-wide environment, health, and safety policies for review • Facilitate discussion for proposed changes and new development of policies, procedures, and guidelines • Inform LSSC of upcoming high-level initiatives stemming from HHS, the White House, Congress, and other external entities that may influence FDA policies and procedures	• Create an environment for enhanced communication and coordination on cross-cutting laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and other related issues at FDA • Provide input on strategic planning and reporting for laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and other related issues • Serve in an advisory role to the Director of OLSS, who is the FDA's focal point for implementation of policies and guidance and coordination with internal/external efforts and queries addressing general laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and related policies and practices • Draft or provide input on Agency-wide laboratory science; laboratory security; and Agency-wide environment, health, and safety policies for consideration by Agency leadership • Provide input on cross-cutting laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and other related issues and activities managed within OLSS, Office of the Commissioner
Communication Channels: Committee participation and meetings	

The National Environmental Safety and Health Committee (NESHC)

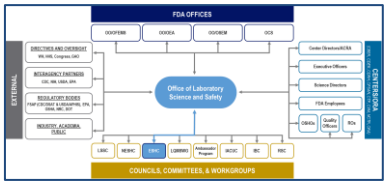


The NESHC is the FDA labor/management joint committee that provides recommendations and reviews of the FDA safety program to the Designated Agency Safety and Health Official. The NESHC is a mechanism to ensure FDA delivers a safety and healthy workplace to its employees, contractors and visitors. The respective roles and responsibilities of OLSS and NESHC are outlined in Table 23.

Table 23: OLSS and NESHC Roles and Responsibilities

Office of Laboratory Science & Safety	NESHC
• The Director of OLSS is FDA's's focal point for development of policies and guidance and coordination with internal/external efforts and queries addressing general laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and related policies and practices • Draft Agency-wide laboratory science; laboratory security; and Agency-wide environment, health, and safety policies for review • Facilitate discussion for proposed changes and new development of policies, procedures, and guidelines • Inform NESHC of upcoming high-level initiatives stemming from HHS, the White House, Congress, and other external entities that may influence FDA policy and procedures	• Create an environment for enhanced communication and coordination on cross-cutting laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and other related issues at FDA • Provide input on strategic planning and reporting for laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, and other related issues • Provide input on Agency-wide laboratory science; laboratory security; and Agency-wide environment, health, and safety policies for consideration by Agency leadership • Provide input on cross-cutting laboratory safety, security, and other related issues and activities managed within the Office of ESEM, Office of the Commissioner
Communication Channels: Committee participation and chairmanships	

Environmental Safety and Health Council (ESHC)

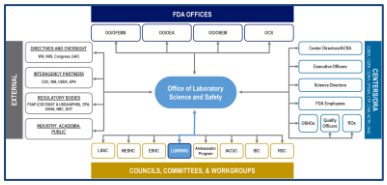


The ESHC serves in an advisory capacity for OLSS. The council supports OLSS' commitment to providing enterprise-level environmental and occupational safety and health (ESH) oversight of Agency operations.[8] The respective roles and responsibilities of OLSS and the ESHC are outlined in Table 24.

Table 24: OLSS and ESHC Roles and Responsibilities

Office of Laboratory Science & Safety	Environmental Safety and Health Council[10]
• Provide and gather information from ESHC members for consideration in policy and procedural development, as well as direction of initiatives and information to disseminate through broader communication channels • Present draft documents for review and communicate finalized policies/procedures/ guidance documents • Deliver sustained review of Agency performance against established metrics • Provide Agency-wide governance and oversight of ESH priorities and performance measures • Increase accountability and transparency of OLSS activities and operations • Communicate recommendations, decisions, and actions on the Agency's ESH policies, plans, and strategies to the Management Council (MC) as appropriate	• Ensure issued policies are addressed and resolved in a manner that enhances operational processes and performance standards • Provide its members with the opportunity for a meaningful exchange of information and collaborative approaches to meeting common challenges related to maintaining a safe and healthy place of employment • Serve as a bi-directional body for operational performance, while enhancing communications and outreach efforts of OLSS and the Center's safety programs • Manage and support safety programs to enhance the effectiveness of the Agency in accomplishing its mission • Leverage the expertise, information, and tools needed to provide the highest practical degree of safety, health, and environmental compliance for all FDA employees • Assist in rectifying causes leading to incidents or near-misses in compliance with applicable federal, state, and local regulations • Provide accountability for implementation of enterprise initiatives • Suggest specific standing topics that should be reported to the leadership team and require customer or stakeholder input • Identify, clarify, and recommend the activities of the ESHC • Advise on strategic priorities affecting employee safety and health • Assist in clarifying roles and responsibilities for internal/external customers and stakeholders in regards to ESH activities • Provide input as necessary to address challenges in operational success of ESH programs • Maintain records of ESHC recommendations, decision, and actions • Provide input to and work with other Agency components as necessary to achieve FDA goals and missions • Establish and oversee subcommittees and Management Advisory Group (MAG) for the purpose of fulfilling the ESHC's responsibilities • Review work products of the subcommittees and MAGs appointed by the ESHC to develop recommendations/options for cross-Agency implementation
Communication Channels: Meetings, forums	

