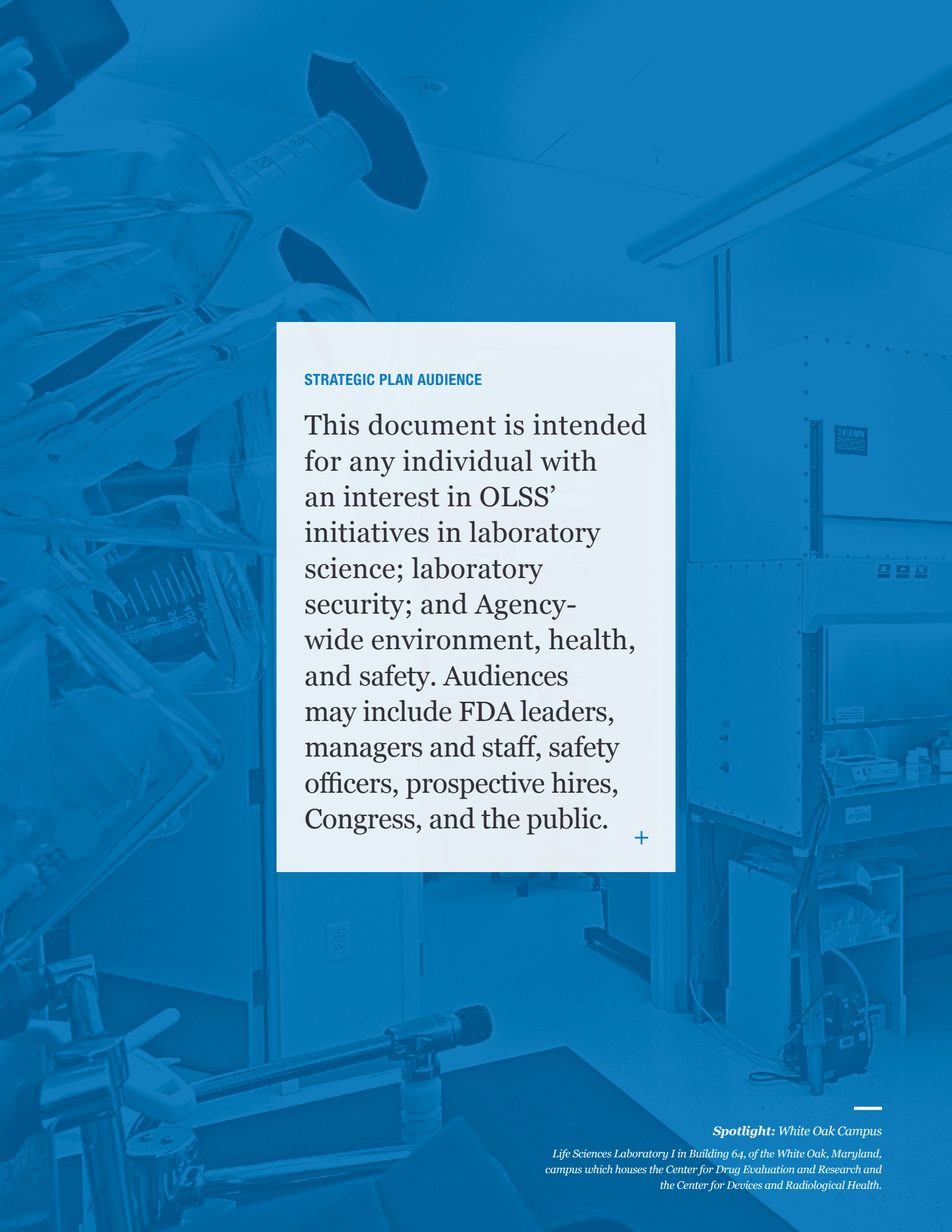
U.S. FOOD & DRUG ADMINISTRATION

2017–2022 STRATEGIC PLAN

OFFICE OF LABORATORY SCIENCE AND SAFETY

Office of the Commissioner



STRATEGIC PLAN AUDIENCE

This document is intended for any individual with an interest in OLSS' initiatives in laboratory science; laboratory security; and Agency-wide environment, health, and safety. Audiences may include FDA leaders, managers and staff, safety officers, prospective hires, Congress, and the public.

Spotlight: *White Oak Campus*

Life Sciences Laboratory I in Building 64, of the White Oak, Maryland, campus which houses the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health.

TABLE OF CONTENTS

Message from the Commissioner 4

Introduction 6

Vision, Mission, and Principles 9

Goals and Objectives 10

Strategies 18

Commitment from the OLSS Director 22

Appendix: FDA's Mission 23

References 23

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MESSAGE FROM THE COMMISSIONER

The establishment of the Office of Laboratory Science and Safety (OLSS) at the Food and Drug Administration (FDA) demonstrates the Agency's dedication to protecting FDA employees and the American public. Safety must be a top priority and a shared responsibility; our actions can have unintended, yet serious and life-threatening consequences if we do not make safety a focal point in our everyday work. In addition, the quality, integrity, and fidelity of our laboratory data and results are critical to support our regulatory goals and public health mission. OLSS will be responsible for enhancing laboratory science and safety, which has impacts that extend beyond us to our colleagues, our families, and our community—making this an Agency-wide priority.

While quality, safety, and security policies and practices are already in place across the FDA, we need to be responsive to the changing landscape of advances in science and technology and cognizant of the evolving risk present in work of this nature (e.g., medical countermeasure resistant organisms, aerosolization or other potential risks posed by a new device or technology). Our science, policies, and practices require continual updating as we anticipate the future and attempt to mitigate tomorrow's potential risks. We cannot become complacent with the status quo and need to diligently work to protect the safety of our employees and the surrounding community.

The laboratory science and safety approach at FDA must be implemented using standards that are agreed to across the Agency, and quality and safety standards should be uniform and consistent. The creation of a central organization that builds consensus and has accountability for the standardization of laboratory science, laboratory security, and Agency-wide safety programs will allow for consistent expectations, opportunities for shared best practices, streamlined training, and more efficient and consistent communication among the labs. The Director of OLSS cannot accomplish this task alone; collaboration, commitment, engagement, and support from Deputy Commissioners, Office Directors, and Center Directors are critical to ensure their personnel are complying with guidance and policies developed and implemented by OLSS.

