NOT MEASUREMENT SENSITIVE

DOE G 151.1-5
7-11-07

BIOSAFETY FACILITIES
Emergency Management Guide

[This Guide describes suggested nonmandatory approaches for meeting requirements. Guides are not requirements documents and are not to be construed as requirements in any audit or appraisal for compliance with the parent Policy, Order, Notice, or Manual.]

U.S. Department of Energy
Washington, D.C.

AVAILABLE ONLINE AT:
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INITIATED BY:
National Nuclear Security Administration
Office of Emergency Management

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1. BIOSAFETY FACILITIES

1.1 Introduction

DOE O 151.1C, *Comprehensive Emergency Management System*, describes the Department of Energy (DOE) and National Nuclear Security Administration (NNSA) Emergency Management System. The Order sets Departmental policy, assigns roles and responsibilities, and provides the framework for the development, coordination, control, and direction for DOE/NNSA emergency management programs. Requirements for emergency planning, preparedness, readiness assurance, and response activities are established and the approach for effectively integrating these activities under a **comprehensive, all-emergency concept** is described. Using this approach, a DOE/NNSA facility/site develops and participates in an integrated and comprehensive emergency management program to ensure that DOE can respond effectively and efficiently to **Operational Emergencies (OEs)** to protect workers, the public, and the environment. Emergency management programs are designed to ensure that all emergencies are promptly recognized and categorized, emergencies are reported and notifications are made, and parameters associated with the emergency are monitored to detect changed or degraded conditions.

Since 1991, DOE/NNSA emergency management programs have focused on radioactive materials and hazardous chemicals. However, priorities in national security emphasizing anti-terrorism have caused a change in national security research priorities at DOE/NNSA facilities/sites to include studies involving hazardous biological agents and/or toxins. The use and storage of these materials in DOE/NNSA facilities has the potential to harm workers and the general public, as do toxic chemicals and radioactive materials, through an unplanned event or condition that releases an agent or toxin to the environment.

Integration of hazardous biological materials into the emergency management program is directed by 10 Code of Federal Regulations (CFR) 851, *Worker Safety and Health Program*, Appendix A, *7. Biological safety*. According to this rule, contractors must establish and implement a biological safety program that establishes an Institutional Biosafety Committee (IBC) or equivalent. The IBC must review the site's security, safeguards, and emergency management plans and procedures to ensure they adequately consider work involving biological etiologic (i.e., disease causing) agents. In addition, the biological safety program confirms that the site safeguards and security plans and emergency management programs address biological etiologic agents, with particular emphasis on biological Select Agents. Other Federal regulations that govern the use and storage of Select Agents and Toxins (to be introduced in subsequent chapters) require that mandated *incident response* planning be "integrated with any site-wide emergency response plans."

The purpose of this guidance is to assist DOE/NNSA field elements and operating contractors in incorporating hazardous biological agents/toxins into emergency management programs. The intended result is an integrated and comprehensive emergency management program that provides assurances of a timely and effective

response to an onsite release of a radioactive, toxic chemical, or hazardous biological material. Note that the guidance presented in this document does not explicitly address acts of terrorism in which biological agents or toxins, not owned or controlled by DOE/NNSA, are brought onto a DOE/NNSA site or facility.

It is not the intent of this guide to establish operational biosafety requirements for biosafety facilities. Topics [e.g., biological agents, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) biosafety, BMBL risk assessment, barriers) will be introduced to familiarize emergency management personnel with various concepts related to hazardous biological materials that they must be cognizant of in order to address integration of hazardous biological materials with site-wide emergency management planning. Likewise, the discussions can also raise the awareness of biosafety experts to recognize aspects of their discipline that are important to emergency management personnel. There has been no attempt to ensure completeness in addressing the various topics in this section and in Chapters 2 and 3. These chapters should not be used to develop, implement, or evaluate a biosafety program. They are focused simply on introducing biosafety concepts relevant to emergency management programs.

1.2 General Approach

Each DOE facility/site or activity is required by DOE O 151.1C to have an **Operational Emergency Base Program,** which provides the framework for response to serious events or conditions that involve the health and safety of workers and the public, the environment, and safeguards and security. Although DOE O 151.1C establishes several DOE-unique requirements and a minimum set of generic requirements for the **Base Program**, the framework for response results mainly from the implementation of the requirements of DOE regulations, other DOE orders, and applicable non-DOE Federal, Tribal, State, and local laws/regulations/ordinances. The specific requirements that constitute the Operational Emergency **Base Program** are the emergency planning and preparedness aspects of these Orders and laws/regulations/ordinances. Examples of emergency response features addressed in other DOE Orders and laws/regulations/ ordinances include: medical support, worker evacuation plans, fire drills, worker notification systems, hazardous material communication, contingency planning for oil spills, environmental spill drills and exercises, and DOE security and safeguards requirements. The ***objective*** of the **Base Program** is to achieve an effective integration of emergency planning and preparedness requirements into an emergency management program that provides capabilities for ***all-emergency*** response, through communication, coordination, and an efficient and effective use of resources.

Some facilities may also require the implementation of an Operational Emergency Hazardous Material Program. In accordance with DOE O 151.1C, a facility that produces, uses, or stores hazardous materials (i.e., radioactive, chemical, or biological agents and toxins) in sufficient quantities (radioactive or chemical materials) or representing specific biological agents/toxins, which pose a serious threat to workers, the public, or the environment, must develop and maintain a quantitative Emergency Planning Hazards Assessment (EPHA) and meet the more detailed emergency planning requirements of a **Hazardous Material Program.** Requirements of DOE O 151.1C

apply to DOE/NNSA facilities, as well as facilities not owned or managed by the DOE, but built on DOE/NNSA land [see DOE O 151.1C, 4.a.(15), and DOE G 151.1-1A, Chapter 4].

For purposes of DOE O 151.1C and this Guide, a ***biosafety facility*** can include a stand-alone building with a single research activity, a floor in a building, or simply a laboratory consisting of a single room or several rooms on a floor in a building where storage is maintained or work/research is performed involving biological etiologic agents or hazardous biological toxins. A *biosafety facility* will have an assigned containment level consistent with applicable guidelines provided in *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, U.S. Department of Health and Human Services (HHS), Public Health Service (PHS), Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Fifth Edition, 2007. The primary focus in this guidance is on biosafety facilities that store or support activities involving biological select agents or toxins, although the approach can also be applied to other etiologic agents and hazardous toxins.

Other activities in a building containing a biosafety facility may be utilizing or storing radioactive or toxic chemical hazardous materials. The Hazardous Material Program for the building/facility should represent an integration of planning, preparedness, and response activities for all hazardous materials. For example, a single EPHA should be produced for the facility covering analyses of all hazardous materials identified in the Hazards Survey. Similarly, response tools [e.g., Emergency Action Levels (EALs); pre-planned protective actions] should cover releases of all types of hazardous materials. Thus, although the guidance in this document in the Emergency Management Guide (EMG) (DOE G 151.1-series) focuses on biological hazards, the facility/site planners will ultimately integrate the biological aspects of the emergency management program elements with those of other identified hazardous materials to produce a single facility Hazardous Material Program.

Specific guidance for implementing a Hazardous Material Program at a DOE/NNSA facility/site can be found in the EMG, DOE G 151.1-series, for facilities containing radioactive materials and/or toxic chemicals. The purpose of DOE G 151.1-5 is to address major aspects of an emergency management program that need to be modified to include emergency response to a release of hazardous biological materials.

The primary requirements specific to DOE/NNSA biosafety facilities using or storing select agents or toxins are contained in the regulations from HHS and USDA regarding certain hazardous biological agents and toxins and their possession and use in the United States (U.S.), receipt from outside the U.S., and transfer within the U.S. of certain hazardous biological agents and toxins. For purposes of this guidance, the CFR rules, which address the HHS and USDA requirements, will be referred to collectively as the **Select Agent Rules**. At a minimum, an entity registering under these requirements needs to develop and implement an *incident response* plan. For DOE/NNSA sites, the biosafety facility *incident response* plan needs to be coordinated and integrated with the implemented site-wide emergency plan.

The required contents of an *incident response* plan are described in brief statements related to various emergency management issues (e.g., identity/quantity of material released, notifications, lines of authority and communication, planning and coordination with local emergency responders, and procedures to be followed by employees performing rescue or medical duties). Emergency management personnel at sites with planned or currently operating biosafety labs will recognize that a DOE/NNSA emergency management program addresses many of the same issues in the Program Elements defined in DOE O 151.1C and the other guidance documents in the DOE G 151.1-series (the EMG). Although the major focus of the current DOE emergency management Order and EMG is on radioactive and chemical hazardous materials, requirements and guidance are *generally* valid for biosafety facilities through modifications to account for the unique properties and issues related to biological hazards. As will become evident in subsequent chapters of DOE G 151.1-5, emergency management plans and programs already implemented on DOE/NNSA sites provide the programmatic and response framework/structure and, in many instances, the specific functions and activities (e.g., training program, offsite interfaces) that will support implementation of all response requirements included in the Select Agent Rules.

Although many aspects of emergency management planning for biological agents can be patterned after the traditional hazardous materials approach that considers radioactive materials and toxic chemicals, problems may arise in the applicability and use of some traditional concepts and methodologies/tools. The applicability of computer modeling to biological release scenarios should be established for the source and conditions of release represented in the specific scenarios. Conventional modeling techniques, such as Gaussian plume models, may not be appropriate for planning calculations and consequence assessments during response for the types, quantities, and release mechanisms of biological agents/toxin of interest. For this reason, and for others to be discussed later, the Order does not require that biological releases be OEs requiring classification (i.e., Alert, Site Area Emergency, or General Emergency), as are traditional hazardous material releases. Also, some non-traditional events involving biological agents can result in releases (e.g., unobserved infected host or contamination) that may not be recognized or detected by the facility staff when they occur. In such cases, detection of the release may only happen when people present with infections at medical treatment locations, onsite or offsite, in sufficient numbers to trigger recognition of an OE.

OE response measures (e.g., protective actions) focus on *collocated workers, the public, and the environment* outside of the biosafety facility, while the biological worker safety program response appropriate for the specific the facility will focus primarily on protection of the *laboratory workers and the environment* inside the biosafety facility. The traditional approach to protective action planning applied to biological releases has the additional complication of ***infection control,*** which deals with vector or person-to-person transmittal of the agent, after initial infection of a receptor. Specific agent data can assist in determining potential spread, dissemination, infectivity, and treatment or prophylactic protocols that can influence the selection of appropriate protective actions. As indicated above, complications influencing application of the traditional DOE

hazardous materials approach to biological releases dictates that each agent be analyzed and researched to examine variations in agent characteristics that may not be bounded by a standard hazardous materials planning and response approach. Hence, emergency management planners need to familiarize themselves with the specifics of each agent in use in the biosafety facility to augment the standard planning and response template, as necessary.

In contrast to the complications mentioned above, there are underlying concepts in the DOE emergency management approach that strongly influence the basic methodology for planning and response to ***any*** hazardous materials release. Hence, any discussion of an approach to DOE emergency management for biosafety facilities should be prefaced with a discussion of the three key concepts that strongly influence the methodology presented in the DOE G 151.1-series. These essential, governing concepts are the following (Cf. DOE G 151.1-1A, Chapter 1):

- **Effective response is the "*last line of defense*" against adverse consequences.** Regardless of how sound fundamental safety programs and hazard controls may be, events will occur that have adverse health effects on people and/or the environment. This principle expresses the DOE position that if hazard controls should fail, the facility/site should be prepared to take actions to limit or prevent adverse health and safety impacts to workers and the public.

- **Planning, preparedness, response, and recovery must be *specific to* and "*commensurate with the hazards.*"** DOE/NNSA is responsible for a large number of different hazards that could threaten the health and safety of workers or the public if released to the environment. Hazards are very different in the nature of their impacts on people, their behavior in the environment and the distance at which adverse impacts would be experienced. While the basic emergency management framework is the same for all DOE/NNSA sites and facilities, specific planning and response measures for each hazard are to be ***tailored*** to the hazard. This is especially important when implementing Hazardous Materials Program requirements for biosafety facilities that may contain small quantities of agents or toxins; the requirements may result in a function or activity that is comparable to a Base Program scale component. For requirements that are not in a Base Program, the tailoring may result in a near minimal version of the Hazardous Materials Program function/activity. In any case, it is extremely important to document the *tailoring to hazards* that resulted in the implemented function or activity.

- ***"Early recognition"* is vital to timely, effective response.** In many cases, warning potentially affected workers and the public and directing them to take actions to prevent or limit their exposure is the only way that mitigating the adverse health impacts of hazardous material releases can be accomplished. Hence, early recognition of a release event is essential if warnings are to be delivered in time to be executed effectively.

Note that these concepts are repeated and emphasized here because they have an overarching influence on both the development and implementation of emergency management programs for hazardous biological materials presented in DOE G 151.1-5.

The guidance contained here is aimed at both biosafety and emergency management professionals responsible for implementing the Select Agent Rules and DOE O 151.1C. To satisfy the needs of both disciplines, the general subject of biosafety is introduced in Chapter 2. Biosafety concepts of containment and barriers, Biosafety Levels (BSLs), and biosafety controls are introduced in the context of the Select Agent Rules and are taken directly from the Centers for Disease Control (CDC)/National Institutes of Health (NIH) publication, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). Note that descriptions of facility operations or biosafety programs are provided to support examples and concepts discussed in Chapter 2. However, these descriptions should not be interpreted as necessarily representing actual DOE/NNSA biosafety facility operations and programs.

