



***Strengthening an organizational culture  
that emphasizes biosafety, biosecurity, and  
responsible conduct in the life sciences***

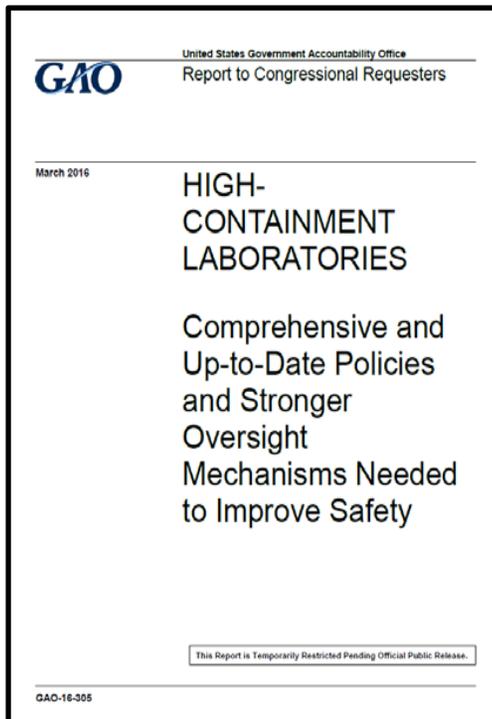
**- Outreach Strategy -**

Template for Outreach to USG Internal and External Stakeholders



# ***Why do we need to optimize biosafety and biosecurity?***

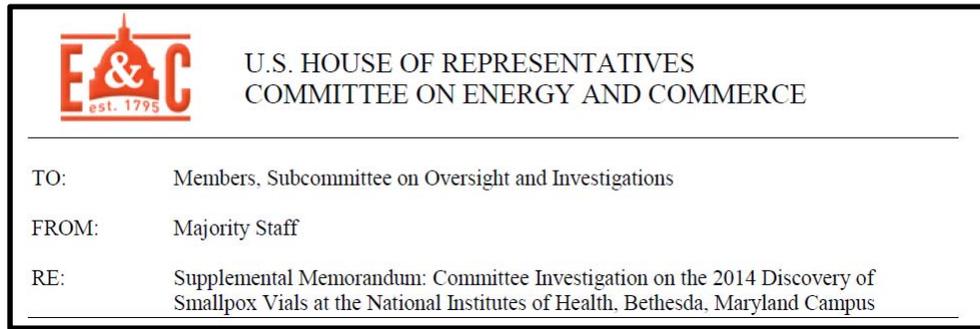
***“In 2014 and 2015, two federal departments reported multiple lapses in laboratory safety that could have exposed personnel and other individuals to hazardous biological agents.***



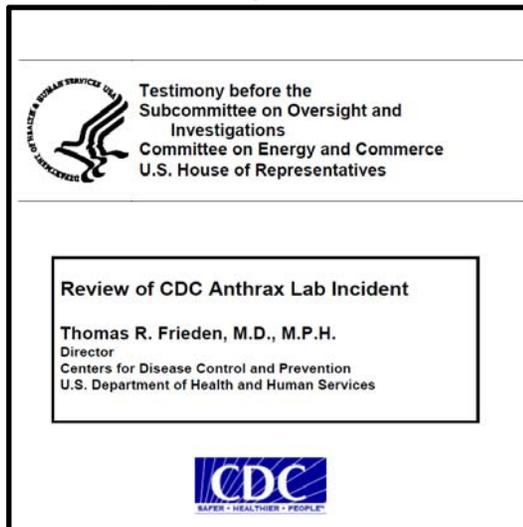
***For example, within the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) reported an incident in June 2014 that had the potential to expose laboratory personnel to live anthrax bacteria, and in July 2014, boxes containing decades-old vials of smallpox - some of which contained live virus - and other hazardous biological agents were found in a storage space of a Food and Drug Administration (FDA) laboratory on the National Institutes of Health (NIH) campus.***

***In May 2015, the Department of Defense (DOD) reported safety lapses at one of its high-containment laboratories stemming from inadequate procedures to fully inactivate anthrax that resulted in DOD shipping live anthrax to other laboratories.”***