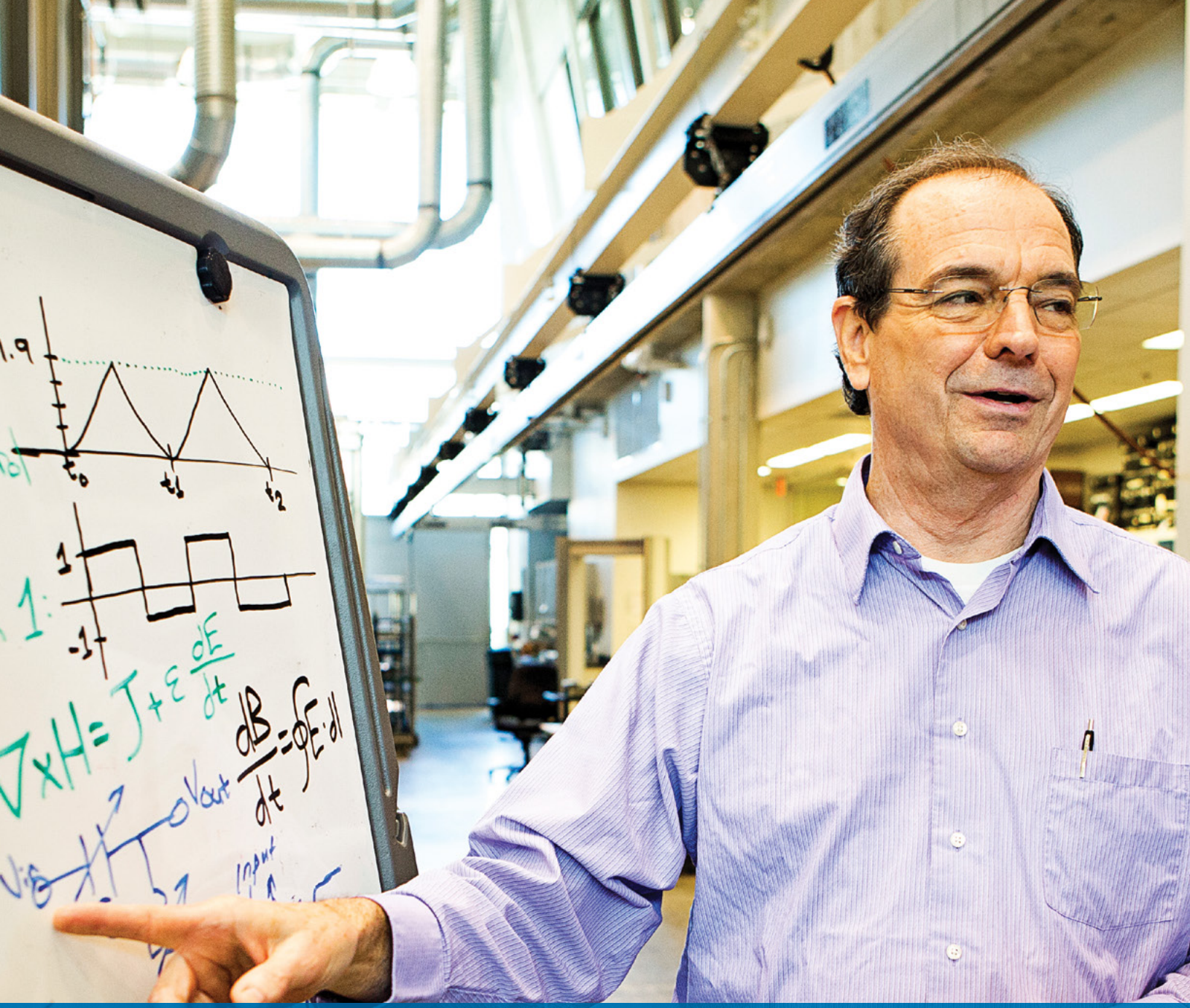
Among other important tasks, the Director of OLSS will be directly responsible for:

- *Serving 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*
- *Providing 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*
- *Providing 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*
- *Serving 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*
- *Serving as the Agency liaison with respect to employee and laboratory safety to the Department of Health and Human Services (HHS) Operating Divisions (OPDIVS) and components of HHS, other federal agencies, and the scientific community*
- *Developing and implementing a robust Laboratory Quality Management System for FDA to ensure that the integrity and quality of data and results support FDA's regulatory mission, which includes routinely requiring laboratories to review and update protocols and inspect and evaluate equipment, facilities, and safety documentation including laboratory design, construction, and maintenance*
- *Conducting and funding appropriate applied research to enhance laboratory science, laboratory security, and Agency-wide safety*

> *"Safety must be a top priority and a shared responsibility; our actions can have unintended, yet serious and life-threatening consequences if we do not make safety a focal point in our everyday work."*

Good laboratory science and safety practices are a prerequisite to conducting or engaging in any laboratory science and research work. The Office of Laboratory Science and Safety will provide oversight to ensure our Agency maintains this priority and delivers data and results of the highest quality, integrity, and fidelity to better enable the FDA to accomplish its mission of protecting public health.

Robert M. Califf, M.D.
Commissioner, Food and Drug Administration



INTRODUCTION

Spotlight: *FDA Scientist*

Don 'Skip' Witters working in the radio frequency lab which houses the anechoic chamber, Office of Science and Engineering Laboratories, Center for Devices and Radiological Health.

Background and Brief History

In February 2017, the Commissioner of Food and Drugs—in collaboration with the Secretary of the U.S. Department of Health and Human Services—established the Office of Laboratory Science and Safety. As requested by Congress, OLSS was aligned to report directly to the FDA Commissioner. The establishment of OLSS reflects the Department's and Agency's commitment to public health and enhancing laboratory science;* laboratory security; and Agency-wide environment, health, and safety (EH&S) programs to protect FDA employees and the surrounding community.

At the time OLSS was established, each Center or Office had independent laboratory science, laboratory security, and safety programs with differing policies, practices, expectations, cultures, and needs. This has arisen for several reasons. 1) Each Center or Office was established to focus on different aspects of the FDA's statutory obligations. 2) Research programs were developed to support those regulatory requirements, and as such, the focus of the research may have involved different hazards (for example, Center for Biologics Evaluation and Research laboratory research involves extensive use of infectious biological agents). Thus safety programs, specifically those for laboratory research or testing, have been specialized to address the distinctive and sometimes unique work being conducted. 3) FDA facilities are spread across the U.S. and must deal with location variables (e.g., earthquakes, flooding), as well as state and local regulations. Geographic distribution also naturally leads to the development of safety programs at the site where they are needed. Until recently, there was limited geographic colocation, and only since 2014 have three major Centers with laboratory programs been consolidated onto the FDA White Oak Campus: Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), and Center for Devices and Radiological Health (CDRH).