According to 10 CFR 851 Appendix A, 7. *Biological safety*, DOE/NNSA biosafety facilities are required to establish an IBC to review any work with biological etiologic agents for compliance with appropriate CDC (i.e., **BMBL**), NIH, World Health Organization (WHO), and other international, Federal, Tribal, State, and local guidelines and the site security, safeguards, and emergency management plans and procedures. Understanding the basic biosafety concepts contained in these guidelines is essential for interpreting and implementing the guidance to be presented in this guidance document. In addition, because of the impact that agent characteristics and diverse transport/transmission mechanisms have on specific emergency management planning issues (e.g., threshold quantities, measures of severity, protective actions), Chapter 3 provides a brief discussion of these issues to support the approach contained in DOE O 151.1C and the DOE G 151.1-series. Agents and their relevant general characteristics are discussed with special emphasis on potential transport/transmission mechanisms. OEs related to the release of biological agents to the environment, the characterization of biological release scenarios, and tools for their recognition are also discussed.

Basic program elements of the DOE/NNSA emergency management system are presented in Chapters 4 through 6. Chapter 4 addresses the technical planning basis for the emergency management program, where the Hazards Survey is the first component of the technical planning basis. The Hazards Survey identifies requirements of the Base Program and the need for further analysis of hazardous biological materials in an EPHA. As for all hazardous materials, the EPHA will provide the ***technical planning basis*** for the emergency management Hazardous Material Program. This analysis and the Hazardous Material Program, which are required for any DOE/NNSA facility subject to the ***Select Agent Rule(s)***, address the actual or potential release of biological agents outside of the secondary barriers of biocontainment. Results of the EPHA will form the basis for the emergency management program that will be commensurate with the biological hazards in the facility. Planning, preparedness, and response activities will

reflect the characteristics and release transport/transmission mechanisms of the potential hazards.

Because a strictly quantitative analysis of Select Agents may not be an appropriate or feasible planning technique for many biological sources found in DOE/NNSA facilities, a structured qualitative analysis approach is presented for EPHAs, which can be used to reveal release scenario parameters necessary for recognizing OEs and for developing initial protective action strategies for protecting onsite workers and the offsite public. Appendix A contains several notional OE release scenarios developed to provide examples of the analysis approach.

Chapters 5 and 6, which contain guidance related to programmatic and response elements, address selected issues that should be modified by the presence of hazardous biological materials in the facilities. Some requirements of the Select Agent Rules and their integration into existing program elements are also described. Other aspects of the elements may be modified by the existence of Select Agents, but are not explicitly addressed. DOE G 151.1-1A through DOE G 151.1-4 should be used for more general issues (e.g., emergency public information, offsite interfaces) related to program elements. Users should always be aware that the guidance may have to be adjusted because the specific facility emergency management program is focused on hazardous biological materials.

Biological Select Agents are emphasized in the guidance contained in DOE G 151.1-5; biological toxins are essentially *extremely* toxic chemicals generally covered by guidance contained DOE G 151.1-1A through DOE G 151.1-4. However, clarifications and discussions in this Guide will specifically address the release of toxins when necessary (e.g., classification not required for biological toxin releases). In addition, this current version of DOE G 151.1-5 will focus on planning for human or overlap (i.e., able to infect both humans and animals) Select Agents. Future guidance will include toxins and agents that are solely animal and plant pathogens.

2. HAZARDOUS BIOLOGICAL MATERIALS AND BIOSAFETY

The purpose of this chapter is to provide a brief introduction to characteristics of hazardous biological materials and biosafety concepts related to the safe use and storage of these materials in approved facilities. An understanding of basic biosafety concepts will facilitate the integration of biosafety requirements and DOE/NNSA facility/site emergency management program elements. Although much of this chapter was taken directly from the **BMBL**, its contents should ***not*** be used to develop, implement, or evaluate biosafety programs for DOE/NNSA biosafety facilities. Original NIH, CDC, and WHO reference materials should be accessed for a complete and in-depth presentation of the guidance for interpretation or implementation of the various biosafety concepts to be discussed in the following sections.

2.1 Hazardous Biological Agents and Toxins

Biological materials that may be associated with DOE/NNSA facilities fall into two major categories: biological agents (i.e., microorganisms) and biological toxins. Hazardous biological agents include naturally occurring or genetically modified microorganisms (e.g., bacteria, viruses) that can cause disease and death in an exposed and vulnerable population. Biological toxins are toxic chemicals that are biologically produced and behave in the environment much like other toxic chemicals. However, these toxins represent some of the most hazardous in the category of toxic chemicals. An extremely small amount of either an infectious biological agent or a biological toxin can cause disease, severe toxic reaction, or death.

The following briefly describe types of hazardous biological materials may be handled, cultivated, and/or stored in DOE/NNSA laboratories:

- Bacteria are *typically* single-celled microorganisms that lack chlorophyll and reproduce by simple division (fission). Bacteria can grow in nature outside of a human or animal host and in a liquid culture or on semi-solid media (e.g., agar) in a laboratory environment. Pathogenic bacteria cause disease when they establish themselves and reproduce in humans or animals. Some bacteria (e.g., *Bacillus anthracis*) are able to form spores, which is an extremely stable condition that allows them to survive in hostile environments. Most infections resulting from exposure to bacterial agents can be effectively treated with antibiotics, provided treatment is initiated early enough in the course of illness.

  – Rickettsiae are true bacteria, but, like viruses, *they require living cells for growth* outside of a laboratory environment. Many rickettsiae are localized to certain geographic areas and are maintained in nature by a cycle involving an animal reservoir and an arthropod vector (insects, arachnids, etc.) that infects humans.

- Viruses are ultramicroscopic, infectious agents consisting of nucleic acid and protein that do not survive and reproduce in nature outside of a living human or animal host.

Viruses use the cellular machinery of the living host to reproduce. However, viruses can be maintained in artificial laboratory environments for extended periods of time. The stability of various types of viruses in natural environments, outside of a host, varies and, for laboratory purposes, may be artificially extended. Vaccination is a suitable protective measure for some viruses, such as smallpox, as long as it is successfully administered prior to exposure. In some cases, vaccinations can decrease the severity of disease, even if administered after exposure. Antibiotics are not effective against viruses and very few antiviral treatments are available.

- Toxins are poisonous, non-living chemicals produced during metabolism and growth of living organisms. The source of toxins can be microorganisms, such as bacteria, and some higher plant and animal species, including fungi, plants, spiders and fish. Examples are botulinum toxin, from the anaerobic bacteria *Clostridium botulinum*; ricin, from the castor bean plant; and tetrodotoxin from the puffer fish. Most biological toxins are relatively stable in the environment. Medical treatments are generally limited to supportive care. The time for onset of symptoms for biologically produced toxins is typically on the order of minutes to hours. Fatalities may occur hours to days from exposure.

2.2 Select Agent Regulations

Federal regulations establishing requirements for certain biological agents and toxins regarding their possession and use in the U.S., receipt from outside the U.S., and transfer within the U.S. are:

- 42 CFR 73, *Select Agents and Toxins*. Contains two lists of agents and toxins regulated by HHS/CDC: 1) HHS Select Agents and Toxins; and 2) Overlap (posing severe threats to both humans and animals) Select Agents and Toxins.

- 7 CFR 331, *Possession, Use, and Transfer of Select Agents and Toxins*. Contains a list of Plant Protection and Quarantine Programs (PPQ) of the Animal and Plant Health Inspection Service (APHIS), Select Agents and Toxins.

- 9 CFR 121, *Possession, Use, and Transfer of Select Agents and Toxins*. Contain two lists: 1) Veterinary Services Programs (VS) of the APHIS, Select Agents and Toxins; and 2) Overlap Select Agents and Toxins.

HHS Select Agents and Toxins pose severe threats to humans alone, while overlap Select Agents and Toxins pose severe threats to both humans and animals. Overlap Select Agents and Toxins are subject to regulation by both CDC and APHIS; the lists are identical in both regulations. PPQ Select Agents and Toxins have the potential to pose a severe threat to plant health or to plant products. VS Select Agents and Toxins have the potential to pose a severe threat to animal health or animal products. Note that the total aggregate quantity of each toxin under the control of a "principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor" in a biosafety facility must exceed quantities specified in their respective regulations to be subject to rule requirements, while no quantity is specified for biological agents. In addition, Select

Agents or Toxins may also be excluded from the regulations if they meet any of several other criteria (e.g., non-viable Select Agents or nonfunctional Toxins). As indicated in Chapter 1, the three rules will be referred to as the ***Select Agent Rules*** for purposes of this guidance, unless there is a reason to cite the specific rule.

The *entities* regulated under the Select Agent Rules include Federal facilities/laboratories. The rules establish requirements concerning registration, security risk assessments, safety plans, security plans, incident response plans, training, transfers, record keeping, inspections, and notifications. The external exportation and transportation of these materials are not covered under this rule; the U.S. Department of Commerce (DOC) and DOT regulate these activities.

A key element of the HHS/CDC regulations is the development and implementation of a safety plan considering the following biosafety standards and Federal regulations:

- CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories* (**BMBL**);

- OSHA regulations in 29 CFR 1910.1200, *Hazard communication*, and 29 CFR 1910.1450, *Occupational exposure to hazardous chemicals in laboratories*; and

- *NIH Guidelines for Research Involving Recombinant DNA Molecules* (April 2002).

The APHIS regulation related to PPQ Select Agents/Toxins (plant pathogens) is not specifically addressed in this version of DOE G 151.1-5.

2.3 Principles of Biosafety, Containment, and Barriers[1]

Biosafety is the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The two basic principles of biosafety are containment and risk assessment, as defined below:

- The fundamentals of containment include the microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public from exposure to infectious microorganisms that are handled and stored in the laboratory.

- Risk assessment is the process that enables the appropriate selection of microbiological practices, safety equipment, and facility safeguards that can prevent laboratory-associated infections (LAI).

Risk assessment is the **BMBL** biosafety methodology used to select the appropriate microbiological practices, safety equipment, and facility safeguards that define the level

[1] Unless otherwise indicated, biosafety, containment, and barrier concepts/definitions are derived directly from BMBL (1999) and/or BMBL (2007). However, since the discussion of these topics is not complete, the original source document(s) should be accessed for developing and implementing a biosafety program.

of containment to be implemented in a facility/laboratory, ***commensurate with the hazards*** associated with the biological agent(s) used or maintained within. The risk assessment process is similar in purpose to the EPHA process, which results in the emergency management technical planning basis for ***commensurate-with-hazards*** Hazardous Materials Programs at DOE/NNSA facilities/sites.

The principles of biosafety and the associated risk assessment process are described in the **BMBL**. All facilities registered under 42 CFR 73 or 9 CFR 121 are required by the regulation to consider the **BMBL** in developing their safety programs. The **BMBL** describes a comprehensive approach that evaluates hazards of the biological agents present in the facility, the type of work to be performed, and the mitigative features utilized (e.g., vaccines, training, medical surveillance). The application of this risk assessment process results in a determination of the appropriate biosafety level (BSL) for each infectious biological agent/toxin to be used or stored in the facility. The information developed for the risk assessment process (e.g., Agent Summary Statements) will provide much of the information needed as input to the EPHA process for the biosafety facility.

Facilities/laboratories, equipment, and procedures appropriate for work with toxins of biological origin should also reflect the intrinsic level of hazard posed by a particular toxin as well as potential risks inherent in the operations performed. If both toxins and infectious agents are used, then both need to be considered when containment equipment is selected and when policies and procedures are written. If animals are used, animal safety practices must also be considered.

A basic understanding of containment and barriers is essential for developing an integrated emergency management program that addresses all hazards. The term ***containment*** (or equivalently, biocontainment) is used in describing safe methods for managing infectious materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents. The use of vaccines may provide an increased level of personal protection.

The BMBL defines three *elements* of containment:

- Laboratory Practice and Technique. The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or potentially infectious materials should be aware of potential hazards and must be trained and proficient in the practices and techniques required for handling such material safely. The BMBL recommends that each laboratory develop or adopt a biosafety or operations manual that identifies the hazards that will or may be encountered and that specifies practices and procedures designed to minimize or eliminate exposures to these hazards. Personnel are advised of special hazards and are required to read and follow the required practices and procedures.

  When standard laboratory practices are not sufficient to control the hazards associated with a particular agent or laboratory procedure, additional measures may be needed.

The laboratory director is responsible for selecting additional safety practices, which must be commensurate with the hazards associated with the agent or procedure.

Strict adherence to *standard* microbiological practices and techniques (including additional measures) by laboratory personnel is supplemented by appropriate facility design and engineering features, safety equipment, and *management practices*.

- Safety Equipment (*Primary Barriers* and *Personal Protective Equipment*). Safety equipment includes Biological Safety Cabinets (BSCs), enclosed containers, and other engineering controls designed to eliminate or minimize potential exposures to hazardous biological materials. The BSC is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. Three types of BSCs (Class I, II, III) are used in microbiological laboratories: open-fronted Class I and Class II BSCs, which are ***primary barriers*** that offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques, and gas-tight the Class III BSC, which provides the highest attainable level of protection to personnel and the environment. [Schematics of these BSCs can be found in Appendix A of BMBL (2007)]. An example of another ***primary barrier*** is the safety centrifuge cup, an enclosed container designed to prevent aerosols from being released during centrifugation. To minimize aerosol hazards, containment controls, such as BSCs or centrifuge cups, are recommended when handling infectious agents.