# ***Why the emphasis on the culture of safety?***

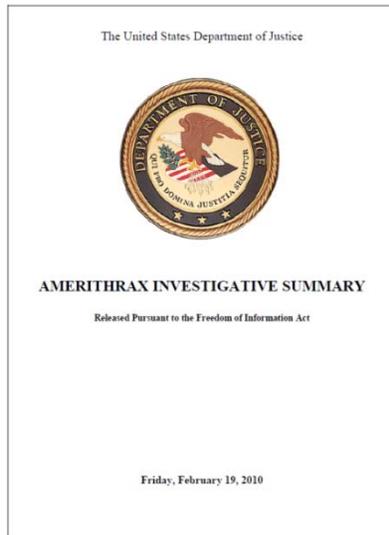


***“The hearings and reports show a pattern of recurring issues, of complacency, and a lax culture of safety. The lesson learned from past reviews is that Federal agencies must address cultural factors in addition to its policy and management efforts to ensure the effectiveness of its lab safety programs”.***



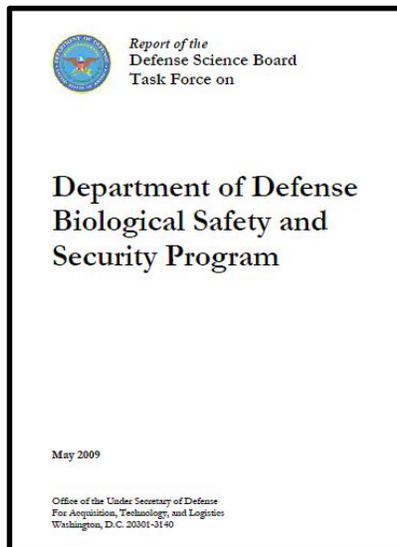
***“While specific corrective actions were taken in response to individual incidents in the past years, the broader pattern of inadequate laboratory safety was not addressed effectively. Addressing that broader pattern and our safety culture is what we are doing now.”***

## ***What about the culture of security?***



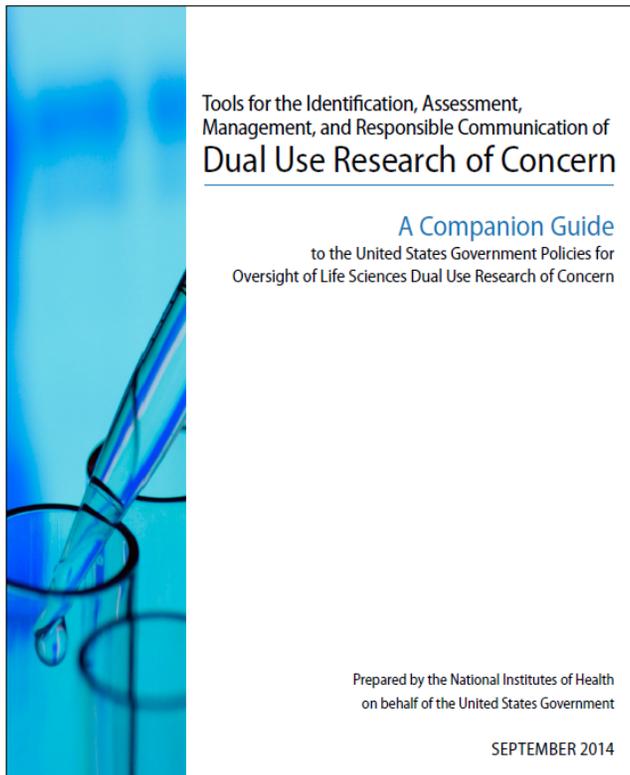
***“Administrative and investigative steps taken in the past year toward closure of the investigation confirm the conclusion that Dr. Ivins perpetrated the anthrax letter attacks”.***

***“The single overarching finding of this investigation is that a determined adversary cannot be prevented from obtaining very dangerous biological materials intended for nefarious purposes, if not from DoD laboratories, then from other sources”.***



***Recommendations include making “changes to monitoring activities to improve effectiveness without introducing overly intrusive measures. Hold periodic meetings with laboratory personnel to reinforce values, moral obligations, and observations that should be reported”.***