The current state presents both opportunities and challenges for OLSS. Opportunities include evaluating the current programs and supporting and sharing best safety practices among the Centers and Offices, in addition to introducing consistent policies to reduce costly redundancies and programmatic gaps. The challenges include how to establish procedures that offer sufficient flexibility to address unique or specialized safety and laboratory needs for the staff across the FDA and to oversee safety programs that may be in different geographic regions of the U.S. and abroad. Without consistent policies, there is a risk for costly redundancies or different interpretations of regulatory requirements across the Agency. The FDA also needs to engage in collaborative partnerships across the Agency and with other agencies.

> *"Effective laboratory safety programs typically employ aspects of a centralized program."*

Effective laboratory safety programs typically employ aspects of a centralized program.[1–4] This approach allows stakeholders to take advantage of the knowledge and best practices within an organization as well as economies of scale and infrastructure that promote visibility, efficiency, and cost-effective use of staff and resources. A central office can also help reinforce institutional expectations for safety and security, enhance communications among FDA safety staff, and provide Center/Office program support.

Recent history demonstrates that programmatic and systemic gaps in laboratory safety and security exist. A series of laboratory accidents and near misses at the FDA, the Centers for Disease Control and Prevention (CDC), the Department of Defense (DoD), the National Institutes of Health (NIH), and academic institutions have prompted the formation of OLSS. These accidents and near misses involved improper management or handling of hazardous materials. In August 2014, the White House urged all federal departments and agencies that possess, use, or transfer select agents (i.e., biological agents and toxins that could pose a significant threat to public, animal, or plant health or to animal or plant products)

**Laboratory science refers to the implementation of a robust laboratory quality management system across the Agency.*

to conduct a "safety stand-down" to inventory all of their laboratories. The White House also initiated a federal review to identify necessary improvements to biosafety and biosecurity practices.

In response to these events, the CDC announced the formation of an External Laboratory Safety Workgroup (ELSW) to provide advice and input to the CDC Director. The FDA invited the ELSW to review FDA's laboratory programs and efforts to improve safety policies and practices, with the intent of preventing these types of events from recurring. In July 2015, the ELSW released its recommendations to the FDA.[1] The report included a strong recommendation to establish a centralized program "that promotes the establishment of institutional expectations in the realm of lab/research safety that are consistent across the Agency."

Spotlight: *FDA Scientist*

Matt Brown, using a nutrient analyzer at FDA's Office of Blood Research and Review, Center for Biologics Evaluation and Research. Photo courtesy of Dr. Wen Jin Wu and Brittany Chavez of FDA's Office of Biotechnology Products, Center for Drug Evaluation and Research.

Internal to the FDA, the Laboratory Safety Practices and Policies Workgroup (LSPPW) was established in July 2014, and then was renamed the Laboratory Science and Safety Council (LSSC). The LSSC has served as an advisory body focused on laboratory safety and will continue to serve as an advisory and review body for OLSS operations.

While the recent laboratory safety and security incidents functioned as catalysts for establishing this central office, its mandate encompasses the Agency-wide EH&S program both inside and outside of the laboratory. To that end, Employee Safety and Environmental Management (ESEM) staff has been realigned to OLSS. OLSS has also been charged with reviewing, implementing, and maintaining policies and practices that ensure the highest accuracy, reliability, and timeliness of laboratory results. OLSS will work with FDA subject matter experts to define and establish appropriate laboratory quality procedures that can be used throughout the Agency to ensure continued confidence and credibility in FDA's research.

Purpose of the Strategic Plan

This document is intended to formally outline the purpose of OLSS and deliver a statement of its commitment to protecting the health and safety of the FDA community and enhancing the quality of data generated in FDA laboratories, in terms of reproducibility and reliability.

The Strategic Plan outlines OLSS' vision and mission, goals and objectives, and the high-level strategies to achieve its mission. The plan is informed by external recommendations; FDA stakeholders' input; best practices in laboratory science, safety, and security; and the leadership of the Director of OLSS. Further, the plan is intended to provide clarity on common terms (e.g., culture of responsibility and safety, laboratory quality management) and the scope in which they are used to convey the guiding principles.

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 of OLSS

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 for OLSS

Actions and initiatives in pursuit of the mission are guided by principles of good laboratory science and safety through an embedded culture of responsibility, collaboration and cooperation, transparency, and evidence-based practices.

Culture of Responsibility and Safety	Collaborative Development	Transparent Operations	Evidence-Based Practices
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.	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.	As a default, OLSS will operate in the open, 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 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.

Definitions

Laboratory Quality Management System (LQMS): "Coordinated activities (including policies, processes, and procedures) on all aspects of a laboratory operation (including organization, personnel, and equipment) to direct and control the quality of research and results that are accurate, reliable, and timely."[5]

Laboratory Security: Measures used to control access to laboratories and laboratory assets in order to mitigate a range of vulnerabilities.

Environment, Health, and Safety (EH&S) Programs: The FDA EH&S programs provides comprehensive services including regulatory compliance oversight, technical guidance, training programs, inspections, emergency response assistance, risk management, and loss control services. All EH&S programs are committed to protecting FDA employees, contractors, and visitors and promoting environmental stewardship within the community.

Culture: "An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement, or enhance operating procedures, rules, and practices as well as professional standards and ethics."[6]

GOALS AND OBJECTIVES

Spotlight: *FDA Biological Science Technician*

Andrea Kouneski feeds a calf born at FDA's Office of Research, Center for Veterinary Medicine.

Goal 1

Minimize risks to employee health and safety attributable to the FDA workplace, outside of laboratory activities.

To best serve FDA's mission, FDA must ensure that its employees have a safe working environment. The FDA seeks a culture of responsibility and safety that minimizes risks to its employees and prevents injuries, illnesses, and deaths at work, in homes, and in its communities. The EH&S program at FDA is a primary responsibility of OLSS. Workplace safety objectives include environmental management, government vehicle safety, emergency response, and occupational safety and health (e.g., indoor air quality concerns, excessive noise, slips, trips, falls, and ergonomics).

Goal 1: Objectives

1.1 Reduce or eliminate the likelihood of non-laboratory associated occupational accidents, injuries, illnesses, and incidents.

