

program should at a minimum address physical protection, personnel suitability/reliability, pathogen accountability (onsite and through the transportation process), and biosecurity incident response.

Proactive Measures to Implement a Biosecurity Program

Measures should fulfill identified functional requirements with consideration to mission objectives, goals, and other operating constraints. Institutes, their biosecurity requirements, and approaches to meeting those requirements may vary. Some applied requirements identified by a broad range of facilities may include general aspects of managed access that encompass visitor control, location of biological materials within a facility and access to biological materials, and material accountability. Approaches should include the development of written and documented security procedures and should optimally provide funding for a designated site security administrator (and trained security staff) to ensure compliance and consistency in implementation. Since one commonality across facilities is that personnel are key assets, a combined approach to (1) adhere to hiring practices that select for honest, well-balanced employees, (2) establish a personnel reliability/suitability program, (3) institute an effective Employee Assistance Program, and (4) raise the level of security awareness among employees may be among the most important factors in developing an effective biosecurity program.

Conclusion

As a discipline, biosecurity has been evolving at institutes and across various agencies and industries in an independent manner. It would be beneficial to develop a national guideline or set of recommendations for biosecurity in facilities working with, storing, and transporting pathogens. A proponent organization that develops these guidelines will have to intimately understand the intricacies and unique aspects of pathogens and work with pathogens. While various Government agencies are developing their own regulations, a unified approach would be of national and international benefit. The Task Force is in the process of developing a supplemental pamphlet to provide more applied information regarding how to identify requirements and implement a biosecurity program.

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A Summary: USDA's Security Policies and Procedures for Biosafety Level 3 Facilities

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The USDA's Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS) operate high-level biocontainment laboratory facilities that work with crop, animal, zoonotic, and human pathogens. These are Biosafety Level 3 (BSL-3) or USDA's enhanced BSL-3 biocontainment laboratories (referred to as BSL-3 Agriculture or BSL-3AG). If released into the environment, some pathogens could pose a risk to plant and animal production within the United States. Also, if mishandled certain pathogens could also be a threat to human health. USDA facilities working with these pathogens have biosafety programs designed to the specific needs of each laboratory. In the past, these biosafety programs varied from facility to facility due to the different organisms being

handled, the type of work undertaken, and the location of the facilities. Physical security programs also varied among USDA's facilities.

In December 2001, the USDA established new Policies and Procedures ("P&P": *USDA Security Policies & Procedures for Biosafety Level 3 Facilities*) that uniformly charge all those with biosafety responsibilities at these USDA facilities with parallel responsibility for biosecurity. The biosecurity program has been integrated into facility safety and security programs to provide the level of biosecurity USDA has determined appropriate for its high-level biocontainment facilities. Initially, this new P&P has been applied to USDA locations where BSL-3 and BSL-3AG laboratories are located. USDA recognizes that some pathogens, which can be manipulated at lower than BSL-3, may also pose a risk to American agriculture and public health. USDA officials are currently establishing a list of important agricultural pathogens that will be defined as "high consequence pathogens" (HCP) and, thus, require consideration for enhanced biosecurity measures.

The P&P document was assembled by USDA officials at both the Department and Agency levels by facilities management and security personnel, laboratory biosafety professionals, Office of Personnel Management staff, and regulatory and investigatory agency personnel. Many of the elements of the P&P document come directly from biosafety programs and personnel security programs currently in effect in several of USDA's high-level biocontainment laboratories. Elements of physical security are based on USDA, Department of Energy, and Department of Justice standards. The P&P document takes into account unique aspects of managing biological assets at a facility. Thus, an appropriate balance of physical security, personnel credentialing, and biological system management comprises an effective biosecurity program.