## ***Beyond the culture of safety and security - example for consideration -***



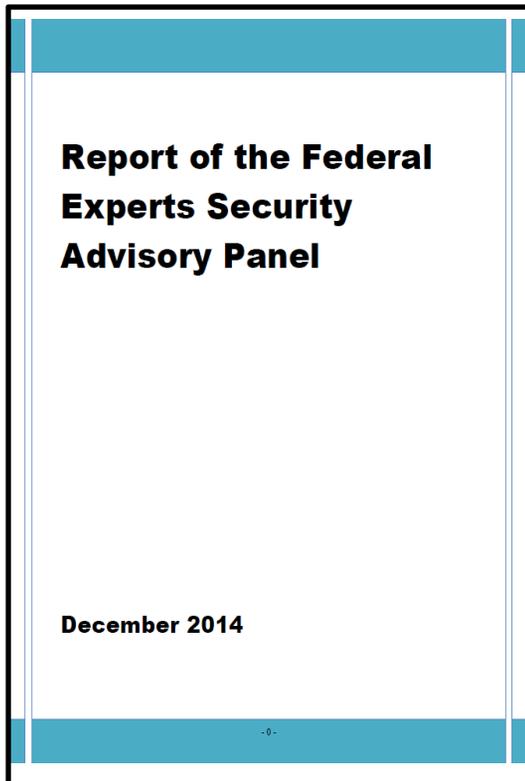
**Is the individual and institutional oversight of DURC (which includes policies, practices, and procedures to ensure DURC is identified and risk mitigation measures are implemented, where applicable) an example of area where cultural factors are important?**

**Yes.** DURC policies emphasize a culture of responsibility by reminding all involved parties of the shared duty to uphold the integrity of science and prevent its misuse

***“All scientists—especially those working in the life sciences—are called to cultivate among themselves a culture of responsibility with regard to the conduct and the achievements of their research”***

*- 2011 NSABB Guidance for Enhancing Personnel Reliability and Strengthening the Culture of Responsibility*

# Culture in context



***“Recent incidents involving BSAT have raised serious safety and security policy issues. The White House National Security Council (NSC) staff tasked the FESAP, in September 2014, to 1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT; 2) identify actions and any regulatory changes to improve biosafety and biosecurity; and 3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer BSAT”.***

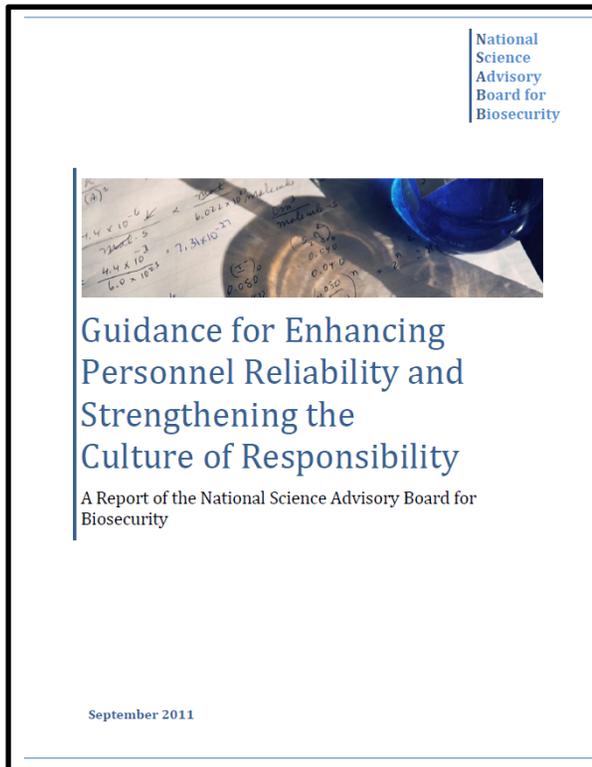
***Recommendation 1.1: Create and strengthen a culture that emphasizes biosafety, laboratory biosecurity, and responsible conduct in the life sciences. This culture of responsibility should be characterized by individual and institutional compliance with biosafety and laboratory biosecurity regulations, guidelines, standards, policies and procedures, and enhanced by effective training in biorisk management”.***