  Safety equipment may also include items for personal protection, such as gloves, coats, gowns, shoe covers, boots, respirators, face shields, safety glasses, or goggles. Such Personal Protective Equipment (PPE) is often used in combination with BSCs and other devices that contain the agents, animals, or materials being handled. In some situations in which it is impractical to work in BSCs, PPE may form the ***primary barrier*** between personnel and the infectious materials.

- Facility Design and Construction (*Secondary Barriers*). The design and construction of the biosafety facility (also referred to in the BMBL as facility safeguards) contributes to laboratory worker protection, provides a ***barrier*** to protect persons outside the laboratory and protects persons or animals in the community from infectious agents that may be accidentally released from the laboratory.

  The recommended ***secondary barrier(s)*** will depend on the risk of transmission of specific agents. For example, when the exposure risks for most laboratory work in a biosafety facility will be direct contact with the agents, or inadvertent contact exposures through contaminated work environments, then ***secondary barriers*** in these laboratories may include separation of the laboratory work area from public access, availability of a decontamination facility (e.g., autoclave), and hand washing facilities.

  When the risk of infection by exposure to an infectious aerosol is present, higher levels of ***primary containment*** and multiple ***secondary barriers*** may become necessary to prevent infectious agents from escaping into the environment. Such

design features include specialized ventilation systems to ensure directional air flow, air treatment systems to decontaminate or remove agents from exhaust air, controlled access zones, airlocks as laboratory entrances, or separate buildings or modules to isolate the laboratory.

Containment includes microbiological practices, safety equipment, and facility safeguards that protect laboratory workers, the environment, and the public. Two tiers/ layers of protection provided by containment are defined as follows:[2]

- ***Primary containment*** – focused on the protection of biosafety facility/laboratory workers and the immediate laboratory environment from exposure to infectious agents and provided by both good microbiological techniques and the use of appropriate safety equipment.

- ***Secondary containment*** – focused on the protection of the environment external to the laboratory from exposure to infectious materials and provided by a combination of facility design and construction practices.

Process of biological risk assessment will determine the appropriate levels of ***primary*** and ***secondary containment*** for each infectious biological agent to be used or stored in the facility. As will be discussed in subsequent chapters, these tiers/layers of containment play a key role in defining HHS/CDC notification criteria and DOE/NNSA Operational Emergencies.

2.4 Risk Assessment and Biosafety Levels[3]

Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a LAI, and the probable consequences of such an infection. The information identified by a risk assessment will provide a guide for the selection of appropriate BSLs and associated microbiological practices, safety equipment, and facility safeguards that can prevent LAIs; the information will also provide much of the basic data required for performing an emergency management hazards assessment. Biological risk assessment is an important responsibility of directors and principal investigators in DOE/NNSA biosafety facilities. IBCs and other biological safety professionals should also share in this responsibility.

The primary factors to consider in risk assessment and the selection of biosafety precautions fall into two broad categories: agent hazards and laboratory procedure hazards. In addition, the capability of the laboratory staff to control the hazards must also be considered. This capability will depend on the training, technical proficiency, and

[2] The term *tier/layer of containment* is defined for this Guide; the definitions provided are a modification of those found in BMBL (1999).
[3] Unless otherwise indicated, risk assessment concepts/process definitions and the biosafety level methodology are derived directly from BMBL (1999) and/or BMBL (2007). However, since the discussion of these topics is not complete, the original source document(s) should be accessed for developing and implementing a biosafety program.

good habits of all members of the laboratory, and the operational integrity of containment equipment and facility safeguards.

- **Agent hazards.** The principal hazardous characteristics of an agent are its capability to infect and cause disease in a susceptible human or animal host, its virulence as measured by the severity of disease, and the availability of preventive measures and effective treatments for the disease. Other hazardous characteristics of an agent include probable routes of transmission of laboratory infection, infective dose, stability in the environment, host range, and its endemic nature. The origin of the agent is also important in risk assessment. Non-indigenous agents are of special concern because of their potential to introduce risk of transmission, or spread of human and animal or infectious diseases, from foreign countries into the United States.

  For genetically-modified agent hazards, it is particularly important to address the possibility that the genetic modification could increase an agent's pathogenicity or affect its susceptibility to antibiotics or other effective treatments. Workers who handle or manipulate human or animal cells and tissues are at risk for possible exposure to potentially infectious latent and adventitious agents that may be present in those cells and tissues. In addition, human and animal cell lines that are not well characterized or are obtained from secondary sources may introduce an infectious hazard to the laboratory.

- **Laboratory procedure hazards**. Investigations of LAIs have identified five principal routes of laboratory transmission. These are parenteral inoculations with syringe needles or other contaminated sharps, spills and splashes onto skin and mucous membranes, ingestion through mouth pipetting, animal bites and scratches, and inhalation exposures to infectious aerosols.

  Aerosols are a serious hazard because they are ubiquitous in laboratory procedures, are usually undetected, and are extremely pervasive, placing the laboratory worker carrying out the procedure and other persons in the laboratory at risk of infection. There is general agreement among biosafety professionals, laboratory directors and principal investigators who have investigated LAIs that an aerosol generated by procedures and operations is the probable source of many LAIs, particularly in cases involving workers whose only known risk factor was that they worked with an agent or in an area where that work was done.

- **Capability of the laboratory staff to control the hazard**. Laboratory workers must be well aware of hazardous characteristics of laboratory procedures which may be associated with the agents. Workers are the first line of defense for protecting themselves, others in the laboratory, and the public from exposure to hazardous agents. Protection depends on the conscientious and proficient use of good microbiological practices and the correct use of safety equipment. Training, experience, knowledge of the agent and the procedure hazards, good habits, caution, attentiveness, and concern for the health of coworkers are prerequisites for a laboratory staff in order to reduce the inherent risks that attend work with hazardous

agents. Not all workers who join a laboratory staff will have these prerequisite traits, even though they may possess excellent scientific credentials. Laboratory directors or principal investigators should train and retrain new staff to the point where aseptic techniques and safety precautions become second nature.

The capability of the laboratory staff to control the hazards also depends on the operational integrity of containment equipment and facility safeguards. An active surveillance program, which monitors the status of containment equipment and facility safeguards and ensures that periodic inspections, operational checks, calibration, preventive maintenance and tests are carried out as required, can provide assurances that equipment and safeguards will perform as expected. Routine surveillance programs are discussed in more detail in Section 2.5.

Biological risk assessment is a subjective process requiring consideration of many hazardous characteristics of agents and procedures, with judgments based often on incomplete information. Although there is no standard approach for conducting a biological risk assessment, the five-step approach presented in BMBL (2007) gives some structure to the risk assessment process.

Using the results of the risk assessment, the primary risk criteria used to define the four ascending levels of containment, referred to as biosafety levels 1 (BSL-1) through 4 (BSL-4), are: *infectivity*, *severity of disease*, *transmissibility*, and the *nature of the work being conducted*. Another important risk factor for agents that cause moderate to severe disease is the *origin of the agent*, whether indigenous or exotic.

BSL-1 is the basic level of protection and is appropriate for agents that are not known to cause disease in normal, healthy humans. BSL-2 is appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure. BSL-3 is appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin. Exotic agents that pose a high individual risk of life threatening disease by infectious aerosols and for which no treatment is available are restricted to high containment laboratories that meet BSL-4 standards.

Each level of biosafety containment describes the microbiological practices, safety equipment, and facility safeguards for the corresponding level of risk associated with handling a particular agent. Similarly associated with each biosafety level is a level of ***primary*** and ***secondary containment*** commensurate with the agent risk.

The essential elements of the four biosafety levels for activities involving infectious microorganisms and laboratory animals are summarized in **Table 2-1**. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Standard microbiological practices are common to all laboratories. Special microbiological practices enhance worker safety, environmental protection, and address the risk of handling agents requiring increasing levels of containment.

Table 2-1. Summary of Essential Elements of the Four BMBL Biosafety Levels (BSLs) for Infectious Agents[4]

BSL	*Agents*	*Practices*	*Primary Barriers and Safety Equipment*	*Facilities (Secondary barriers)*
1	Not known to consistently cause diseases in healthy adults	Standard Microbiological Practices	None required	Open bench and sink required
2	• Agents associated with human disease • Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	• BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: • Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPEs*: • Laboratory coats, gloves, face protection as needed	BSL-1 plus: • Autoclave available
3	• Indigenous or exotic agents with potential for aerosol transmission • Disease may have serious or lethal consequences	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	Primary barriers: • Class I or II BSCs or other physical containment devices used for all open manipulations of agents PPEs*: • Protective lab clothing, gloves, respiratory protection as needed	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhaust air not recirculated • Negative airflow into laboratory
4	• Dangerous/exotic agents which pose high risk of life-threatening disease • Aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practices plus: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	Primary barriers: • All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	BSL-3 plus: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination systems • Other requirements outlined in **BMBL**

* PPE – Personal Protective Equipment

Note that the risk assessment process for assigning agents to BSL facilities may not be entirely appropriate for prioritizing or judging risk for emergency management purposes. Emergency management should characterize hazardous materials in terms of their

[4] Table from BMBL (2007)

inherent risk given a release to the environment, and should not be based on a risk assessment that is modified by factors that are primarily focused on worker safety. Thus, BMBL methodology results, although generally appropriate for emergency management purposes, may be inappropriate for characterizing risks once an agent has entered the environment.

2.5 Routine Surveillance of Biosafety Controls

The routine surveillance of biosafety protocols and practices, safety equipment, and facility systems can provide assurances that required maintenance, equipment tests, certifications, inspections, reviews, and other activities intended to maintain laboratory control measures at a high level of performance are accomplished as required. In addition, a rigorous and structured approach to these surveillance activities provides the opportunity for recognizing abnormal events or conditions that, in combination with other events or conditions, might indicate the potential for the *unobserved* release of a hazardous biological material from the biocontainment area. For example, discovery of an abnormal condition associated with a primary barrier during a routine inspection or test could initiate further investigation of other barriers that, if failed during the same time frame, might indicate the potential for a release to the environment.

The essential elements of the four biosafety levels for activities involving infectious microorganisms are summarized in Table 1 of the previous section. In addition to these elements, Chapter IV of the BMBL (2007) also lists various routine monitoring, testing, certification, and verification activities associated with each biosafety level. Examples of routine surveillance appropriate for monitoring biological facilities can include *operational*, *equipment & facility,* and *medical surveillance*. *Training and skill level* for at-risk personnel can also be monitored to provide assurances that a high level of performance is maintained.

Selected examples of routine surveillance activities taken from the BMBL (2007) are presented below:[5]

- ***Operational Surveillance*** is conducted to ensure that procedures and protocols are in place and effective. Examples include:

  – Along with limited applications of pesticides, pest control is achieved through implementation of an **Integrated Pest Management (IPM)** program consisting of proactive operational and administrative intervention strategies to correct conditions that foster pest problems. *Monitoring* is the central activity of an IPM program and is used to minimize pesticide use. Traps, visual inspections, and staff interviews identify areas and conditions that may foster pest activity. Records of structural deficiencies and housekeeping conditions should be maintained to track problems and determine if corrective actions have been completed in a timely manner and were effective. Quality assurance and program review should be performed to provide an objective, ongoing evaluation of IPM activities and

[5] These examples should not be interpreted as requirements for DOE/NNSA biosafety facilities. They are intended to represent selected examples taken from BMBL (2007) for illustrative purposes only.

effectiveness to ensure that the program does, in fact, control pests and meet the specific needs of the facility program(s) and its occupants.

– Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents and must be supervised by scientists competent in handling infectious agents and associated procedures.

- ***Equipment & Facility Surveillance*** can help ensure that safety-related equipment and facility systems are operating within appropriate parameters. Examples include:

  – Laboratory personnel must be able to verify directional air flow. A visual monitoring device, which confirms directional air flow, must be provided at the laboratory entry. Audible alarms should be considered to notify personnel of air flow disruption.

  – High-Efficiency Particulate Air (HEPA)-filtered exhaust air from a Class II BSC can be safely re-circulated into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations.

  – Provisions to assure proper safety cabinet performance and air system operation must be verified. BSCs should be certified at least annually to assure correct performance.

  – Equipment that may produce infectious aerosols must be contained in devices that exhaust air through HEPA filtration or other equivalent technology before being discharged into the laboratory. These HEPA filters should be tested and/or replaced at least annually.

  – HEPA filter housings should have gas-tight isolation dampers; decontamination ports; and/or bag-in/bag-out (with appropriate decontamination procedures) capability. The HEPA filter housing should be certified at least annually.

  – The BSL-3 facility design, operational parameters, and procedures must be verified and documented prior to operation. Facilities must be re-verified and documented at least annually.

- ***Medical Surveillance*** helps verify that personnel safeguards implemented for a biosafety program produce the expected health outcomes. It may include serum banking, monitoring of employee health status, and participating in post-exposure management. This monitoring activity is similar to routine bioassays taken as part of selected radiation protection programs. Similarly, medical surveillances are required by various health and safety regulations for workers involved with hazardous chemicals. A documented medical surveillance program should be implemented that defines at-risk positions, specifies risks versus benefits of prophylactic immunization, and distinguishes between required and recommended vaccines for specific organisms. A practiced plan for rapid response to a post-exposure event should

include the ability to rapidly track personnel location, potential exposure, movement, and method for testing and prophylaxis.