Laboratory Quality Management System Working Group (LQMSWG)

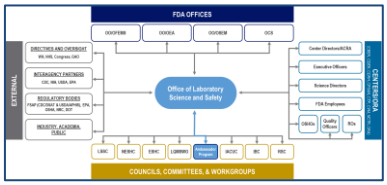


The LQMSWG is responsible for providing ongoing guidance, recommendations, and support for FDA's quality management policies, practices, and procedures for Agency laboratories.[9] The respective roles and responsibilities of OLSS and the LQMSWG are outlined in Table 25.

Table 25: OLSS and LQMSWG Roles and Responsibilities

Office of Laboratory Science & Safety	Laboratory Quality Management System Working Group
• Engage to understand current LQMS programs/policies • Collaborate to form a new LQMS program • Develop an Agency-wide standard for LQMS	• Provide current state of LQMS program/policies • Provide counsel/advice and expertise • Draft consistent LQMS policies/practices • Develop a common understanding and policy with respect to an Agency-wide LQMS • Identify and communicate shared best practices • Implement a robust LQMS at the Center level based on Agency policy and guidance
Communication Channels: Working group meetings	

Ambassador Program

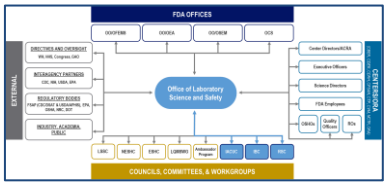


Ambassadors engage with both leaders and staff to emphasize that laboratory science and safety is a high priority at FDA; promote OLSS' mission, activities, products; and spread the word that everyone at FDA is responsible for exercising best laboratory science and safety practice across the Agency. Two people (representing leadership and staff) from each Center and ORA site will serve as Ambassadors of OLSS. The goals of the Ambassador Program are to: help all laboratorians understand and adopt FDA's renewed focus on lab science and safety; encourage and facilitate open, two-way communication between OLSS and all FDA laboratorians; and provide mechanisms for sharing best practices and lessons for laboratory safety and science across FDA. The respective roles and responsibilities of OLSS and the Ambassadors are outlined in Table 26.

Table 26: OLSS and Ambassadors Roles and Responsibilities

Office of Laboratory Science & Safety	Ambassadors
• Communicate • Solicit feedback • Inform Ambassadors and staff of tools/resources • Organize Lab Staff Forum • Initiate and chair the FDA laboratory science and safety Ambassador Program • Lead the activities of the FDA Laboratory Science and Safety Ambassador Program initiative • Serve as the primary point of contact for all internal coordination and information dissemination • Represent the consensus view of the FDA Laboratory Science and Safety Ambassador Program to the Commissioner	• Promote an ongoing partnership between OLSS and a rotating cadre of ambassadors at both the leadership and employee levels • Emphasize laboratory science and safety as a high priority at FDA • Promote OLSS' mission, activities, and products • Encourage employees to respond to the call in the e-Newsletter to submit stories that reflect safety in action • Facilitate OLSS' outreach to employees within their specific workplaces and advocate on behalf of laboratorians and provide OLSS with candid feedback on what is resonating with laboratorians and what is not. • Create opportunity for OLSS to receive both solicited and unsolicited feedback on its products and activities • Actively promote, encourage, and motivate others to embrace a culture of responsibility and safety actively promote, encourage, and motivate others to embrace a culture of responsibility and safety • Promote the monthly theme and embrace a culture of responsibility and safety at the Centers and ORA • Serve as a link for sharing information between OLSS and the Centers/ORA.
Communication Channels: Existing meetings, other forums, and one-on-one conversations	

Committees (IACUC, IBC, and RSC)



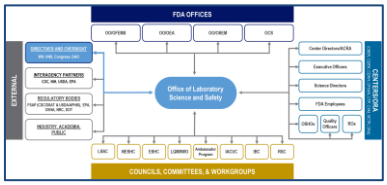
Laboratory risk committees (e.g., IACUCs, IBC, and RSC) exist as a checkpoint to review laboratory protocols before they are implemented. The respective roles and responsibilities of OLSS and the risk committees are outlined in Table 27.