1.2 Decrease the impact of incidents that occur.

1.3 Increase awareness of potential workplace hazards.

1.4 Protect the workplace environment.

1.5 Maintain and disseminate employee safety guidance through the FDA Staff Manual Guide for Safety and Occupational Health Programs.

1.6 Increase the proportion of incidents and near misses that are reported Agency-wide and support the development and/or implementation of mitigation strategies, as needed.

1.7 Assess and report compliance with EH&S-related policies.

1.8 Coordinate compliance actions regarding federal, state, and local EH&S regulations.

Goal 2

Minimize risk to employee health and safety attributable to laboratory activities.

No laboratory is 100 percent safe as there is inherent risk when working with hazardous biological or chemical materials, animals, ionizing and non-ionizing radiation, laboratory equipment, and other hazardous materials. While some measure of risk is unavoidable in order to advance science and medicine, the goal of OLSS is to maximize implementation of practices that will minimize risk.

> *"FDA must help ensure that its employees have a safe working environment. The FDA seeks a culture of responsibility and safety that minimizes risks to its employees…"*

Reducing risk requires identification and anticipation of potential hazards, understanding how to avoid or mitigate them, and regularly refreshing awareness and training on safety policies and practices. To identify and mitigate potential risks, OLSS will develop a common risk assessment framework that can be used by the Center/Office safety staff and made available to all researchers before beginning laboratory work. In addition, the Institutional Biosafety Committee (IBC), under OLSS, will ensure that identified risks to the health and safety of FDA personnel, the public, and the environment will be minimized by providing an initial and continuing review of safety for proposed research activities involving high-consequence hazardous biological agents and materials. OLSS aims to manage laboratory hazards and hazardous materials by establishing a regular schedule for reviewing and updating Agency policies, promoting awareness and adherence to these policies through training and facilitating a culture of responsibility and safety, assessing the outcomes of initiatives, and routinely reporting incidents and select agent laboratory inspection results to interagency senior officials.

Goal 2: Objectives

2.1 Decrease the likelihood of incidents that occur in FDA laboratories.

2.2 Decrease the impact of incidents that occur in FDA laboratories.

2.3 Decrease the likelihood of laboratory-acquired infections.

Spotlight: *FDA Chemist*

A chemist with FDA's Office of Regulatory Affairs uses gas chromatography to measure levels of melamine in food samples.

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System-Wide Causal Analysis

When incidents occur, they provide valuable opportunities to learn how to improve policies and practices. OLSS is committed to system-wide causal analysis, intended to discover not only the last circumstance that led to the incident, but any system-wide conditions that contributed to the incident. For example, an eye injury in the laboratory could be prevented through the use of personal protective equipment (PPE). However, injury can also be avoided through a message from leadership that describes the importance of wearing PPE as a laboratory norm, followed up with frequent reminders. The systemic causes are addressable, and a thorough analysis of these causes is more likely to result in fewer incidents than blaming an individual, laboratory, Center, or Office.

2.4 Increase the proportion of incident and near miss reporting Agency-wide and support the development and/or implementation of mitigation strategies, as needed.

2.5 Provide and maintain Agency-wide policies to mitigate exposure and risks from laboratory hazards.

2.6 Provide training resources to educate and update FDA staff on how to mitigate exposure and risks from laboratory hazards.

2.7 Assess and report on adherence to laboratory safety policies.

2.8 Continuously learn and improve by developing new knowledge and investigating the causes of laboratory incidents.

2.9 Coordinate compliance actions regarding federal, state, and local occupational safety and health requirements for the laboratory.

2.10 Contribute to facility design and maintenance to promote safe and high-quality laboratory operations.

Definitions of Incident Types

> *Definitions taken from the FDA Incident Reporting Form, version date 11/04/16.*

Incident: An unplanned, undesirable event that hinders completion of a task and may cause injury or other damages; may result in property damage without perceived injury or exposure

Laboratory Accident: An incident that results in bodily injury (e.g., slip, trip, or fall) or a potential exposure (e.g., chemical, biological, radiological) in a laboratory setting

Non-Laboratory Accident: An incident that results in bodily injury (e.g., slip, trip, or fall) or a potential exposure (e.g., headache caused by paint fumes, inhalation of mold spores) outside of a laboratory setting

Near Miss: An incident where no property is damaged and no personal injury sustained, but where, given a slight shift in time or position, damage and/or injury could have easily occurred

Laboratory-Acquired Infection: An exposure to a pathogen in the laboratory that resulted in an infection; this would be checked after an infection was determined by a qualified health professional after a potential exposure

Goal 3

Ensure appropriate security and procedural safeguards are implemented in laboratories with biological, chemical, radiological, and other hazardous materials.

Laboratories at the FDA conduct critical research to fulfill FDA's regulatory and public health mission. Many of these activities are performed by dedicated scientists working with advanced technologies, hazardous biological and chemical materials, and ionizing and non-ionizing radiation. These laboratory facilities must be secured to prevent unauthorized access to information, equipment, and controlled hazardous materials. OLSS is committed to providing executive leadership for standardization of laboratory security policies and practices across the Agency. OLSS will provide guidance and tools for inventory control and access, and collaborate with the Office of Security and Emergency Management to address personnel and physical access control.

Goal 3: Objectives

3.1 Ensure that hazardous materials are properly secured and access levels are correctly assigned (e.g., access is only granted to laboratory workers who are trained to handle hazardous materials).

3.2 Contribute to laboratory facility design to ensure that appropriate physical barriers are incorporated into the design, depending on the particular hazardous materials that will be used.

3.3 Integrate security into the entire lifecycle of laboratory activities, including inventory control, management, and access.

3.4 Provide and maintain Agency-wide policies for laboratory physical access and inventory security.

3.5 Provide training resources to educate and update FDA staff on laboratory security policies.

3.6 Provide tools for laboratories to effectively manage inventory in compliance with manuals and policies.

3.7 Support adherence to the Federal Select Agent Program and the Nuclear Regulatory Commission requirements.

3.8 Support compliance with policies for correctly labeling laboratory inventory and stock, hazard warnings, and schedule classifications for controlled substances.

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Select Agent Laboratory Security

In response to the events of September 11, 2001, Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act),[7] which President Bush signed into law on June 12, 2002. The Bioterrorism Act requires institutions possessing select agents to notify the Department of Health and Human Services or the U.S. Department of Agriculture and to limit access to the agents to those with a legitimate need to handle or use such agents. The Federal Select Agent Program now oversees the possession, use, and transfer of select agents and toxins. The Program provides oversight of the nation's safety and security of select agents by ensuring that individuals who work with these agents undergo a security risk assessment; inspecting laboratories that possess, use, or transfer select agents; and other activities.