The P&P document, while fully in force, is undergoing revision and fine-tuning as new information is being acquired from internal and external studies, which were underway during the time the first P&P was written. Thus, the P&P is considered a "living document" which will continue to be refined as new information is gathered and integrated into the USDA biosecurity program. The USDA biosecurity program is specifically designed for implementation at its own high-level biocontainment laboratories. Other laboratories considering developing similar plans will need to consider the nature and levels of risk concerning biosecurity and develop appropriate plans for their own facilities.

The USDA Policies & Procedures for Biosafety Level 3 Facilities

The P&P document contains sections that describe the basis for the USDA biosecurity program and a series of specifications that make up the structure of the program. The document (about 25 pages) specifies the basic elements of the USDA biosecurity program, but does not describe the exact details for implementation of the program for each facility location. These are to be implemented at each facility to meet the requirements of the program.

A Summary of the P&P Sections

Section I. Introduction and Background. Introductory and background information is provided describing the work done at USDA's BSL-3 facilities and the need for the USDA to maintain a high level of biosecurity at its high-level biocontainment laboratories.

Section II. Definitions. This section defines the Agencies and personnel involved in the program and the terms describing levels of biocontainment, characterization of infectious agents, personnel suitability, and other terms used in the document.

Section III. Authorities, References, and Organizations. This section identifies the authorities

(regulations and policies), technical reference documentation sources, and professional/governmental organizations providing guidance, which USDA laboratories follow in the biosecurity program.

Section IV. Procedures. Finally, there is a procedures section that defines the USDA Biosecurity Program.

USDA Biosecurity Four Levels of Management

The USDA biosecurity program covers four logical, if not obvious, areas of management: (1) the facility itself; (2) the personnel working within the facility; (3) data management at the facility; and (4) the materials that are being manipulated within the facility. The P&P provides minimum specifications for both the configuration of the components of the program and for their operation. These in unison provide the level of biosecurity that the USDA has determined necessary to protect against accidental or deliberate release of potentially hazardous pathogens.

Five Elements of the Procedures Section of the USDA P&P

- A) Physical Security
- B) Personnel Suitability
- C) Biohazardous Material Accountability
- D) Cyber Security
- E) Incident Response Plans

The first four elements are prospective and the last responsive in nature. A summary of these main elements follows.

A) Physical Security

Somewhat self-explanatory. These are the requirements at the facility to control access of personnel and materials to and from the facility. Information is provided to assist in the assessment of facilities and specifications are given to design appropriate features of the security system. The systems should be designed to provide a graded protection relative to the level of risk for loss of certain materials and information. The section provides a tiered layer of incrementally more restrictive zones. The personnel controls described in the next section address access requirements to each level.

1. **Property Protection Area (Perimeter Security)**—This section defines the property and its boundaries that are to be protected. There are requirements for signage, physical barriers, and securing buildings within the protected area.
2. **Limited Area (Facility or Building Security)**—This represents the buildings where biocontainment facilities are housed. There must be access controls to limit entry to authorized personnel and intrusion detection systems.
3. **Exclusion Area (Laboratory Security)**—Biocontainment laboratories are physically separated from “public” areas and are kept locked. Access is by card-key or similar device plus a unique identifier to insure entry of only authorized personnel. All freezers containing BSL-3 pathogens must be in the exclusion area and be locked.

B) Personnel Suitability

There are specific requirements for investigation of personal backgrounds to establish the suitability

of personnel to work within different areas of biocontainment facilities. Thus, the term “Personnel Suitability Levels” is used by USDA in the P&P. These are designated as PSL-1, PSL-2, and PSL-3. The background investigations required for each level of PSL are as follows:

- PSL-1, National Agency Check with Inquiries (NACI);
- PSL-2, Limited Background Investigation (LBI); and
- PSL-3, Background Investigations (BI).

All staff working at a USDA BSL-3 facility, but without access to pathogens, must minimally have a PSL-1; those with assignments within BSL-3 facilities must be PSL-2 approved; and those with leadership and program management roles at BSL-3 facilities must be PSL-3 approved. Additional classification for access to Confidential, Secret, and Top Secret documents may be required for selected individuals through appropriate security clearance investigations.