Table 27: OLSS, IACUC, IBC, and RSC Roles and Responsibilities

Office of Laboratory Science & Safety	Committees (IACUCs, IBC, and RSC)
• Participate as seated member of the risk committee • Collaborate with committees to develop tools for efficiency and quality (e.g., HBAT training records attached to protocols) • Inform of new requirements from external/ regulatory bodies and OLSS initiatives that directly impact committee function and/or decisions • Lead and oversee the IBC	• Inform OLSS of opportunities for system improvement • Collaborate in the development of tools and processes for efficiency and quality • Collaborate in the development of policies • Provide feedback to OLSS when issues arise • Review protocols and IBC applications to make sure that the research is done in a safe manner.
Communication Channels: Committee participation and chairmanships	

OLSS and Key External Stakeholders

Directives and Oversight: The White House (WH), the U.S. Department of Health and Human Services (HHS), Congress, and the Government Accountability Office (GAO)

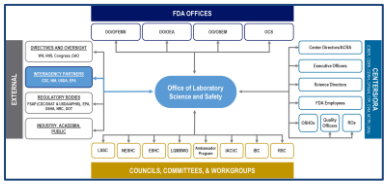


Several entities have general oversight of FDA programs and policies. WH, HHS, and Congress shape FDA programs and policies through law, regulations, guidance, policy, and directives. GAO and other bodies, provide oversight and accountability of the FDA. Roles and responsibilities are outlined in Table 28.

Table 28: OLSS, Directives and Oversight Roles and Responsibilities

Office of Laboratory Science & Safety	Directives and Oversight: WH, HHS, Congress, and GAO
• Collaborate with WH, HHS, Congress, and GAO (and other relative counterparts) to produce documents relating best practices to the broader community • Communicate these activities to relevant Agency committees, Center leadership, etc. • Execute directives and recommendations • Compile requested information in a transparent and timely manner	• Review FDA safety policies and provide guidance • Communicate best practices, guidance, regulations and issue laws that may impact laboratory and employee safety and security practices at FDA
Communication Channels: Meetings and direct interaction	

Interagency Partners: Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), United States Department of Agriculture (USDA), Environmental Protection Agency (EPA), and Other Interagency Partners

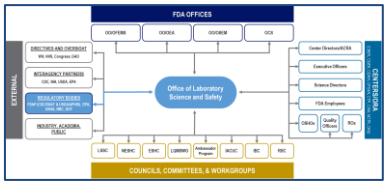


In pursuit of improving FDA laboratory science, laboratory security, and EHS programs, FDA will partner and collaborate with a variety of interagency partners, including the CDC, NIH, USDA, EPA, and other interagency partners. Roles and responsibilities are outlined in Table 29.

Table 29: OLSS and Interagency Partners Roles and Responsibilities

Office of Laboratory Science & Safety	Interagency Partners: CDC, NIH, USDA, and EPA
• Collaborate with CDC, NIH, USDA, and EPA (and other interagency partners) to produce documents relating best practices to the broader community	• Communicate best practices • Leverage OLSS capabilities and expertise • Ensure participation of OLSS in developing policies, guidance, rules, and regulations
Communication Channels: Meetings and direct interaction	

Regulatory Bodies: The Federal Select Agent Program (FSAP) [CDC/DSAT & USDA/APHIS], Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), the Nuclear Regulatory Commission (NRC), and the Department of Transportation (DOT)

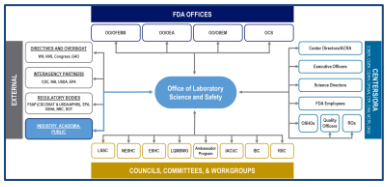


Regulatory bodies such as FSAP, EPA, OSHA, NRC, and DOT develop common requirements, standards, and practices for national or worldwide use, inside and outside the laboratory, and ensure compliance with federal, state, and local regulations pertinent to FDA laboratories and FDA workplaces overall. The roles and responsibilities of OLSS and regulatory bodies are outlined in Table 30.