3.9 Assess and report on compliance with laboratory security policies.

Goal 4

Protect and preserve the quality—including accuracy, reliability, reproducibility, and timeliness—of laboratory results and data.

Sound science requires accurate, reliable, and timely results. A recent study (focused on drug discovery) estimated that 75 percent to 80 percent of experimental laboratory results are not fully reproducible,[8] and a significant portion of the reproducibility problems can be attributed to poor training, concerns with reagents and equipment maintenance, experimental design flaws, and inconsistent or unclear protocols.[9] High-quality data is required to support good decision-making to maximize beneficial public health impact. FDA laboratories have a long history of producing accurate, reliable, and reproducible results; FDA is committed to upholding its reputation as a credible

Spotlight: *FDA Researcher*

B.J. Yakes, Ph.D., preparing samples and programming automated biosensor instrumentation for the detection of foodborne pathogens and toxins at Office of Regulatory Science, Center for Food Safety and Applied Nutrition.

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LQMS Essentials

"In a quality management system, all aspects of laboratory operation, including the organizational structure, processes, and procedures, need to be addressed to ensure quality. Laboratory factors to consider in a quality system include the laboratory environment, quality control procedures, communications, recordkeeping, competent and knowledgeable staff, and good quality reagents and equipment."[10] OLSS will collaborate with internal stakeholders to understand the current state of laboratory quality management at FDA and with external stakeholders to understand the current state of laboratory quality management across the Department of Health and Human Services.

and trustworthy source of data as well as proactively identifying and defining laboratory quality standards to ensure the integrity of laboratory results.

Goal 4: Objectives

4.1 Promote an FDA-wide common understanding of laboratory quality management and quality control elements for a given laboratory function.

4.2 Establish a culture of continuous improvement in laboratory quality management.

4.3 Provide laboratories with adequate resources to ensure compliance with requirements and to achieve the appropriate level of quality management.

4.4 Create a flexible LQMS that will grow to meet future needs.

4.5 Define metrics to help laboratories measure the strength of their quality system and help them identify areas for continuous improvement.

4.6 Disseminate information on lessons learned and best practices for laboratory quality operations.

Goal 5

Increase efficiency related to laboratory science; laboratory security; and Agency-wide environment, health, and safety.

Historically, FDA's Centers and Offices have operated mostly independent safety and laboratory quality assurance programs. While each Center or Office has unique requirements, many laboratory science, safety, and security functions are common across all Centers. These common requirements represent opportunities for increased efficiency and consistency of policies and practices across the Agency.

Efficiencies are measured by observable reductions in resources without a reduction in scope or effectiveness. Contracts (e.g., for hazardous waste removal), IT systems, responses to external inquiries, training, and policy updates each present opportunities for economies of scale through central provisioning and accountability. OLSS intends to increase efficiency, reduce deficiencies and redundancies, and decrease the burden on the Centers and Offices wherever possible while not interfering with laboratory- and site-specific needs.

Goal 5: Objectives

5.1 Serve as central point of contact for external communications. Coordinate with the Government Accountability Office, Office of Inspector General, Department of Health and Human Services, Congress, the White House, media, and public on activities associated with laboratory science; laboratory security; and Agency-wide environment, health, and safety programs. Disseminate new requirements from these external bodies to the FDA community.

5.2 Serve as single point of accountability for FDA's laboratory science; laboratory security; and Agency-wide environment, health, and safety programs.

5.3 Identify common components in safety manuals and policies that are implemented by the Centers and Offices. When applicable, consolidate duplicative safety manuals and policies. Regularly update and enhance manuals and policies as needed to maintain compliance and best practices. Provide staff with access to information relevant to them.

5.4 Provide IT systems and associated processes (e.g., inventory management, incident reporting, and database management), while accommodating the unique requirements of Centers, Offices, and laboratories.

5.5 Share subject matter expertise to support Centers and Offices (e.g., industrial hygienists).

5.6 Reduce unnecessary duplication in ordering, inventory, and contracts administration, where needed.

5.7 Streamline laboratory science; laboratory security; and Agency-wide environment, health, and safety programs, policies, and processes (e.g., the IBC review process), using automation where practicable.

5.8 Optimize the number of forms and steps needed to comply with program policies (e.g., reduce steps to submit an incident report).

5.9 Advocate for optimal organizational design (e.g., support Occupational Safety and Health Officers [OSHOs] and Center or Office leadership to find the optimal placement of the OSHO within the organizational structure).

5.10 Evaluate the costs and benefits of opportunities for efficiency as they emerge, including both the costs and benefits to the Agency overall as well as to individual Centers or Offices.

Efficiency and Cost Savings

Historically, EH&S, biosafety, and laboratory quality assurance programs have not received adequate resources. As a result, organizations may have been exposed to unnecessary and avoidable risk. Initially, the Agency will bear additional costs to set up OLSS and provide consistent policies and practices for the Agency's laboratory science, laboratory security, and Agency-wide EH&S programs. After the initial increase in cost to eliminate deficiencies, the centralized functions should result in cost savings across the Agency and reduce workloads within the Centers and Offices.

Goal 6

Conduct a program of applied research to generate evidence for best laboratory science and safety practices.

Following Recommendation 1.6 of the Federal Experts Security Advisory Panel (FESAP) Report,[3] OLSS will fund and/or conduct applied research to develop innovative and advanced approaches to enhance laboratory safety and safeguard the accuracy, reliability, and timeliness of data across the Agency. A robust applied research program will produce data to support safe practices and provide evidence to support implementing improved practices and operations. OLSS will support a research program to improve the management of biological, chemical, radiological, and other hazardous materials to reduce occupational exposures and adverse environmental impacts (e.g., sample inactivation studies or disinfection methods/procedures). OLSS will help ensure the utility and impact of its applied research studies by sharing information and collaborating with laboratories across the Agency, Department, and federal, industry, and academic partners.

Goal 6: Objectives

- **6.1** Participate in external working groups to efficiently coordinate applied biosafety research across HHS.
- **6.2** Conduct a gap analysis to determine areas where an applied research program could have the largest impact across the Agency.
- **6.3** Develop a plan for an applied research program that emphasizes enhancing laboratory science and safety to protect FDA employees and the surrounding community.
- **6.4** Administer a grants program (intramural and extramural) for applied research laboratory practices and technologies.
- **6.5** Share developments of the applied research program through demonstrations, partnerships, and technology transfer efforts.