## ***Definition of culture as it relates to biorisk management***

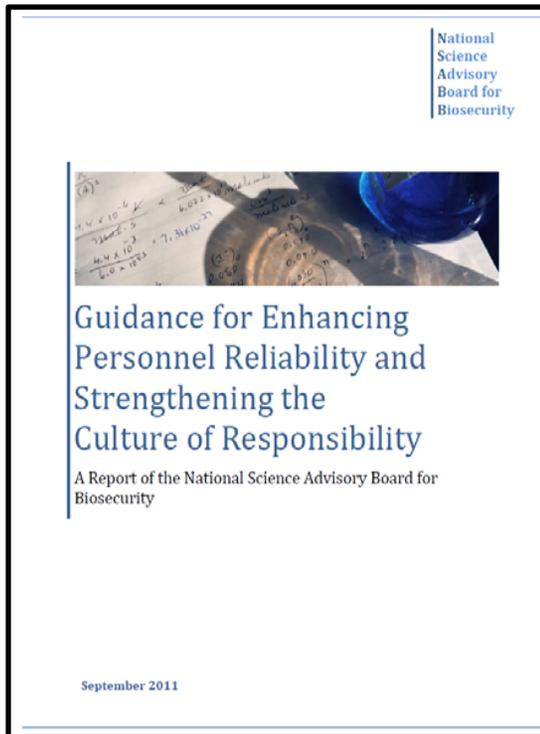
***An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents.***

# ***What elements should we consider for strengthening the organizational culture?***

<b><u>Management systems which prioritize biosafety, biosecurity, and responsible conduct</u></b>	Processes, procedures and programs in the organization which prioritize biorisk management and have an important impact on the biosafety/biosecurity functions
<b><u>Behavior of leadership and personnel to foster more effective biosafety and biosecurity</u></b>	<i>Leadership behavior</i> (i.e. specific patterns of behavior and actions which are designed to foster more effective biorisk management) should emphasize inter alia expectations, decision making, management/ supervisory oversight, effective communication, and motivation. <i>Personnel behavior</i> (the desired outcomes of the leadership efforts and the operation of the management systems) should emphasize inter alia professional conduct, adherence to approved/validated procedures and research protocols, team work and cooperation, and vigilance.
<b><u>Principles for guiding decisions and behavior as they relate to biorisk management</u></b>	Emphasis should be placed on <i>principles for guiding decisions and behaviors</i> as they related to biorisk management (i.e. motivation, leadership, commitment and responsibility, professionalism and competence, learning and improvement, maintaining public trust)
<b><u>Beliefs and attitudes on biosafety and biosecurity</u></b>	<u>Beliefs and attitudes on biosafety and biosecurity</u> should be assessed periodically and reinforced through training and education aiming to: raise awareness on the risks associated with working in a laboratory with biological materials (e.g., accidental exposure, infection or release; intentional theft and/or misuse; others such as radiological/chemical/physical safety), the potential ramifications if such risk events were to occur and risk mitigation strategies; raise awareness and increase understanding of the ethical, legal, and societal issues and consequences concerning life sciences research, development, and associated technologies; raise awareness and place emphasis on the importance of quality systems and practices in lab biosafety and biosecurity training and research design; review codes of ethics and social responsibility guidelines in life sciences research; and review biosafety, biosecurity, and dual use research of concern regulations, guidelines, policies and procedures, and any other specified training requirements.



***“Above all, good management practices are the foundation that underpins the development of a culture of responsibility, integrity, trust, and effective biosecurity. In addition, strong institutional and laboratory leadership, clear articulation of priorities and expectations, and an institutional framework that provides relevant education, training, performance review, and employee support will facilitate responsible practices, personnel reliability, safety, and security, while allowing research on biological select agents and toxins (BSAT) to flourish”.***



**The scientists’ “goal remains that of the generation and advancement of knowledge, but, in some cases, such knowledge may be applied for both beneficial and harmful purposes; their beliefs, attitudes, and values must reflect a heightened consciousness of the implications of their research, especially of any potential for the deliberate misuse of the information, products, and technologies generated from their research; they must consciously live and demonstrate these beliefs, attitudes, and values through day-to-day practices of mindful research.**

**With transparency, they must examine their own research with consideration of its potential for misuse, and they must conduct and communicate their research in ways that mitigate any risks of misuse.**

**Finally, in cultivating and sustaining a culture of responsibility, scientists who conduct research must recognize that they engage in a continuous, reciprocal process of promoting and bearing mutual responsibility for their work: **They must hold themselves and their peers accountable—collegially and with a shared commitment to advancing science and maintaining public trust.”****

## ***Foundational values of an organizational culture that emphasizes biosafety, biosecurity, and responsible conduct***