Table 30: OLSS and Regulatory Bodies Roles and Responsibilities

Office of Laboratory Science & Safety	Regulatory Bodies: FSAP (CDC/DSAT & USDA/APHIS), EPA, OSHA, NRC, DOT
• Create manuals and other supporting documents that articulate applicable regulations • Communicate issues and seek regulatory guidance as necessary • Prepare documents and complete applicable forms as requested by external entities • Provide training to staff to ensure compliance with all external regulating entities • Ensure compliance with rules, regulations, and regulations associated with licenses • Coordinate responses to inspection findings • Prepare timely renewals of licenses • Support needs of Centers/ORA who may be subject to direct regulation by one or more of these bodies (i.e., Select Agent Programs)	• Provide standards, regulations, guidance, and best practices through publications • Provide interpretations, when applicable • Audit FDA facilities and programs as necessary, and hold FDA accountable for compliance to published standards and regulations • Provide responses to FDA-specific questions, as applicable, in a timely manner • Issue permits and approvals after successful review of facility laboratories and programs • Provide licenses to operate • Inspect FDA safety and environmental programs
Communication Channels: Regulations, regulatory guides, standards, inspection reports, licensing activities, compliance reports	

The Industry, Academia, and Public



The industry (e.g., consulting firms, accreditation firms), the public, and academia's respective roles and responsibilities are outlined in Table 31.

Table 31: OLSS and the Industry, Public, and Academia's Roles and Responsibilities

Office of Laboratory Science & Safety	Industry, Public, and Academia
• Communicate best practices • Communicate information about the environmental and occupational safety and health programs openly	• Communicate best practices • Hold FDA accountable for effective environmental and occupational safety and health programs
Communication Channels: Publications and the media	

CONCLUSION

OLSS is committed to the mission, vision, guiding principles, and goals defined in its Strategic Plan. The Operating Model formally outlines the functions, organizational structure, and internal/external interactions that the Office intends to put in place to achieve those goals: Ensure employees have a safe working environment inside and outside the laboratory; implement appropriate laboratory security and procedural safeguards; preserve high-quality FDA laboratory results through the implementation of a robust LQMS; increase efficiency and consistency of policies and practices across the Agency; produce evidence for best laboratory science and safety practices and leverage tools and technologies through applied research; and promote an Agency-wide culture of responsibility and safety.

The Office will function as the single point of accountability for laboratory science, laboratory security, environmental, and occupational safety and health programs.

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[8] FDA, Employee Safety and Management Office. (2015). *Environmental Safety and Health Council Charter* (ed., Vol. 1).