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The Science of Laboratory Operations

As a steward of the public's trust and taxpayers' dollars, FDA's innovations in laboratory science, safety, and security should be shared with the public. OLSS will facilitate the sharing of new or innovative laboratory management, operations, and tools among the Centers/Offices and disseminate the information to the public.

Goal 7

Reinforce and promote the Agency-wide culture of responsibility and safety.

As stewards of the public's trust and taxpayers' dollars, FDA workers must be productive and innovative, while also upholding the Agency's high standards for laboratory science, laboratory security, and Agency-wide EH&S programs. It is impossible for policies, manuals, and training to encompass every situation an employee could encounter. Individuals must internalize their own high standards for quality of science, safety, and security to make proper choices when planning, preparing, and executing their work. They must be cognizant of the impact their work has on others (e.g., their family, their laboratory coworkers, and everyone within the workplace environment) and must make responsible choices that prioritize the safety of the FDA community.

A strong culture of responsibility and safety will provide reinforcement of shared expectations among peers and leadership and provide opportunities for recognition of appropriate behaviors. Staff should be confident that being transparent about safety issues will not lead to any form of retaliation. For example, the Agency should continually review procedures for staff raising a safety concern, reporting a near miss, or discussing a non-conformance matter to ensure the process is convenient and readily available with an option for anonymous reporting. Leadership should continually encourage staff to report concerns without the fear of reprisal and handle raised concerns openly without shame or blame. As issues are raised, lessons learned should identify opportunities for improvements in workplace safety.

Spotlight: *FDA Scientist*

Yukinori Endo, Ph.D. and Jiangsong Jiang, Ph.D., investigating potential toxicities of anti-cancer biotech medicines, Office of Biotechnology Products, Center for Drug Evaluation and Research.

Goal 7: Objectives

7.1 Listen and respond to employees' and the communities' perceptions of the existence and/or lack of a culture of responsibility and safety.

7.2 Create and share messages that reinforce laboratory science; laboratory security; and Agency-wide environment, health, and safety as priorities.

7.3 Increase leadership participation in and championing of laboratory science; laboratory security; and Agency-wide environment, health, and safety activities.

7.4 Ensure that FDA staff has no fear of retaliation, real or perceived, when raising concerns or reporting an incident.

7.5 Create organizational structures and mechanisms that reflect laboratory science; laboratory security; and Agency-wide environment, health, and safety as priorities.

7.6 Establish a practice of investigating incidents to find systemic causes, without placing blame on any specific individual.

7.7 Recognize and reward behaviors and communications that reflect high standards for quality of science, safety, and laboratory security, and integrate them into award programs and performance plans.

7.8 Identify and share best practices for safety, laboratory security, and quality management across Centers/Offices and increase knowledge transfer among them.

7.9 Establish and maintain high standards for quality of science, safety, and laboratory security across FDA through policies, manuals, training, and tools.

7.10 Measure and report on the impact of culture initiatives.

7.11 Prevent negative impacts on mission-critical activities across Centers and Offices as a result of policy changes.

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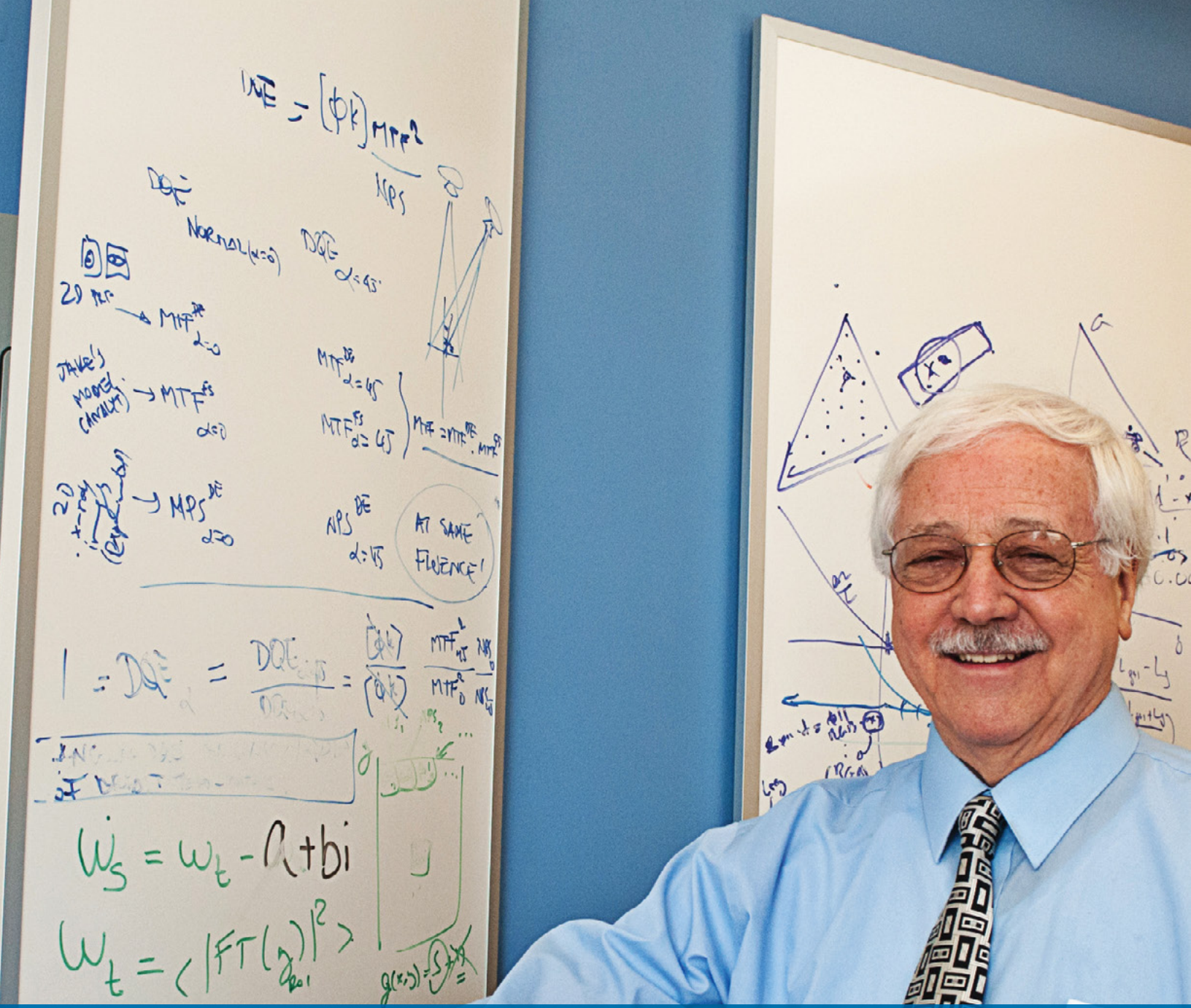
Culture of Responsibility and Safety[11]