- **Research excellence**: foster quality in life sciences activities, which is the basis for developing new treatments and therapeutics, strengthening health research systems, and promoting public health surveillance and response activities. These elements are essential to protecting and improving the health and well-being of all people.
- **Bioethics** –promote responsible and good research practices, the provision of tools and practices to scientists and institutions that allow them to discuss, analyze and resolve in an open atmosphere the potential dilemmas they may face in their research, including those related to dual use research of concern, the possibility of accidents or misuse of the life sciences.
- **Biosafety and biosecurity** –implement and strengthen of measures and procedures to: minimize the risk of worker exposure to pathogens and infections; protect the environment and the community; and protect, control and account for biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release. Such measures reinforce good research practices and are aimed at ensuring a safe and secure laboratory environment, thereby reducing any potential risks of accidents or deliberate misuse.

## ***Assessment of the organizational culture that emphasizes biosafety, biosecurity, and responsible conduct in the life sciences***

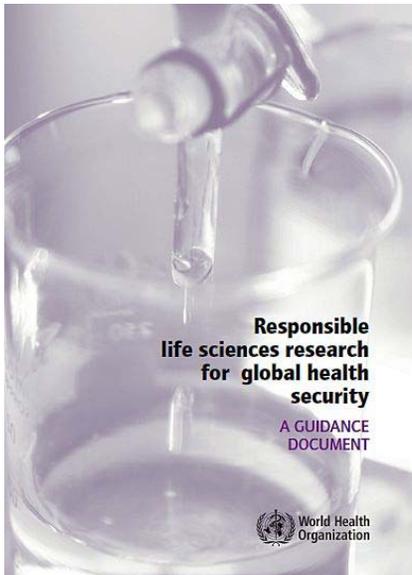
- **Organizations / laboratories are encouraged to develop methods for outcome measurement (i.e. systematic determination and evaluation of their training and oversight systems aiming to strengthen the culture of biosafety, biosecurity, and responsible conduct, and comparison with the strategic goals and intended or projected results)**
- **Outcome measurement has become increasingly important given the complexity of biosafety/biosecurity oversight systems, the need for evidence-based decision-making (e.g. on staffing, areas for improvement, choice of training programs), and the ability to detect changes associated with a particular intervention**
- **Such a systematic assessment (conducted periodically) is critical to understanding the efficiency/effectiveness of the biorisk management framework, causality of system breakdowns or analysis of incidents, sources of human error or breaches of biosafety/biosecurity, efficiency/effectiveness of training, etc.**

## ***Methods of assessment of the organizational culture that emphasizes biosafety, biosecurity, and responsible conduct in the life sciences***

- **Basic** (based on statistical methods and information derived mostly from document review, observations, and other sources- i.e. percentage of employees who have received safety/security refresher training during the previous quarter or year; percentage of safety/security improvement proposals submitted, considered, or implemented during previous quarter or year; number of laboratory safety/security incidents or near-misses, etc);
- **Intermediate** (based on managers' own "yes" or "no" judgment regarding the evolving structure and functionality of the biosafety/biosecurity framework; areas assessed requiring a "yes" or "no" response may include: information on the availability of safety/security policies, regularly held management meetings covering significant safety and security issues, professional rewards or recognition are associated with the achievement of safety/security goals, etc.) or
- **Comprehensive** (multi-stage process comprising both non-interactive and interactive assessment tools focusing on management and behavior characteristics of the biorisk management culture). Methods to be included in the plan may include: 1) non-interactive methods (surveys, document review, and observations) and 2) interactive methods (individual interviews and focus-group discussions).

**Aim to develop a continuous improvement system that provides feedback, reassessment, and on-going training and learning opportunities**

## ***International perspectives***



***WHO “promotes a culture of scientific integrity and excellence, distinguished by openness, honesty, accountability and responsibility. Such a culture is the best protection against the possibility of accidents and deliberate misuse, and the best guarantee of scientific progress and development”.***

***States Parties noted that implementation of BWC includes inter alia measures to “... ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins...”***,

***“implement voluntary management standards on biosafety and biosecurity; promote the development of training and education programs for those granted access to biological agents ... encourage the promotion of a culture of responsibility amongst relevant national professionals and the voluntary development, adoption and promulgation of codes of conduct...”***



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***Questions?***