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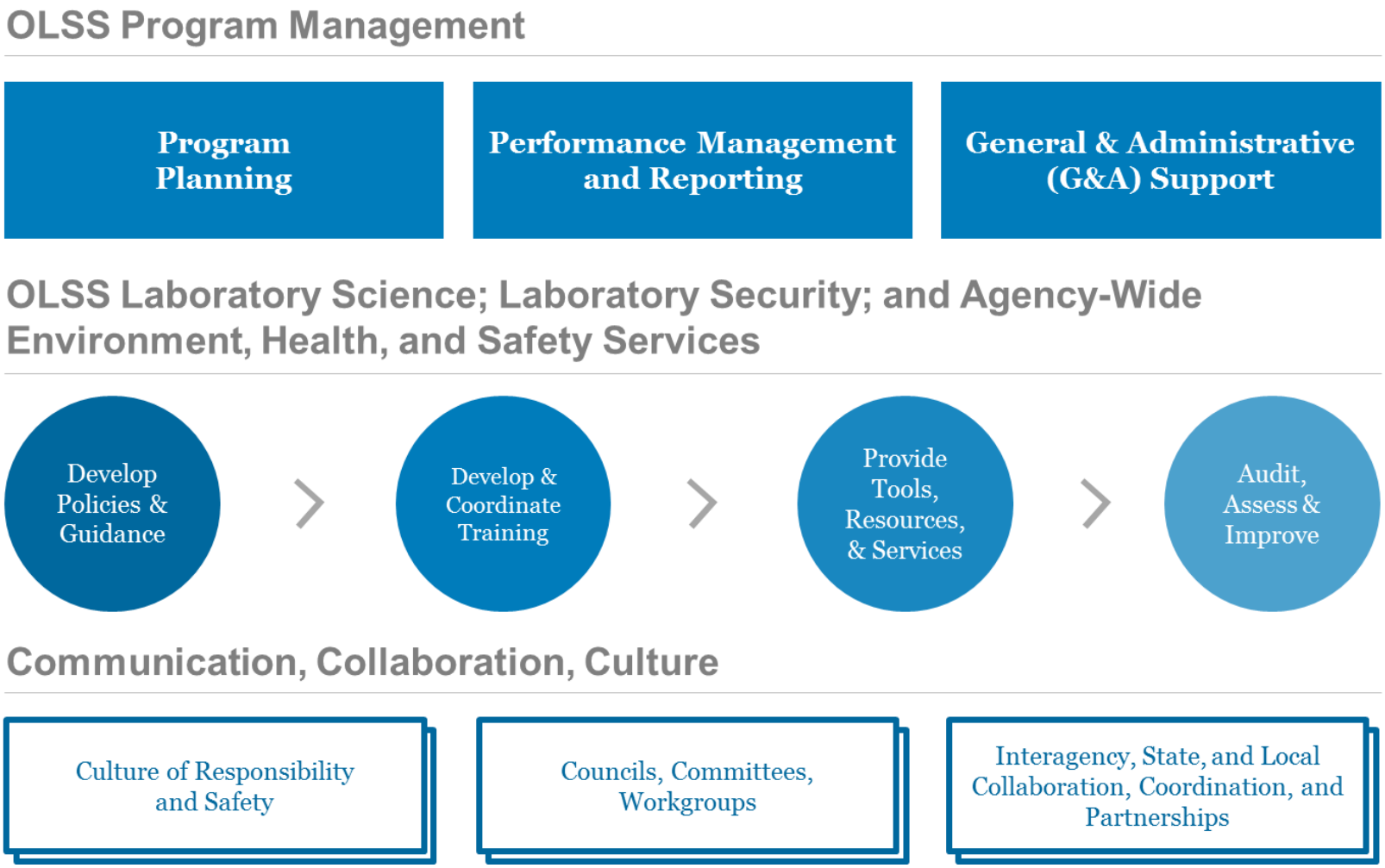
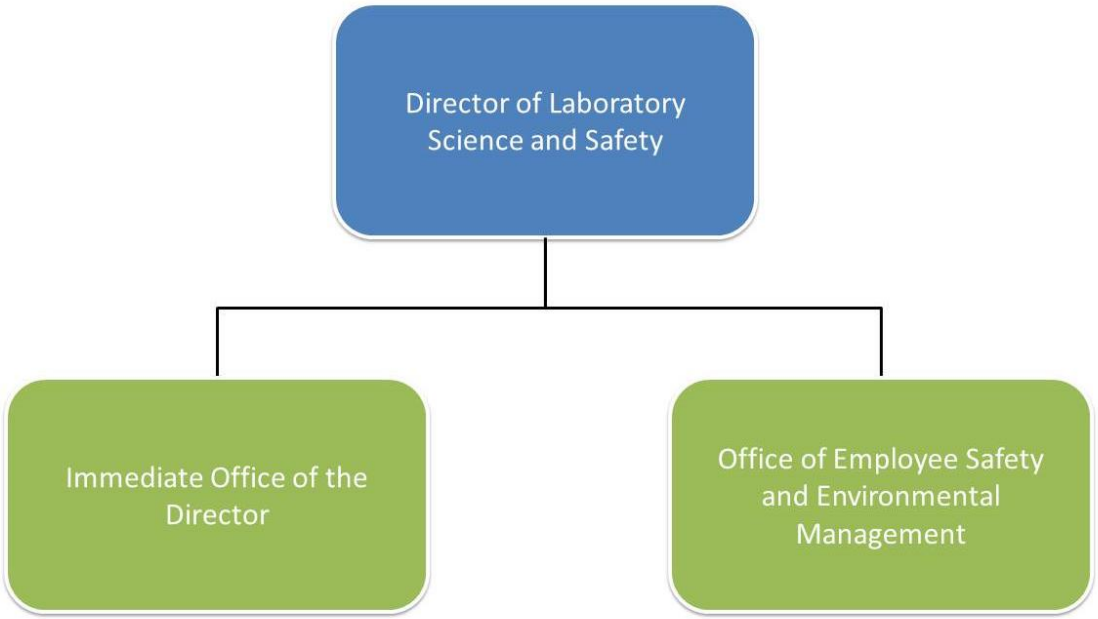
APPENDIX A: OLSS FUNCTIONAL MODEL



APPENDIX B: OLSS INTERIM FY18 OLSS ORGANIZATIONAL STRUCTURE (DRAFT)



APPENDIX C: OLSS INTERACTIONS MAP