A culture of responsibility and safety refers to an organization's shared values, assumptions, and beliefs specific to workplace safety, or in this case, laboratory science, laboratory security, and Agency-wide EH&S. A safety culture aims to create and strengthen a working environment that emphasizes laboratory safety, laboratory security, and responsible conduct. A strong, positive safety culture arises not because of a set of rules, but because of a commitment to safety throughout an organization. As the priority placed on safety increases, the emphasis on compliance with regulations shifts toward fostering a strong, positive safety culture where leadership affirms a constant commitment to safety. This culture of responsibility should be characterized by individual and institutional compliance with laboratory safety and security regulations, guidelines, standards, policies and procedures, and enhanced by effective training. Such a culture supports the free exchange of safety information, emphasizes learning and improvement, and assigns greater importance to identifying and solving problems rather than placing blame. High importance is assigned to safety all the time—not just when it is convenient or does not threaten personal or institutional productivity goals.



STRATEGIES

Spotlight: *FDA Engineer*

Charles Warr showcasing his clever design used to hide breaker boxes while leaving them accessible and providing additional workspace at the White Oak, Maryland campus, Center for Devices and Radiological Health.

> *"OLSS will serve as the principal point of accountability for the laboratory science, laboratory security, and Agency-wide EH&S programs."*

OLSS was created following the recommendations of Congress, the White House, and CDC's ELSW, and with attention to the Association for Public Land-Grant Universities Report.[1–3, 12] In addition to following external recommendations and best practices, OLSS will integrate existing FDA organizational norms and expectations, along with lessons learned from laboratory accidents, incidents, near misses, and laboratory-acquired infections. Synthesizing the recommendations of the ELSW, the LSSC, academic institutions, and knowledge of the existing FDA culture, OLSS will pursue its mission using the strategies outlined below.

Collaboratively develop and standardize policies and expectations for the laboratory science, laboratory security, and Agency-wide EH&S programs.

OLSS will develop standardized information for Agency-wide manuals and policies that conform to external requirements and best practices. Wherever applicable, OLSS will use existing policies from Centers and Offices. Manuals and policies must include flexibility for laboratory- and site-specific needs. Where external requirements are insufficient to meet FDA's desired level of safety and accuracy, reliability, and timeliness of laboratory results, OLSS will collaboratively develop definitions and standards. For example, Centers, Offices, and individual laboratories may view the concept of a LQMS differently, so OLSS will work collaboratively with them to ensure the appropriate implementation of laboratory quality management practices to meet their needs. OLSS will carefully plan changes to ensure there will be no inadvertent deviations in accreditation or negative impacts on mission-critical activities.

Centralize oversight and accountability into a single Office.

OLSS will serve as the principal point of accountability for the laboratory science, laboratory security, and Agency-wide EH&S programs. Functions relating to Center- and Office-specific laboratory science, laboratory security, and Agency-wide EH&S programs will remain in place and report to the Center management. OLSS will support the Agency's goal to maintain full compliance with Occupational Safety and Health Administration (OSHA) law and regulations; the Federal Select Agent Program; the Biosafety in Microbiological and Biomedical Laboratories (BMBL) Guide; U.S. Government Policy for Oversight of Life Science (Dual-Use Research of Concern); and all other relevant laws, regulations, and policies related to laboratory science, laboratory security, and Agency-wide EH&S programs.

Provide consistent and standardized training materials to disseminate policies, standards, and expectations to appropriate FDA staff.

OLSS will establish minimum common standards required for training employees and laboratory workers. OLSS will produce and provide information for on-boarding, refresher, new policy, and leadership training across the Agency. OLSS will provide templates and support Centers and Offices in their unique laboratory- and site-specific training needs. OLSS will provide recommendations for role-based training curricula and a system of tracking and reporting training completions.

Provide or advocate for resources required to meet high standards for laboratory science, laboratory security, and Agency-wide EH&S programs.