Selected examples of medical surveillance activities from the BMBL (2007) are presented below:

– Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.

– Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.

– Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.

A medical surveillance program with expanded post-exposure symptom recognition and reporting linked to community response assets differs from a standard hazardous materials approach. Employee education with agent-specific updates, rapid tracking, screening, definitive laboratory testing, prophylaxis and treatment pharmaceuticals, as well as appropriate access to diagnostic and supportive medical care are key elements to an effective, community integrated medical surveillance program.

- ***Training and Skill Level Surveillance*** of at-risk positions such as laboratory technicians/workers and maintenance, housekeeping, and animal care personnel can help to ensure employee safety. This surveillance activity involves the establishment of a regular, documented education/recertification process, which tracks personnel functions and activities to ensure that training for their duties is appropriate and current.

  Selected examples of experience and skill level surveillance activities taken from the BMBL (2007) are presented below:

  – The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur.

  – The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-3 agents.

These examples of general surveillance activities can be potential sources of ***recognition factors*** to be utilized in developing an Emergency Action Level (EAL)-like tool that will

be part of the DOE emergency management program for biosafety facilities. For this purpose, routine surveillance should include an ***active process*** that integrates and interprets the data in the context of potential release scenarios, rather than simply as individual datum to be monitored, compared to expected performance or requirements, and recorded.

3. OPERATIONAL EMERGENCIES INVOLVING THE RELEASE OF HAZARDOUS BIOLOGICAL MATERIALS

The purpose of this chapter is to introduce emergencies involving the release of hazardous biological materials from a DOE/NNSA biosafety facility. The following issues will be discussed:

- Hazardous biological materials covered under DOE O 151.1C
- Issues related to hazardous biological materials ***and*** emergency management
- Definition of the DOE **Operational Emergency (OE)** involving the release of biological materials from a biosafety facility into the environment
- Transport mechanisms potentially involved in biological OEs
- Characterization of OE release scenarios involving biological agents

This chapter will focus *primarily* on biological agents, not toxins. Emergency planning for the release of biological toxins to the environment is similar to that for the release of a toxic chemical. Its extreme toxicity, however, places it in a special category for regulation and, as defined in DOE O 151.1C, in the same OE category (i.e., events that do not require classification) as hazardous biological agents.

3.1 DOE O 151.1C and Hazardous Biological Materials

The emergency management order, DOE O 151.1C, includes criteria for identifying hazardous biological materials subject to its requirements. In addition, according to the Order, each DOE/NNSA facility with specific biological agents or toxins that pose a serious threat to workers, the public, or the environment, must develop and maintain a "*quantitative Emergency Planning Hazards Assessment (EPHA) and meet more detailed emergency planning requirements.*" At a minimum, these agents and toxins must include " . . . *Federally regulated agents and toxins identified in lists published by the Department of Health and Human Services (HHS) in 42 CFR 73 and the Department of Agriculture (USDA) in 7 CFR 331 and 9 CFR 121.*" If any listed biological agents or toxins are excluded from federal regulation under the Select Agent Rules [e.g., 42 CFR 73.3(d)], then the exclusion also applies to the requirements of DOE O 151.1C.

According to DOE O 151.1C, if a DOE/NNSA facility is governed by HHS and/or USDA Select Agent Rules because it uses and/or stores Select Agents or Toxins, then an EPHA needs to be prepared and an Operational Emergency Hazardous Material Program is required for that facility. The scope and contents of an EPHA for hazardous biological materials are described in Chapter 4 of this Guide. Subsequent chapters address the DOE

Emergency Management Program Elements that constitute the Hazardous Material Program.

Although the requirements of the current version of DOE O 151.1C and this guidance document focus on Select Agents and Toxins, other hazardous biological materials used or stored at biosafety facilities may also have the potential to harm workers and the general public. An emergency management program consistent with the current Order and Guide can be developed and implemented that provides workers and the public with an appropriate level of protection from non-Select Agents/Toxins.

3.2 Emergency Management Issues

Hazardous biological agents are similar to hazardous chemicals and radioactive materials in that they:

- Are defined as hazardous materials in the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120)
- They *(most)* can be dispersed into the air to pose a threat to workers and the public via the inhalation pathway
- Have a range of responses to environmental conditions

The characteristics of hazardous biological agents differ from other hazardous materials and these differences impact DOE emergency planning and response. Some unique characteristics of hazardous biological agents are described below:

- ***Threshold Quantities***. Since biological agents differ dramatically in terms of characteristics that determine their ability to cause harm to humans, animals or plants, firm *de minimus* hazard levels are difficult to discern. In addition, the characteristics of available transport mechanisms for biological agents make the definition of a general threshold screening value even more difficult, if not impossible. Consequently, judging the perceived risk associated with the release of a specific agent involves an assessment of the agent characteristics and activities conducted, irrespective of the volume or concentration of agent involved.

  The Select Agent Rules provide minimum quantities for each HHS and Overlap hazardous biological toxin subject to the regulations. These quantities establish *de facto* minimum hazard levels for the toxins that determine whether the toxin is subject to the requirements. Similarly, minimum quantities should also represent *screening thresholds* in the context of the DOE emergency management system.

- ***Infection Control Concepts*.** Agent characteristics related to the transfer of an agent from one human to another and the capability of the agent to cause infection in a human are important for emergency management planning for biological agents, but are not applicable to other hazardous materials. Because definitions of these terms vary, several were specifically selected for this guide:

- Infectivity:
  - **Infection:** detrimental colonization of a susceptible host by a disease-causing microorganism (pathogen), where the infecting microorganism seeks to enter and survive in a host and to utilize the host's resources in order to multiply at the host's expense.
  - **Infectious:** the capability [of a disease-causing microorganism (pathogen)] of entering, surviving and multiplying in a susceptible host.
  - **Infectivity**: a relative measure of the capability with which a disease-causing microorganism (pathogen) establishes an infection in a susceptible host.
- Virulence:
  - **Virulent:** the capability [of a disease-causing microorganism (pathogen)] to rapidly overcome the natural defenses of a host, causing a serious and injurious condition(s).
  - **Virulence:** a relative measure of the capability of a disease-causing microorganism (pathogen) to rapidly overcome the natural defenses of a host, causing a serious and injurious condition(s).
- Transmissibility:
  - **Transmission:** the passing/transmitting of a disease from an infected individual or group to a previously uninfected individual or group. One or more of the following mechanisms may transmit the disease-causing microorganism (pathogen) from one person to another (person-to-person):
    - Droplet contact - coughing or sneezing on another person
    - Direct physical contact - touching an infected person
    - Indirect contact - usually by touching a contaminated surface
    - Airborne transmission - if the microorganism can remain in the air for long periods
    - Fecal-oral transmission - usually from contaminated food or water sources
    - Vector-borne transmission - carried by insects or other animals
  - **Transmissible:** the capability [of a disease-causing microorganism (pathogen)] to be passed person-to-person. [*Transmissible* will also be used to describe a disease that is transmitted person-to-person (i.e., *transmissible* disease)]

- **Transmissibility:** a relative measure of the capability with which a disease-causing microorganism (pathogen) spreads person-to-person.

- ***Measure of Severity.*** The DOE emergency management system uses a Protective Action Criterion (PAC) as a measure of severity for the airborne release of a radioactive or chemical hazardous material. When the consequences of a release exceed their respective PAC, adverse health effects are possible and protective actions should be taken. (Cf. DOE G 151.1-2, Appendix F.)

  Individuals vary widely in their susceptibility to a particular biological agent. For example, the ID (Infectious Dose) for anthrax that results in disease in 10 percent of the population, ID_{10}, is hundreds of organisms. ID_{50} is tens of thousands and ID_{95} is millions of organisms. Since the characteristics of IDs for many agents do not reflect a delimiting value that can be used to represent infectious vs. not infectious doses or permissible vs. not permissible exposure levels, a specific value of infectious dose will not be used in DOE emergency management programs to measure release severity (i.e., below a specific value, no protective actions required vs. above the value, take actions.)

  This position is supported in part by a study that asked whether "infectious doses for organisms could be defined in such a way to potentially develop permissible exposure levels to those infectious agents." The study concluded that ". . . attempts to develop quantitative values for human infectious dose are not currently feasible." [*OSHA Infectious Dose White Paper,* Applied Biosafety, Volume 8, Number 4 (2003), pp. 160-165.]

  Because no measure of severity is currently available for use as a PAC for releases of hazardous biological materials, DOE O 151.1C specifies that ***immediate protective actions are required for any release of biological agents and toxins outside of secondary containment barriers.***

- ***Amplification***. Biological agents (bacteria, viruses) are living organisms and have the ability to grow and multiply – to ***amplify***. The communicable nature of some biological agents means that the amount may amplify and spread dramatically after it is released to the environment. If a host is infected with a communicable agent, it could be transmitted from host to host, growing and multiplying within each infected subject.

  This characteristic of living biological agents presents an additional unique, and possibly unsolvable, challenge for emergency management planning and response in attempting to define a quantity of biological material that represents a threat to collocated workers and the public.

- ***Stability in the Environment.*** The persistence of hazardous biological agents in the environment can vary dramatically among different types of such organisms. Some viruses may survive in the environment from minutes to hours, while some bacteria, such as *Bacillus anthracis*, can transform into extremely stable dormant spore forms

under adverse conditions that can survive for decades in the environment under adverse conditions. Stability in the environment can influence specific initial protective actions taken and the time duration for maintaining them.

- ***Incubation Period***. The time between infection/uptake and the onset of symptoms (i.e., incubation period), which can vary from hours to days, may in some cases enable the facility staff to analyze the event and perform lab tests and monitoring to confirm that a ***suspected*** (e.g., *observed* through recognition indicators) release has in fact occurred. Once confirmation takes place, the incubation period can allow a window of opportunity during which effective treatments can begin (prior to onset) for individuals who may have been exposed.

  However, the incubation period does not provide a similar opportunity to reduce or eliminate further exposures. Unless appropriate initial protective actions are promptly implemented (e.g., access control, decontamination, evacuations, etc.), the source of biological material released during the event may continue to expose workers or the public. This is particularly true for the infected host, since some infections are most *transmissible* during the incubation time.

  The incubation period is a mitigating (i.e., degrading) factor in the *timely detection* of individuals who are unknowingly infected or who do not report an exposure or incident. Variability in symptom onset also makes it difficult to establish the time of the release when attempting to confirm that the release originated at the facility.

- ***Detection Difficulties.*** Releases of biological agents are difficult to detect directly and to identify with certainty in real time. Various generic detection devices respond to the presence of biological agents, but do not identify the specific agent. Unlike radiation monitors and hazardous chemical detection devices, real-time equivalent biological identification devices currently available may not be feasible for use in DOE biosafety facilities. Consequently, laboratory testing is generally used to *confirm* the presence of biological agents, although results can take up to several days to obtain.

  Reliable detection of the onset of an outbreak of infections, due to an ***unobserved*** release of a biological agent from a DOE/NNSA facility, cannot be based solely on the initial appearance of symptoms among site workers or in the local community. A biological agent release could be due to a natural outbreak or epidemic. Also, early symptoms may appear to be the same as many non-lethal diseases produced by common infectious agents.

3.3 Biological Operational Emergencies

The ***Select Agent Rules*** require immediate notifications to CDC and/or APHIS upon discovery of ". . . a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area...." These criteria for notification of CDC and/or APHIS Headquarters are consistent with the fundamental objective of an OE categorization, namely, to ensure prompt notifications to

initiate a timely, effective response. To maintain consistency with the Select Agent Rules, the DOE Order and guidance incorporate, where applicable and appropriate, concepts and requirements of the rules. The DOE OE definition will supplement this general condition for notifications of biological events with the additional criterion that any actual or potential release of a hazardous biological agent or toxin be ". . . outside of the secondary barriers of the biocontainment area." The infectious nature of Select Agents and the lack of defined *de minimus* hazard levels support OE declarations under conditions that leave undefined a specific level of consequences (and hence health effects) or the quantity released into the environment.

The OE represents an actual or potential release beyond the ***secondary barriers of the biocontainment area*** into the environment. The environment may be the public area outside of a laboratory contained within a facility or may refer to releases directly outside a facility/building. Multiple transport mechanisms can be associated with the OE. Hazardous biological materials can be released to the outside environment or can contaminate humans, vectors, and fomite (i.e., inanimate objects such as clothing or equipment), and then be carried outside the facility. In the environment, they can persist in water systems and on surfaces (including environmental matrices such as soil) and again be transported by multiple mechanisms. Susceptible hosts that contact contaminated air, water, or surfaces may be vectors for further transmission of infectious biological agents.

3.4 Biological Agent/Toxin Transport Mechanisms

In general, ***airborne*** transport and dispersion of hazardous materials can have the greatest area of impact and require the most time-urgent emergency response actions. This is especially the case when source terms consist of large quantities of hazardous materials and inhalation is the primary receptor pathway. For hazardous chemicals and radioactive materials, the spread of significant amounts of contamination by animate or inanimate objects is often easily detected and the initial area of contamination caused by airborne dispersion predictable. Implementation or recommendation of applicable protective measures to prevent or limit worker or public exposures is straightforward.