The PSL requirements apply to all working at USDA’s high-level biocontainment facilities whether they are USDA Staff, visiting scientific collaborators, operations and maintenance contractors, or other support services. Those without an appropriate PSL determination or those for whom an appropriate PSL determination cannot be made must be escorted within biocontainment spaces at a BSL-3 facility by a person holding an appropriate PSL. There are review requirements to determine if PSL levels are appropriately assigned to workers. Also, periodic reinvestigations of positions are required to determine that staff continue to meet the requirements of existing PSLs.

C) Biohazardous Material Accountability

This section defines USDA procedures to store and maintain accountability for collections of pathogens at BSL-3 research and diagnostic facilities. It also specifies packaging and shipping requirements for infectious materials, review procedures of accountability records, security of stored pathogens and access controls, sample labeling requirements, inactivation and disposal of pathogens, internal transfer of pathogens, and the roles of responsible parties.

Accountability records are a key part of this section. Three types of accountability records are maintained by the USDA: (1) a detailed inventory of repository materials kept at the facility; (2) materials accountability for experimental or working stocks; and (3) a summary inventory of pathogens at USDA agency headquarters termed the National Pathogen Inventory (NPI).

1. **Repository Inventories.** Management Units at a facility maintain a detailed inventory database of materials held in storage, and the facility maintains a master database of all materials at the facility. Records are maintained for current materials in storage, and a historical record is maintained for materials previously used.
2. **Experimental or Working Stocks.** Materials that are allocated for experimental purposes or samples collected from experiments are tracked in laboratory notebooks or other laboratory records. At the conclusion of experiments, the disposition of materials is recorded to maintain accountability for infectious materials. Materials retained after the conclusion of experiments are entered into the repository inventory for tracking.
3. **National Pathogen Inventory.** Agencies maintain a summary inventory of pathogens held at its laboratory locations. This allows agency management officials to determine the facilities where particular agents are in use. The database is regularly updated to keep the NPI current, but for security reasons is not publicly available.

D) Cyber Security Systems

Included in the Biosecurity plan is a section on cyber security. It is intended to protect the integrity

of USDA information and especially information relating to BSL-3 level pathogens. A detailed series of instructions and parameters are given for the assessment, design, and implementation of a cyber security system.

E) Biosecurity Incident Response Plan

This section details the appropriate responses and notification chains for incidents that impact the biosecurity of a facility. This section is highly site-specific as it is tailored to the characteristics of an individual facility and the resources that are available to respond to an incident. Depending on the level of incident, the incident may be handled internally or, if more serious in nature, law enforcement and public health officials may be contacted. The categories of incidents are listed below. Each facility will develop a detailed operating procedure to deal with specific incidents.

1. **Biocontainment Breach.** This involves the physical compromising of a laboratory's biocontainment envelope. It could also involve the release or removal of infectious or potentially infectious materials from a facility.
2. **Inventory Violation.** This involves the unauthorized access to stored infectious materials at a facility resulting in the destruction of material or the possibility of unauthorized removal of materials. Procedures must be in place to determine if inventories have been compromised. This process may involve the reconciliation of physical inventories with inventory records in affected storage units.
3. **Biocontainment Security Violation.** This section regards the violation of biosecurity rules and regulations at a facility. It may involve the deliberate or accidental violation of safety procedures by staff of the facility or by those from outside the facility. The response to the violation is intended to detect and correct inappropriate activities and also to limit the compromise in biocontainment that the activity may create.
4. **Nonbiological Incident.** This section addresses incidents at a facility that do not directly relate to the infectious materials themselves or to procedures concerning infectious material handling, but that could compromise their security. Occupant emergency plans for fire and other disaster preparedness are covered in this section. The plans are written to take into account, to the extent possible, the preservation of biological stores at a facility and their containment within the facility during emergency situations.

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