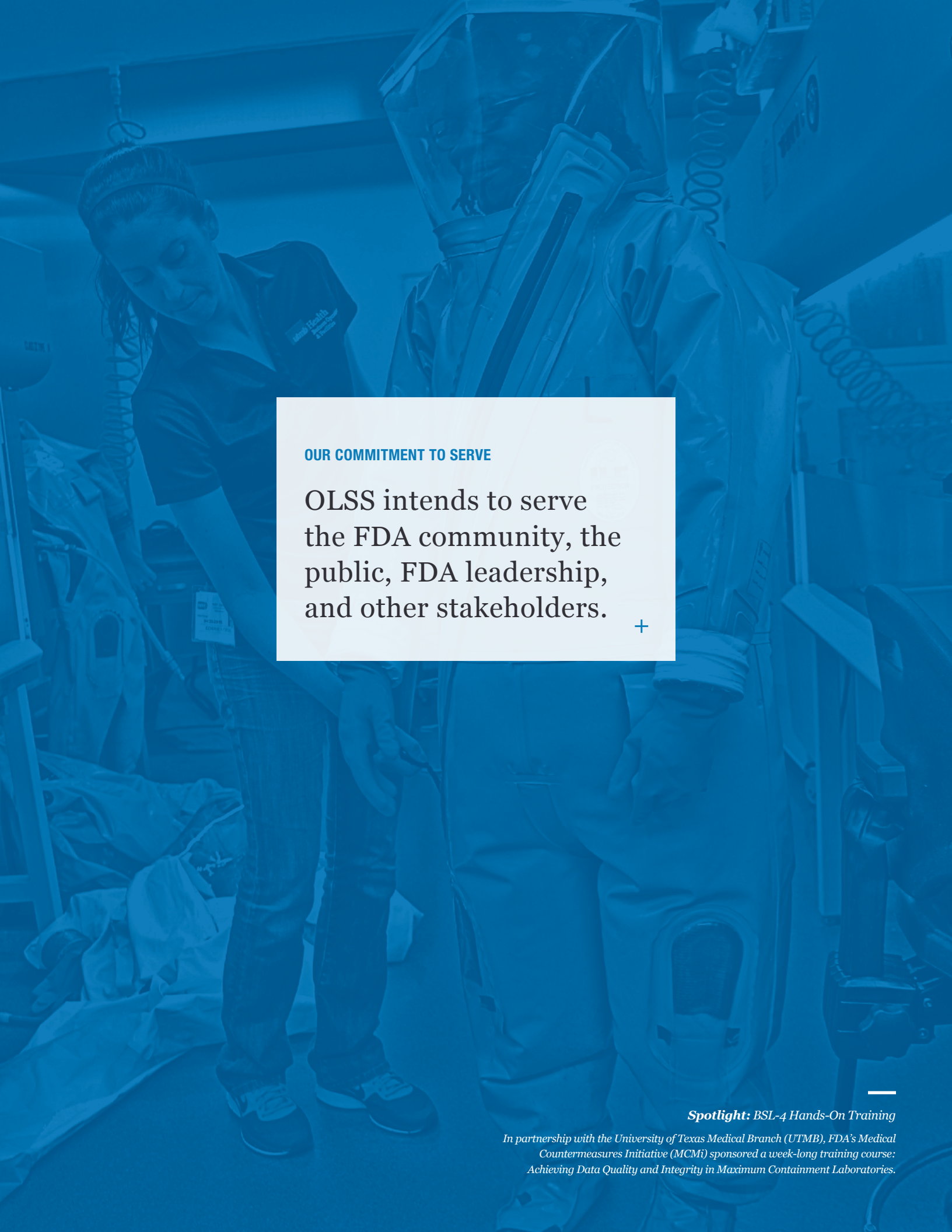
OLSS will provision tools (e.g., a centrally provisioned LQMS software infrastructure), time (e.g., full-time equivalent [FTE] staff and subject matter experts required to manage contracts), and other resources (e.g., training modules) to support the implementation of laboratory science, laboratory security, and Agency-wide EH&S programs. OLSS will produce templates and support the process for Center- and Office-specific standard operating procedures and guidance.

Spotlight: *FDA Chemist*

Patrick Gray, Ph.D., tests food samples for the presence of arsenic using a scientific instrument called the inductively coupled plasma mass spectrometer (ICP-MS), Office of Foods and Veterinary Medicine, Center for Food Safety and Applied Nutrition.

Assess laboratory science, laboratory security, and Agency-wide EH&S programs.
Evaluating the Agency's laboratory science, laboratory security, and Agency-wide EH&S programs to ensure they are meeting the Agency's high standards is required for effective management and leadership. Assessments facilitate the identification of gaps, which in turn inform management of where resources are needed. OLSS understands and acknowledges that data calls, surveys, and audits require time and resources that may detract from research productivity. OLSS is committed to communicating the value and results of assessments and measurements, and discontinuing data collection activities or processes that do not prove to be effective.

Communicate activities, plans, achievements, obstacles, and findings to the broadest extent practicable.
OLSS intends to serve the FDA community, the public, FDA leadership, and other stakeholders through its activities. OLSS is committed to documenting its work, and that of the Centers and Offices, in support of the mission and maintaining transparency by disseminating the work through a wide-ranging communication program.



OUR COMMITMENT TO SERVE

OLSS intends to serve the FDA community, the public, FDA leadership, and other stakeholders.

Spotlight: *BSL-4 Hands-On Training*

In partnership with the University of Texas Medical Branch (UTMB), FDA's Medical Countermeasures Initiative (MCMi) sponsored a week-long training course: Achieving Data Quality and Integrity in Maximum Containment Laboratories.

COMMITMENT FROM THE OLSS DIRECTOR

In February 2017, the Commissioner of Food and Drugs—in collaboration with the Secretary of the U.S. Department of Health and Human Services—established the Office of Laboratory Science and Safety. This office was established to provide tools and knowledge to scientists and researchers to support the FDA's critical public health mission while maintaining high-quality laboratory science and ensuring laboratory security and Agency-wide environment, health, and safety.

Collaboration will be key in managing laboratory science and safety programs and requirements. While we focus on coordinating science and safety policies and operations, we will also continue to grow strategic alliances with our partners across FDA laboratories, other federal agencies, and the private industry.

As the Director of OLSS, I am committed to the principles, goals, objectives, and strategies described in this plan. I am devoted to ensuring that FDA's workforce is able to conduct mission-critical science safely and effectively, and serving as FDA's single point of accountability for its laboratory science; laboratory security; and Agency-wide environment, health, and safety programs. Our jobs cannot be done alone; we must collaborate across organizational boundaries to accomplish this mission. This Strategic Plan represents my commitment to the FDA community and the public, and I invite our stakeholders to hold me accountable to it.

"As the Director of OLSS, I am committed to the principles, goals, objectives, and strategies described in this plan. I am devoted to ensuring that FDA's workforce is able to conduct mission-critical science safely and effectively and serving as FDA's single point of accountability..."

I look forward to your support as we work together to provide a safe environment for our scientists, their families, and our community.

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

Appendix: FDA's Mission

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

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

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

FDA also plays a significant role in the nation's counterterrorism capability. 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.

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For more information, visit fda.gov and search for
Office of Laboratory Science and Safety

Spotlight: *FDA Chemist*

Laura Schnackenberg, Ph.D., prepares auto sampler for the Nuclear Magnetic Resonance (NMR) imaging system, Office of Research, National Center for Toxicological Research.

[Front Cover] ***Spotlight:*** *FDA Scientist Ross Marklein, Ph.D., staff fellow at FDA, examines images of stem cells, Office of Tissue and Advanced Therapies, Center for Biologics Evaluation and Research.*

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FDA ADMINISTRATION

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1.0	03/10/2017	Content edits by OLSS Leadership Team	Office of Laboratory Science and Safety (OLSS)
1.1	05/30/2017	Content edits by OLSS Leadership Team	Office of Laboratory Science and Safety (OLSS)
1.2	05/31/2017	Content edits by OLSS Leadership Team	Office of Laboratory Science and Safety (OLSS)
1.3	06/30/2017	Minor wording edits made to Goals 4, 6, and 7. Updated text for objectives 7.8-7.9.	Office of Laboratory Science and Safety (OLSS)