Significant quantities of living biological agents (microorganisms) can be transported as aerosols and by additional transport mechanisms, including transmission from an infected or contaminated host or object to one or many other receptors. Biological agents can spread beyond their point of initial release in air-handling systems, by the re-aerosolization of contaminants (i.e., from floors and other surfaces as a result of foot traffic or indoor air handling systems; through adhesion to people or their clothing; and by transmission from one person to another.) The result could be widespread dispersal of contaminants (e.g., within a building, into transportation and transit vehicles, into homes or other sites.) Since no threshold or permissible quantities have been established for biological agents, transport mechanisms not normally considered or applicable when hazardous chemicals and radioactive materials are released should be evaluated for biological agents.

Biological toxins are non-living chemical materials produced by living organisms. The transport mechanism for toxins is basically the same as for particulate inorganic or organic hazardous chemicals. However, because they represent extremely toxic materials (poisons), release of even small quantities from the facility as an aerosol, either to be inhaled directly by receptors or to be deposited as contamination, is of time-urgent concern.

Three general categories of transport mechanisms that should be considered for hazardous biological materials:

1. Environmental dispersion

2. Infected host (agents ***only***)

3. Contamination

Transport of hazardous biological materials from a facility to external receptors in the environment can involve combinations of several mechanisms. The specific paths available will depend on facility design, geographic and demographic characteristics of the surrounding area, and, especially, characteristics of the biological agent. The following sections contain brief discussions of these transport mechanisms.

3.5 Environmental Dispersion

Two potential mechanisms for the transport and dispersal of biological agents/toxins in the environment are **airborne** and **waterborne**. Although many can be dispersed into the air and transported as aerosols, most do not readily aerosolize in their natural form. If the agent/toxin has been processed to readily aerosolize (e.g., weaponized), then the airborne dispersal of material could be the most likely mode of transport with the greatest impact. The ability to aerosolize is an individual agent/toxin characteristic and may be modified dramatically by the formulation of material containing the biological agent. This enhanced ability to aerosolize should be specifically identified in analyzing potential emergency scenarios. The ability of the agent/toxin to survive in the environment after release should also be assessed in determining the impact of a release into the air. The aerosolized agent or toxin can directly impact receptors through inhalation or other pathways and/or by ingestion when receptors are exposed to contaminated food products.

Some biological agents/toxins also have the ability to remain viable in water and can pose a serious hazard if released into wastewater or drinking water. The ability of a particular agent/toxin to survive and remain a threat once it enters a water supply needs to be considered.

3.6 Infected Host

A transport mechanism unique to biological agents is the exposure of receptors (collocated workers or the public) to a biological agent by an infected host. The infected host moves from the facility to the environment and in the environment to a receptor.

The infected host transmits the agent through direct or indirect contact with receptors. This method of transport applies only to a subset of hazardous biological agents referred to as transmissible agents. These agents, such as the virus responsible for smallpox or the bacteria that causes plague, can be transmitted from one individual or animal to another, where it can establish an infection, multiply, and be passed on to other individuals or animals. Other types of hazardous biological agents, such as the bacteria that cause anthrax, are not transmitted directly from person to person. The transmissibility of hazardous biological agents should be established for any agent handled in a facility in order to understand the potential consequences of a release to the environment.

Transmissible diseases present the greatest potential danger since they can result in epidemics and pandemics. The Severe Acute Respiratory Syndrome (SARS) epidemic is a recent example. This disease was initially detected in poultry and was then transmitted to humans through close contact. The disease then proved to be highly contagious and lethal in humans. If small rodents or insects enter a facility and become infected, they can infect humans and non-humans. Infections can spread through droppings (e.g., mouse droppings shed the Hanta Virus that becomes aerosolized in dry, windy climates), biting (e.g., West Nile Virus mosquitoes biting infected animals and then biting other animals and humans), and contamination of food sources outside the facility (e.g., deer droppings in fields have contaminated vegetables with E. Coli.)

If a release of a hazardous biological agent to the environment occurs via an infected host, such as a facility worker or a vector (e.g., insects or rodents), the event could go undetected until symptoms are recognized in one or more individuals or animals as the result of infection. Medical surveillance of facility workers, identification of a disease outbreak by the local medical community, or diagnosis of diseased domesticated or wild animals by veterinarians may provide this recognition.

- **Human Host** – Infection of a human host by a biological agent within a facility can occur due to an accident, such as a needle stick, that penetrates PPE. Other mechanisms that can create an infected host are also due to human errors, which could occur where PPE is not used properly or safety precautions are not followed. Once the human host is infected, the agent can grow within its host and infect collocated workers and the public through aerosolization (sneezing, coughing), direct physical contact, or through foods (e.g., preparation process, sharing food or utensils). Humans are highly effective carriers of some transmissible agents and can be effective sources of dissemination.

- **Animal/Insect Hosts (Vectors)** – Infected, live vectors (i.e., non-human carriers) can spread vector-borne diseases. Arthropod or rodent vectors, for example, that enter laboratory spaces may become infected and carry an infectious agent out of the facility. The most common vectors are arthropod hosts such as mosquitoes, ticks or fleas. Rodents are the most likely animal vectors (other than humans). Infected laboratory animals that are the subjects of scientific investigations may transmit the agent via direct contact, droppings, or being bitten by a vector.

- **Plant Host** – As with human and animal diseases, infected plants can spread disease to other plants. Plant bacterial, viral, fungal, and protozoan pathogens can spread through direct contact, proximity, or carrier/vector. Plant epidemics can have severe economic consequences.

3.7 Contamination

Biological agents and toxins can also be transported outside a biosafety facility through contamination. The contamination mechanism for agents is only possible if the agent can also survive in the environment for a time sufficient to allow a receptor to become infected. Workers in a biosafety facility may come into physical contact with a biological agent and carry it outside the facility on their skin or clothing, where it may be deposited or transferred to suitable hosts and/or receptors. If an infectious biological agent contaminates a surface (e.g., skin, hair, clothing, objects) within the facility that is potentially transportable to the outside, then contamination should be considered as a transport mechanism. It is possible for an insect or rodent to make contact with a biological agent and carry it outside the facility. Alternatively, insects or rodents could be exposed to the agent outside the facility from another source. Objects (i.e., fomite) within a facility may become contaminated with a biological agent and transport the agent to receptors outside the facility.

3.8 Biological Agent Release Scenarios

Analyses of OE releases of biological agents from a biosafety facility will involve an understanding of the characteristics of the agent, its formulation and use (activities) in the laboratory, barriers and failure modes, potential initiators of releases, mechanisms for transport from the facility and in the environment, the external environment, how the agent interacts with potential receptors, and the medical indicators of infection. In the context of OE releases of biological agents, the "environment" might be the public area within the facility, but outside the biocontainment area, where the specific biosafety protocols associated with the agent/toxin are not required.

In order to facilitate analyses, a simplified schematic representation of scenario development is given in **Figure 3-1**. The scenario sequence is divided into six groups of parameters or components to be addressed:

1. Source
2. Failure(s)
3. Transport outside biocontainment area to the environment
4. Transport in the environment to the receptor
5. Agent-Receptor interactions
6. Effects on the receptor

The schematic shown in **Figure 3-1** represents the sequence of agent-activity-facility characteristics that may contribute to a particular biological release scenario. The agent needs to be specified in order to determine which characteristics play a role in each step in the scenario. As should be apparent, the figure is ***not*** to be interpreted as a description

of the parameters and considerations that enter into the analysis of every biological agent release scenario. The agent-activity-facility and scenario to be analyzed will dictate the characteristics that will enter into the analysis (e.g., barriers, transport mechanisms, pathways, diagnosis indicators.)

Each potential release scenario has six basic components:

- **Source**. The source term for each scenario will depend on the specific agent, its form/formulation (e.g., aerosolized) and quantity (and concentration), and, if applicable, the specific activity involving the agent that results in a release. Other source terms may apply to scenarios involving initiators such as natural phenomena or external events. The procedures and protocols associated with use of the agent and its containment status (e.g., in Class II BSC, PPE required, ventilation design) will provide the characterization of the hazard required for analysis.

  The maximum planned quantity of material to be used by the scientists/technicians will determine the upper limits for emergency management analysis and the potential release quantity to assume for planning purposes, especially related to *environmental dispersion* and *contamination* transport mechanisms. Although the quantity in use will certainly influence the chance for an exposure to occur, it will have little effect on pre-planning for releases via an *infected host* transport mechanism, given that an exposure has occurred.

- **Failure(s)**. In DOE emergency management analyses of hazardous material releases, barriers are physical or administrative features that maintain each material in a safe condition. The primary barrier is generally the one physically nearest to the material to be controlled. In contrast, the **BMBL** methodology for addressing biological containment uses the term primary barrier more generally. ***Primary barriers*** are intended to ***protect personnel and the immediate laboratory environment*** from exposure to infectious biological agents. The biocontainment area may consist of multiple *primary barriers*, with some barriers having dual roles in preventing exposures both within the area and outside in the environment (*secondary barriers).*

  A postulated release of biological material will usually involve failure of one of the primary barriers (to be referred to as the ***initial barrier*** in this guidance), while additional primary and secondary barriers are intended to protect the personnel and the immediate laboratory and to prevent release of material outside the laboratory. Biocontainment *barriers* intended to prevent releases of material are generally consistent with emergency management terminology for *barriers*. Significant exceptions are the PPE and similar worker safety barriers that have a role as a barrier to a biological release *only* for the infected host transport mechanism.

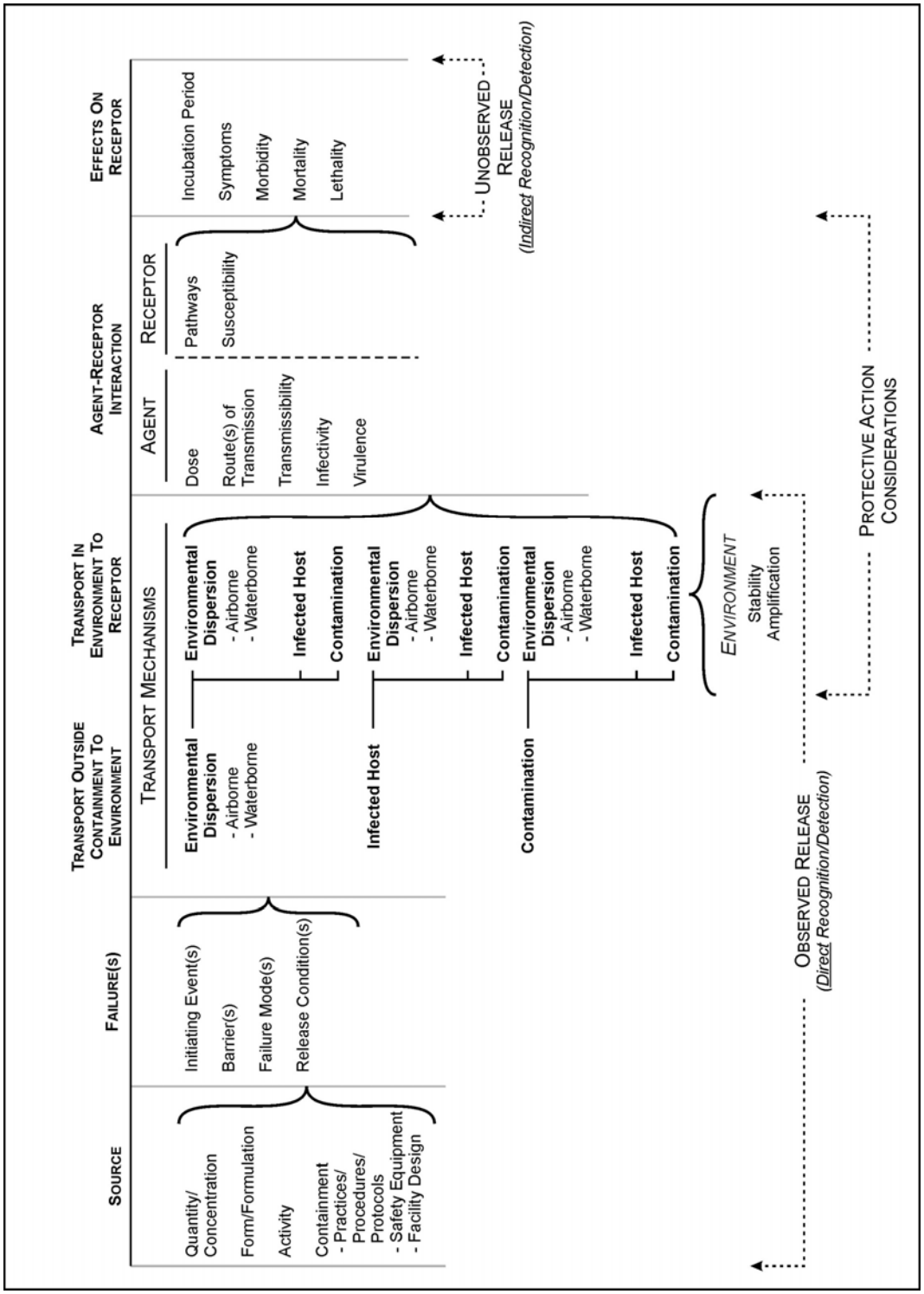

Figure 3-1. Schematic Representation of Biological Release Scenario

Potential failures associated with the barriers and additional mitigating factors can represent variations in the quantities of released material and expected transport mechanisms associated with the specific biological source term. **Table 3-1** contains representative examples of generic types of barriers/controls and the primary agent transport mechanism they may effectively prevent. Many of these will become the barriers/controls and release conditions or mitigating factors involved in the scenarios.

Table 3-1. Transport Mechanisms and Barriers/Controls

Barriers	***Transport Mechanisms to the Environment***		
	Environmental Dispersion	***Infected Host***	***Contamination***
Access control		X	X
Precautionary Safety Reminders	X	X	X
Decontamination			X
Medical Surveillance		X	
Physical Containment	X		X
PPE		X	
Physical Separation(s)	X	X	X
Portal Design	X		X
Air Handling Design	X		X

As indicated in Figure 3-1 under Failure(s), a potential release of biological materials will depend on the initiator causing the failure of the *initial barrier* (i.e., closest to the material), failures in additional barriers or controls, and potential mitigating release conditions. Further detailed discussions associated with failure analysis and release scenarios are contained in DOE G 151.1-2 Chapter 2, *Hazards Assessments*, and will be discussed later in this Guide, Section 4.2.

- **Transport Outside Containment to the Environment**. In this step, the initiator(s) is specified for each failure mode, the source term is estimated, and specific transport mechanisms that apply to each initiator are identified. The agent release scenario should specify how the agent is transported into the environment from the facility. Each agent transport scenario will provide an individual set of parameters that will contribute to the analysis of the scenario.

- **Transport in the Environment to the Receptor**. Initial transport of an agent out of the biocontainment area may continue through a variety of mechanisms. For example, an environmental dispersion of an agent out of the biocontainment area can result in a host becoming infected outside or the contamination of a vector that continues to spread the agent in the environment. Thus, a release that may begin as a single transport mechanism can eventually involve several candidate paths to a receptor. This is indicated schematically in Figure 3-1.

- **Agent-Receptor Interaction**. The effects of agent-receptor interactions depend on agent characteristics (e.g., transmissibility, route of transmission, infectivity,

virulence), exposure level (i.e., dose), and available receptor pathways and receptor susceptibility. These parameters may not directly impact the analysis of the scenario, but can certainly influence the selection of initial pre-planned protective actions.

- **Effects on Receptor**. The final scenario characterization step reflects potential effects of the agent and its associated disease on the receptor. The resulting infection caused by a specific agent could be recognized through consideration of the characteristics shown in the figure. Hence, scenarios may reflect releases that went unobserved at the facility, which should now be recognized by onsite worker medical surveillance or at offsite disease surveillance centers.

The brief introduction of the release scenario in this section will be continued in this Guide, Section 4.2. Scenarios form the basis for planning and response to OEs involving biological agents. The purpose of the EPHA is to analyze a spectrum of these scenarios to enable the facility to recognize that an agent has been or might have been released and to respond appropriately. The ***recognition*** of OEs is introduced briefly in the next section.

3.9 Recognizing Operational Emergencies

For emergency response measures to be effective, early recognition of an actual or potential release of a hazardous biological material is essential. Transition to ***emergency operations*** depends on detection and recognition of specific emergency event or condition indicators/symptoms that suggest an actual or potential release outside of secondary barriers. At any given time, different indicators and symptoms may be monitored to determine if facility conditions are normal or if any abnormal event/ condition may have occurred. Monitoring of these indicators and the recognition of the significance of abnormalities is generally a routine function of the biosafety facility staff.

Routine surveillance (cf. Section 2.5) should include an ***"active"*** process that **integrates and interprets** the data in the context of potential releases, rather than simply as individual datum to be monitored, compared to expected performance, and recorded. Methods employed to implement detection and recognition of emergency events/ conditions and to make the transition to emergency response should be **integrated with routine operational practices** to the greatest extent possible. Staff responsible for this routine surveillance should be specifically trained to perform this recognition function.

To implement an "active" recognition activity/function, an emergency management program at a laboratory facility should take advantage of control capabilities that are already an integral part of good microbiological practices and the biosafety program in the facility. Biosafety control measures, such as routine surveillance activities, are features of laboratory operations that could support development of recognition factors for an emergency management program. Requirements and criteria for establishing a specific biosafety level and for implementing a risk assessment methodology represent

a variety of measures intended to control the biological agents or toxins contained within the laboratory. They range from laboratory practices and equipment reflecting direct control to routine surveillance activities monitoring and maintaining expected performance of the biosafety systems and at-risk personnel involved in the work. These biosafety control measures are barriers to the release of hazardous biological material, and, hence, failure of one or more of these controls could result in a release of an agent or toxin outside the laboratory via one of the transport mechanisms.

Any site working with hazardous biological agents should have an effective agent identification capability either in-house or available on an as-needed basis from an external source. Note, however, that it is ***not*** the intent of this section to support the purchase of new equipment or capabilities, if the current situation adequately supports the needs of emergency response *commensurate with the hazards*. Various technical methods are available for detecting and identifying the presence of hazardous biological materials. The surest method (the "gold standard") is laboratory analysis, which takes hours to days, and is most appropriate as a confirmatory test and not a real-time detection method. Other methods vary from real-time *generic* (i.e., lacking specificity) detection to various field and laboratory devices and methods that can identify the presence of an agent in minutes to hours. Some commercial detection and identification systems are available and a number of others are being developed. Simple antibody-based methods yield results in less than 15 minutes and are suitable for routine monitoring of specific agents being used in a particular laboratory, but, in general, they are limited in terms of throughput and scope of agents detected. Antibody-based methods may also lack specificity and sensitivity. More complex nucleic acid-based systems are sensitive and specific. However, the time to detect ranges from about 20 minutes to several hours, and they are costly to operate and maintain. In addition, nucleic acid-based systems are limited in terms of throughput scope of agents detected. Since the agents/toxins to be used or stored in a biosafety facility will usually be known, it may be possible to identify the specific detection methods needed and to include these in emergency planning.

Note that the scenario components that may provide recognition factors are indicated in Figure 3-1 associated with two separate groups of scenario components, those that may be directly observable at the facility and those that are associated with manifestations of the infection caused by the disease. This implies that two categories of biological agent releases should be considered in emergency management planning: ***observed*** and ***unobserved*** releases. Recognition of ***observed*** releases will likely occur at the facility, as the result of direct detection of the release through observations of event indicators (e.g., initiating event, barrier failure). In this case, the agent will generally be known and response measures can usually be initiated shortly after recognition of the event.

In contrast, ***unobserved*** releases (e.g., unreported infected host, contaminated vectors) could remain undetected for a substantial period following the actual event at the facility. Recognition of these events can occur as the result of indirect detection of the release, when infected receptor(s) present symptoms of the disease. An active, ongoing medical surveillance program within the DOE/NNSA community and in the local

community can provide an essential detection capability for identifying a possible release from the facility. As with ***observed releases***, early recognition of an actual or potential unobserved release of a biological agent is essential for emergency response measures to be most effective.

3.10 Initial Protective Actions

Planning and developing initial protective actions for biological agents and toxins require a coordinated effort between DOE/NNSA site medical personnel and ***offsite public health agencies***. In the event of an OE at a biosafety facility, it is expected that local and/or State public health agencies will assume responsibility for initiating long-term measures for protecting the local population, including onsite workers, while the site will be responsible for initiating prompt, initial protective actions ***onsite*** and recommending protective actions ***offsite***. For an effective response, it is imperative that site medical personnel coordinate protective action planning with the local/State public health agency to ensure that initial measures taken by the site or recommendations made to offsite response organizations are consistent with expectations of local/State public health authorities, as different public health jurisdictions may have different capabilities.

The specific initial protective actions to be taken will depend upon a number of factors (indicated schematically in Figure 3-1), including:

- Transport mechanism of the release (i.e., airborne, infected host, contamination)
- ***Observed*** vs. ***unobserved*** release
- Characteristics of the biological agent released (e.g., transmissibility, infectivity, stability in the environment)
- Location of populations in relation to the source of biological agents/toxins
- The time available to issue and take protective actions

Initial protective actions that can be taken in the event of a biological OE release are general measures that can apply to many ***observed*** releases of hazardous agents/toxins. These measures may include:

1. **Access control:** Control of personnel access to areas of potential exposure and/or contamination outside the biocontainment area to prevent unnecessary exposures and minimize the spread of contamination. Access control is most effective when implemented immediately upon recognizing that an area has been, or will be, affected by a hazardous material release.

2. **Sheltering/Shelter-in-place:** Directing people to seek shelter inside a building or similar location and to remain inside until the threat of exposure at dangerous levels passes. Shelter-in-place means directing people to stay inside at their current

locations until the threat of dangerous exposure passes. Sheltering/shelter-in-place is used when evacuating collocated workers and/or the public would cause greater risk than staying where they are or when an evacuation cannot be performed. Identification of areas for sheltering with potential isolation capacity should be considered.

3. **Evacuation:** Moving all people from a threatened area to a safer place. To perform an evacuation, there should be enough time for people to be warned, to prepare, and to leave an area. Evacuees should be sent to a definite place, by a specific route, far enough away from the incident site so they will not have to be moved again if the wind shifts. Consideration should be given to development of a default radius around the facility based on wind speed and a 1- to 2-hour time span after the release, to define the area of immediate concern.

4. **Decontamination:** Removal of hazardous material from personnel and equipment to the extent necessary to prevent potential adverse health effects. Contaminated clothing and equipment should be removed after use and stored in a controlled area until cleanup procedures can be initiated. In some cases, protective clothing and equipment cannot be decontaminated and needs to be disposed of in the proper manner. Decontamination also applies to removal of hazardous materials that may have been deposited on the ground and on other structures in the vicinity of the release. Use of disinfectants on people or material is a form of decontamination.

5. **Medical Surveillance:** Immediate and active medical surveillance activities, including a process to identify, screen, test, and assess people most likely to have been exposed. Based on medical surveillance results, identify candidates for continued monitoring and/or treatment.

6. **Quarantine:** Separation and restriction of movement of persons, who while not yet ill, have been exposed to a transmissible biological agent and therefore may become infectious. Since quarantine may sometimes require long periods of time pending definitive laboratory results, considerations for support of personnel may include food, water and diversionary activities.

Several longer term protective actions may also be initiated soon after a biological OE release has been identified, such as:

7. **Vector control:** Management of vectors by reducing or eliminating their populations and chances of disease transmission; or reducing or eliminating their ability to cause harm. For most scenarios, vector control may be considered a long-term protective action.

8. **Control/Disinfection of Contaminated Water Supplies:** Shutting off contaminated water supply and water supply intake points to prevent contaminated water usage. This decision may be based on recommendations of appropriate health or agricultural agencies. Water supplies may be restricted at the point of origin or distribution, confiscated, stored, or destroyed. Destruction or neutralization

(disinfection) of disease-carrying microorganisms in contaminated water supplies (lakes, reservoirs, tanks, ponds, etc.) may be conducted to restore them to use.

9. **Control of Contaminated Food Products:** The embargoing or destroying of contaminated agricultural products is appropriate to control the physical movement of food products both raw and processed in an affected area (animal, dairy, plant). This decision may be based on recommendations of the appropriate health or agricultural agencies.

10. **Changes in Livestock and Agricultural Practices:** Contamination of pastures and agricultural areas due to deposition of released materials can require specific protective actions to minimize introduction of contamination into the human food chain. Actions could include putting livestock on stored feed, delaying slaughter of animals until the hazardous material has been removed from their systems, and treating soil to minimize uptake of the hazardous material into foodstuffs. Use of severely contaminated land for agricultural purposes may have to be prohibited.

In the case of an ***unobserved*** release, the source may not be confirmed for sometime after recognition (of disease outbreak) and initial protective actions may not be employed until sometime after the release event. However, many of the above measures (e.g., medical surveillance, access control, decontamination) should be considered when any actual or potential release from a biosafety facility is *recognized*.

In general, for either an ***observed*** or ***unobserved release***, State or local public health officials specify long-term protective action criteria and associated measures to be implemented both *onsite* and *offsite*. These measures are often agent-specific, reflecting the different agent characteristics (e.g., transmissibility, incubation period, stability, available hosts, and affected species), facility design, and geographic and demographic characteristics of the surrounding area. For example, a high concentration of material coupled with additional risk factors, such as high potential for airborne transmission and a high infectivity, virulence, and lethality, should elevate the protective actions necessary.

For an effective response, it is imperative that site medical personnel coordinate protective action planning with local/State public health agencies to ensure initial measures taken by the site or recommendations made to offsite response organizations have been agreed upon and can be seamlessly integrated with the public health response. Because public health jurisdictional knowledge and experience may vary, onsite emergency managers may have to provide technical agent expertise necessary to determine appropriate protective actions.

The protective actions indicated above do not directly address worker safety requirements, an integral part of biosafety response to an occupational accident within the laboratory (e.g., hand washing, handling equipment, showering on exiting the laboratory, PPE). In the event of an incident or OE, the laboratory workers will implement the *facility-specific* BSL program safety protocols. Development of these protocols is the responsibility of each DOE/NNSA biosafety facility and will not be

addressed in this version of DOE G 151.1-5. Similarly, specific protective action requirements for *initial responders* will be left to facility and response organizations to identify and address as part of the planning process.

3.11 Public Health Response

A primary function of local, State, and Tribal public health agencies is to provide a capability for identifying a "communicable disease emergency" in communities for which they are responsible and for responding with measures to confine and arrest the spread of the disease. In this capacity, public health assets will play a major role in response to a release of hazardous biological materials from a DOE/NNSA biosafety facility. Whether a release is strictly onsite or involves an offsite impact, public health will ultimately assume primary responsibility for ensuring that the community is protected from further exposure.

Local, State, or Federal public health response falls into three categories, which represent a graded approach[6]:

1. **Continuous Medical Surveillance.** Continuous medical surveillance, a primary community public health function, is a routine activity performed by public health professionals who monitor incoming disease reporting data for indicators and patterns to determine whether a *communicable disease emergency* is imminent. State-based public health departments provide a central communications point for ongoing surveillance, disease reporting, and epidemiological investigations. These departments also serve as repositories for agent-specific knowledge. Routine disease reporting, which is both mandated and regulated, originates from medical facilities, clinics, laboratories, and private clinician offices. These diseases usually have potential for a broad community impact (e.g., pertussis) and necessitate a public health response. Surveillance efforts have been increased and broadened in both the public health and medical communities to include rapidly emerging infectious illnesses (e.g., SARS, avian and pandemic influenzas).

2. **Active Investigation.** Active investigation is a routine public health practice initiated by a positive surveillance event. Active investigations occur on a daily basis as public health professionals interpret incoming data from reports or direct observations. As a result, they make professional judgments on the scope of further actions based on potential impact and anticipated severity.

3. **Emergency Response.** Initiated by public health organizations to mitigate an unusual public health occurrence, emergency response actions can include broader epidemiological investigations, medical screening and laboratory sampling, mass prophylaxis/vaccination, isolation/quarantine, public information and risk

[6] Development of Models for Emergency Preparedness, Personal Protective Equipment, Decontamination, Isolation/Quarantine, and Laboratory Capacity, Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services (HHS), Bettina M. Stopford, RN, Laura Jevitt, Michele Ledgerwood, Christa Singleton, MD, MPH, Martin Stolmack, EMT-P, AHRQ Publication No. 05-0099 August 2005.

communication, hazards/site remediation, and legal involvement. Local public health departments may lack the personnel to support a robust surge response capacity and will need to be linked to regional assets and the State public health agency. Emergency response will vary depending on locale, population affected, and relative hazard as perceived by the local public health officer with legal authority.

DOE/NNSA site emergency managers should become familiar with local and State public health capabilities. They should coordinate and reach agreement on sole and shared responsibilities in order to coordinate efforts during an observed release OE at the biosafety facility, or in response to an identified *communicable disease emergency* that can be associated with an *unobserved* release OE at the facility. To enhance Departmental response capabilities, DOE/NNSA biosafety facilities should provide agent-specific data to local public health agencies as part of pre-planning.

Following an OE declaration, DOE/NNSA emergency managers should expect to provide agent and procedure- /protocol-specific information and personnel accountability data; and should have pre-planned methodologies in place for: 1) rapid identification of potentially exposed personnel; and, 2) isolation for medical screening and treatment purposes. To ensure an integrated response, plans should be developed in coordination with the appropriate public health agencies by providing symptom-specific awareness training for all personnel and maintaining a central reporting process for ongoing medical surveillance. The public health and medical communities will likely look to the DOE/NNSA biosafety facility to provide expert level professionals familiar with facility-specific agents and to initiate an active, systematic monitoring program and response protocols addressing DOE/NNSA personnel tracking and epidemiological investigations.

4. EMERGENCY MANAGEMENT PROGRAM FOR BIOSAFETY FACILITIES: *TECHNICAL PLANNING BASES*

The Emergency Management Program for a DOE/NNSA facility can consist of two components: an Operational Emergency **Base Program** and an Operational Emergency **Hazardous Material Program**. Each DOE facility/site or activity is required by DOE O 151.1C to have an **Operational Emergency Base Program,** which provides the framework for response to serious events or conditions that involve the health and safety of workers and the public, the environment, and safeguards and security. Although DOE O 151.1C establishes several DOE-unique requirements and a minimum set of generic requirements for the **Base Program**, the framework for response results mainly from the implementation of the requirements of DOE regulations, other DOE orders, and applicable non-DOE Federal, Tribal, State, and local laws/regulations/ordinances. The specific requirements that constitute the Operational Emergency **Base Program** are the emergency planning and preparedness aspects of these Orders and laws/regulations/ordinances. Examples of emergency response features addressed in other DOE Orders and laws/regulations/ ordinances include: medical support, worker evacuation plans, fire drills, worker notification systems, hazardous material communication, contingency planning for oil spills, environmental spill drills and exercises, and DOE security and safeguards requirements. The ***objective*** of the **Base Program** is to achieve an effective integration of emergency planning and preparedness requirements into an emergency management program that provides capabilities for ***all-emergency*** response, through communication, coordination, and an efficient and effective use of resources.

DOE O 151.1C requires that emergency management planning efforts begin with identification of facility-hazards and that the scope and extent of emergency planning and preparedness be commensurate with these hazards. The Hazards Survey identifies key components that provide a foundation of basic emergency management requirements and an integrated framework for response to serious events involving health and safety and the environment. Much of the information in the Hazards Survey should already be collected in the course of meeting other DOE, NNSA, and Federal, Tribal, State, and local authority requirements. The Hazards Survey is required by all facilities to identify generic facility-specific hazards and to determine whether hazardous materials in the facility require further analysis in an EPHA. The EPHA analysis provides the additional planning and technical detail needed to ensure timely and effective response for these identified hazards. The Hazards Survey and EPHA form the technical planning basis for the emergency management Hazardous Material Program at the facility.

The following sections will address the impacts of the unique hazards posed by biological agents and toxins on the associated processes and content of the Hazards Survey and the EPHA. Issues, information, and methods that may be different than those typically used to address radiological and chemical hazards will be the focus of this EMG document. This discussion will not attempt to repeat the detailed guidance already provided in DOE G 151.1-2. If the facility has other hazardous materials (chemical, radiological), in

addition to biological agents/toxins, these should be included in the Hazards Survey and subsequent EPHA according to the guidance in DOE G 151.1-2.

4.1 Hazards Survey

Facilities involved in growth, handling, storing, or transporting of hazardous biological materials are required to perform Hazards Surveys containing the same information at the same level of detail as other DOE/NNSA facilities. Much of the content of the Hazards Survey, such as the generic facility-specific hazards and Base Program requirements, is addressed in detail in DOE G 151.1-2, Chapter 1. This chapter of guidance related to biosafety facilities will focus on the screening process for hazardous biological materials.

The ***hazardous material screening process*** identifies hazardous biological materials that require further analysis in an EPHA. All hazardous biological agents and toxins that are subject to the requirements published in 42 CFR 73, 7 CFR 331 or 9 CFR 121, including published updates, require further analysis in an EPHA in accordance with DOE O 151.1C. Thus, DOE/NNSA biosafety facilities that use and/or store any of the Select Agents/Toxins (subject to the Select Agent Rules) need to perform an EPHA and implement a **Hazardous Material Program**.

Note that the screening process for biological agents does not include threshold quantities, since no basis was identified for differentiating between quantities expected to remain strictly an internal facility problem versus those that can potentially result in an external release to the environment. In contrast to agents, each toxin listed should exceed a specified aggregate amount under the control of "a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor" in order to be subject to the Select Agent Rules. If the toxins do not exceed the quantities specified, then they would not be subject to the Select Agent Rules and, therefore, would not require registration or containment in the biosafety facility, as long as the quantities remained below the specified aggregate limits for "a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor." These toxins would ***not*** require further analysis in an EPHA or a Hazardous Material Program. In addition, these *excluded* quantities will not require further analysis even if the same specific toxin is being maintained by others in the facility. It is consistent with the Order to screen out these *excluded* quantities of toxins. Hence, if a toxin maintained by an individual or commercial entity is excluded, it no longer enters into consideration in emergency management planning but becomes the sole responsibility of biosafety response.

The Select Agent Rules require that each biosafety facility maintain an accurate, ***current inventory*** of each Select Agent and toxin held. This inventory includes the following information:

- Name and characteristics of agent/toxin
- Quantity acquired from another individual or entity, date of acquisition, and source of agent/toxin (i.e., individual or entity)

- Location where the agent/toxin is stored
- Record of agent/toxin use:
  - Select agent/toxin used and the purpose of use
  - When moved from storage and by whom
  - When returned to storage and by whom

The emergency management organization should have access to this inventory data and should be notified in a timely manner when changes occur that modify the current Hazards Survey. Changes resulting in a reduction of hazards with no adverse effect on safety or emergency preparedness or response may be included in the next scheduled review and update.

4.2 Emergency Planning Hazards Assessment (EPHA)

The DOE/NNSA biological ***OE*** involves the actual or potential release of a hazardous biological agent/toxin to the environment outside the BSL secondary barriers of the biocontainment area. The environment might be the public area outside of the building/ facility, if the laboratory has external walls or air exhausts to the outside, and could even include publicly accessible corridors or other laboratories, if the biosafety laboratory is contained within a facility.

The Select Agent Rules require that an Incident Response Plan fully describe response procedures for the release of a Select Agent or Toxin, severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc. Response procedures should account for hazards associated with the Select Agents and Toxins and provide appropriate actions to contain them. Each of these events/conditions should be analyzed in the EPHA as potential initiators for the release of hazardous biological materials. Other emergencies, such as *accidents* in the facility and other *external events*, should be also analyzed to develop a spectrum of representative scenarios. The spectrum of scenarios required for the planning basis of the emergency management program should cover the scope of recognition factors and potential protective actions that might be needed for the specific facility inventory.

This section outlines a process for conducting and documenting an EPHA for biosafety facilities. The definition of an OE given in DOE O 151.1C will be the basis for the EPHA analyses to be performed for identified hazardous biological agents/toxins. Suggested steps in the hazards assessment process follow:

1. Define and describe the facility and operations.
2. Characterize the hazardous materials.
3. Select scenarios for analysis

4. Analyze scenarios:

   a) Estimate source term (if appropriate and feasible).

   b) Identify/estimate/calculate consequences (as appropriate).

   c) Identify recognition factors and protective actions.

   d) Finalize technical planning basis scenarios.

5. Document the results of the analyses.

The sections that follow address recommended steps in the EPHA process for biological hazards.

4.2.1 Define and Describe Facility and Operations

In general, this section of the EPHA should be prepared in the same manner as for any other facility containing hazardous materials. Descriptions of the key elements of the ***primary*** and ***secondary containment***, including their governing procedures/protocols, operational practices, and required safety equipment, should be sufficiently complete to support the EPHA analysis of scenarios. In addition, descriptions of applicable facility design features and environmental controls will contribute to analyses of selected release scenarios. Original reference materials (e.g., **BMBL** risk assessment, biosafety plans, and detailed procedures) can be referenced in the EPHA to support the descriptions given.

4.2.2 Characterize the Hazardous Materials

This section should identify material locations, storage conditions, containment requirements, activities involving the materials, forms/formulations of the materials, quantities, and characteristics of the specific biological materials used, stored or transported in association with the facility. Thorough identification of these parameters is crucial for performing the analysis that supports determination of potential consequences and development of appropriate response measures. Much of this information should be readily available since it was likely needed for determining the biosafety level for the facility (e.g., risk assessment). In addition, as discussed in Section 4.1, above, the Select Agent Rules require an accurate and current inventory.

4.2.3 Select Scenarios for Analysis

The objective of this step in the hazards assessment process is to select for detailed analysis potential release scenarios associated with the hazardous materials characterized in the previous section. These analysis cases will ultimately represent a spectrum of possible scenarios that will serve as the technical planning basis for the facility emergency management program.

Specific cases to be analyzed in the EPHA should be chosen through a ***systematic examination*** of:

- All hazardous biological materials in the facility
- Any other hazardous material in the facility (chemical, radiological)
- Barrier(s) that maintain each material in a safe condition, either in a static configuration (e.g., storage) or during an activity in an active configuration (e.g., centrifuging)
- Modes by which the initial barrier (e.g., safety centrifuge cup) could fail
- Initiating events or conditions that could cause barrier failure modes
- Release conditions (additional barriers and mitigating factors) associated with the failure mode and/or the initiating event

Release conditions generally represent failures of the ***secondary barriers*** of the biocontainment area. These ***failures*** provide release pathway(s) through which biological material could be transported to the environment (i.e. beyond the biocontainment area), given a release within the biocontainment area. Success and failure associated with release mitigation systems or barriers may represent additional specific cases for analysis.

DOE G 151.1-2, Chapter 2, introduces a recommended minimum set of event or condition types to be considered for analyzing hazardous material releases. A systematic approach for developing a manageable number of representative scenarios for each hazardous material in a facility is introduced in DOE G 151.1-2, Section 2.5.

Failure of barriers may reveal generic "failure mode" scenarios that can be applied to a number of types of agents/toxins and associated activities to be performed in the laboratory. These generic failures and scenarios will evolve from systematic examination of the spectrum of events and development of the final planning basis. If carefully constructed, this set of generic scenarios may simplify the emergency response tools to enhance their usability and efficiency. This approach may be especially effective for biosafety facilities that use and/or store multiple types of biological hazards.

The spectrum of events and conditions analyzed should include those exclusively affecting onsite personnel, as well as those also affecting the offsite public. **Note that analysis of a spectrum of events does not mean analysis of every imaginable event. The goal is to create a comprehensive picture of the types of events and a range of associated "consequences" that could occur at a facility.** This comprehensive picture of events and consequences will then serve as the basis for emergency response planning (e.g., recognition factors, protective actions).

Select Types of Event/Conditions for Analysis. For each of the agents/toxins previously identified and characterized, the types of OE events and conditions to be considered for inclusion in the technical planning basis should be identified. These, in turn, are developed into a spectrum of release scenarios to reflect the range of release consequences and encompass the scope of possible release events at the facility. Initiating events from four general groups should be considered, namely, accidents, natural phenomena, external events, and malevolent events. The Hazards Survey should be the starting point for identifying the general types of facility-specific hazards that result in emergency conditions at the biosafety facility.

1. **Accident Events:** Accident event initiators include failure causes, such as manufacturing defects, malfunctioning biosafety equipment or control systems, internal events (explosions, fire), process upsets, and procedural or human error. In many cases, these types of events (*observed*) are accompanied by obvious and/or measurable indicators, such as fire, explosion, equipment failure, etc., where immediate monitoring, sampling, and/or surveillance could be initiated to determine if a release of a biological agent/toxin has occurred. An OE condition will usually require that a biosafety control also fail in order to provide a secondary barrier failure that leads to a release to the environment. This situation may be detectable through the *active* routine surveillance program of biosafety controls.

   Because biological hazards can be transported by a variety of mechanisms other than just the airborne pathway and event indicators may be delayed or develop over time, other types of accident event scenarios should also be considered. Scenarios resulting in loss of containment and release of a biological hazard into the environment could include accidental infection of a worker, release or improper disposal of infected laboratory animals, spread of contamination by a vector (e.g., insects, rodents), and facility worker error, such as failure to follow established practices, procedures and protocols. The *transport mechanism* and *time frame* for these types of scenarios can be considerably different than for a radioactive or chemical hazardous material release. For example, the *unobserved* accidental spread of a biological hazard by an infected host or vector could be followed some time later (e.g., days, weeks) by the manifestation of symptoms in infected humans and the *eventual* indirect detection by ***local medical surveillance*** protocols.

2. **Natural Phenomena Events:** These scenarios are based on events caused by natural phenomena that could result in a breach or failure of the facility biocontainment system(s) and loss of control over biological material(s). Types of phenomena that can cause these events include earthquakes, floods, tornados, and high winds (e.g., hurricanes).

3. **External Events:** External events have the potential to initiate the onsite release or loss of control of hazardous biological materials either directly or by disruption of operations or processes onsite. These events include: aircraft crash; fire in adjacent building causing a release of a hazardous material; external impact (e.g., vehicle impact, dropped load); wildland fires; transportation accidents involving release of a hazardous chemical; and loss of power due to offsite facility or utility accident.

These events or conditions might result in the accidental release of biological materials if, for example, proper emergency shutdown procedures are not implemented or biosafety facility workers do not conduct decontamination protocols during an evacuation of the facility.

4. **Malevolent Events:** Malevolent events (e.g., vandalism, sabotage, terrorism), including the use of explosives or flammable material, are possible biological material release initiators within the scope of emergency planning and the EPHA. Many malevolent events are likely to produce releases and consequences similar to those that could be caused by accidental or other external initiators. For example, failure of a biosafety storage container might be postulated due to a seismic or tornado event. It is likely that deliberate failure of a container caused by a malevolent act would result in the same consequences as a failure resulting from another type of initiator. Further discussion of malevolent events and their inclusion in the technical planning basis can be found in DOE G 151.1-2, Appendix E.

   Note that consideration of malevolent events in the EPHA is not intended to include acts in which biological agents or toxins, not owned or controlled by DOE, are brought onto a DOE site or facility as an act of terrorism.

Selection of a Spectrum of Scenarios. From the events and conditions considered above, a broad spectrum of realistic scenarios will be selected to evaluate possible initiating events and accident scenarios that could lead to release of hazardous biological materials. Any contributing events or conditions that could influence the progression of the scenario or alter the magnitude or nature of the consequences should be incorporated. In identifying relevant scenario parameters, analysts should take into account the range of transport mechanisms available with biological agents, including the possibility of multiple transport mechanisms for the same event.

Development of specific scenarios to be analyzed involves taking the types of events and conditions identified above and providing relevant information in the sequence of steps listed below:

1. **Identify the Material-At-Risk (MAR) quantities in the facility** – The **MAR** is the quantity of the agent or toxin that could be released in an emergency event. For many scenarios, the **MAR** may be assumed equal to the total quantity authorized for use in a specific laboratory activity.

2. **Identify barrier(s)** – Physical or administrative features that maintain the hazardous substance in a safe condition should be identified for each **MAR**. The *initial barrier* (e.g., container) is to be evaluated to identify failure modes in Step 3, discussed below. Other barriers should also be identified, since their failures may play a role in permitting the release of materials to the environment [e.g., a safety system that prevents exposures to workers inside the laboratory or a facility design feature that prevents the escape of material to the outside environment (e.g., Class II BSC)].

3. **Select failure mode(s**) – Failure modes are ways in which the initial barrier might lose its integrity or its ability to *confine* or *control* hazardous material. Failure modes that are applicable to the *initial barrier* for the particular **MAR** being addressed should be selected.

4. **Identify initiating event(s)** – Initiating events/conditions cause the failure mode specified in the scenario. A failure mode can be caused by a number of different initiating events/conditions. Initiating events and mechanisms considered should include traditionally defined "accidents" and those arising from natural phenomena, external causes, and malevolent acts.

5. **Identify release conditions(s) -** Conditions that could influence progression of the release scenario or alter the magnitude or nature of the associated consequences should be identified in this step. These *release conditions* can result from failures of other ***primary barriers*** and/or ***secondary barriers*** or the success or failure of ***mitigating factors*** (e.g., fire suppression systems). These *release conditions* will reflect the status or functional condition of barriers/structures and mitigation systems prior to or resulting from the impact/influence of the initiating event.

Biosafety facilities that work with biological agents/toxins may not have a Safety Analysis Report (SAR)/Documented Safety Analysis (DSA) to support the identification and development of scenarios. However, facilities should have a hazard analysis prepared in accordance with DOE Health and Safety Program requirements (e.g., IBC process). Also, the risk assessment used to determine the assigned BSL for the laboratory should provide information about biocontainment barriers.

4.2.4 Analysis of Scenarios

For radioactive and chemical hazardous materials, after a range of possible releases has been identified, representative analysis cases are selected and analyzed. The source term is identified and potential consequences calculated to determine the areas potentially affected and the need for personnel protective actions. Development of a final set of technical planning basis scenarios also includes identification of recognition factors and protective actions for each scenario.

Biological agents can be transported by a variety of mechanisms including airborne, waterborne, infected host and surface contamination. Development of a source term and consequences similar to other hazardous materials can be difficult if a hazardous biological material is transported outside a facility via a transport mechanism other than the airborne pathway. Based on the characteristics of biological agents discussed in Chapter 2 of this Guide and the range of quantities of biological materials likely to be found in DOE/NNSA biosafety facilities, estimation of a source term and calculation of consequences based on a health impact at a specific distance may not be as feasible or reliable as for other hazardous materials. Therefore, analysis of scenarios involving biological agents and toxins may require a different approach. If, on the other hand, sufficiently large size quantities are used and/or stored in these facilities, source terms and calculations of range-to-effect could be expected.

The spectrum of scenarios should first be characterized and then analyzed in order to estimate consequences (if possible) and finalize technical planning basis scenarios. The first step is to identify material form/formulation, estimate the source, and identify the activity. Relevant containment procedures/protocols, safety equipment involved in the activity, and facility design factors that contribute ***secondary barriers*** and ***mitigating factors*** are identified. Next, the specific activity involving the agent should be examined to determine possible external and internal initiating events, *initial barrier* failure modes, and release conditions. Potential transport mechanisms for release from the facility and transport in the environment are identified and expected stability of the agent in the environment estimated. Potential receptors should be considered in estimating the consequences of the release. Factors include the exposure mechanism as well as transmissibility, infectivity and incubation period associated with the particular agent used in the scenario.

A *simplified* approach for analyzing the biological scenarios suggested here will involve an integrated description, including consideration of ***all*** parameters and information related to the source (agent), activity, facility, failures, release, agent transport, agent-receptor interaction, and potential effects on an exposed receptor, as displayed schematically on a common template shown in Figure 3-1. Based on such a structured description of each scenario, development of prompt recognition tools for categorizing ***observed*** release OEs should be facilitated and development of initial protective actions should follow. This analysis should also produce recognition indicators for ***unobserved*** releases to be used by offsite medical surveillance programs to notify the facility if a disease presents symptoms in the local community.

In some cases, calculations might be used to determine dispersion of airborne (aerosolized material) as well as waterborne hazardous biological materials. However, calculations may not be available for distances to specific impacts for many biological scenarios. It is important to estimate a range of concern for most *release mechanisms,* if feasible. Distance estimates such as those found in the DOT Emergency Response Guide (ERG) for transportation accidents might be used as preliminary estimates, to be modified based on the local situation. [Cf. Protective Action Zone distances for biological sources specified in the *2004 Emergency Response Guidebook (ERG)*, U.S. Department of Transportation, Washington, D.C.] For example, an immediate precautionary measure for a transportation accident involving an infectious substance (*ERG,* Guide 158) is to isolate for at least 25 meters (75 feet) in all directions from the accident.

4.2.5 Identify Recognition Factors and Protective Actions

A key to effective emergency response is early recognition of an OE event, rapid initiation of response measures, and activation of response capabilities. The analysis approach suggested in Section 4.2.4, above, should lead to identification and analysis of factors used to recognize a potential or actual release for each scenario. Recognition of *observed* releases will likely occur at the facility, as the result of directly observable indicators in combination with surveillance of biosafety control measures. In contrast, *unobserved* releases are detected when an infected receptor(s) presents symptoms of the

disease and an active, ongoing medical surveillance program onsite and in the local community provides the detection capability. Medical surveillance systems established by State and local health agencies provide a mechanism for event recognition and these agencies may take the lead at some point in the response.

Generic guidance for identifying and using recognition factors is presented in DOE G 151.1-2, Chapter 2, for ***observed*** releases. To ensure a prompt recognition of ***unobserved*** releases, it is essential that DOE/NNSA biosafety facilities provide information related to biological agents and/or toxins used or stored at the laboratory to Tribal, State, and local public health authorities as part of pre-planning. The information provided (*within the constraints of security requirements*) should be sufficient to ensure that medical surveillance programs are able to recognize a manifestation of symptoms related to these materials. Identification of such an outbreak by medical surveillance programs acts as a trigger for initiating notifications to the facility of the possibility of a release.

Associated with the recognition of OEs, emergency responders should be ready to implement protective actions (see Section 4.3.3, below) including expected duration of the measures and where decontamination/clean-up operations should be conducted. Protective actions implemented onsite for collocated workers or recommended for the public are directly dependent on the specific characteristics of the agent/toxin released from the facility, analyzed transport mechanisms for agents, and stability and behavior of the agents in the environment. *Adverse health effects* are assumed to be possible in any areas contaminated by the released agent or toxin.

Note that the OE protective actions addressed in this guidance focus on *collocated workers and the public* outside of the biocontainment area, while the biological worker safety program response appropriate for the BSL of the facility will focus primarily on protection of the *laboratory workers and the environment* inside the biocontainment area.

4.2.6 Emergency Planning Zone (EPZ)

The hazards assessment process includes a determination of the size of the geographic area surrounding the site, known as the Emergency Planning Zone (EPZ). Within the EPZ, special planning and preparedness activities are required to reduce the potential health and safety impacts from an event involving the airborne release of hazardous materials. The methodology for the determination of the size of an EPZ is based on consideration of the range of consequences at various distances calculated for each scenario analyzed in the EPHA. However, because the current approach to analysis of biological hazards for planning purposes does not lend itself to such considerations, hazardous biological material release consequences will not be used at this time for determining EPZ size.

4.2.7 Documentation of the EPHA

As with other EPHAs, an analysis addressing biological hazards should be prepared and documented to permit critical review by independent analysts. Detailed descriptions of

methods, assumptions, and models need not be included in the EPHA if they are documented elsewhere and referenced. In addition to the detailed guidance for documenting the EPHA presented in DOE G 151.1-2, it is of particular important to emphasize the possible impact that the hazards will have on determining the size, scale, characteristics of required functions, activities, or components of the emergency management program. This section of the EPHA should characterize those aspects of the hazards that will enable the emergency management staff to tailor the emergency management program to be *commensurate with the hazards*.

4.3 Example Release Scenarios

A limited set of *notional* OE biological release scenarios has been developed for purposes of further illustrating an approach for analysis in the EPHA. Examples of equipment and operations that may create hazards in a biosafety facility can be found in the World Health Organization (WHO) *Laboratory Biosafety Manual*, 3rd Edition.

The scenarios describe possible failures that could lead to a release of hazardous biological materials outside secondary barriers. Eight notional scenarios were developed to demonstrate various operations and event initiators. Scenario narratives are presented in **Appendix A** of this Guide, where the results of the analysis approach provide a general indication of the information needed to develop an effective and prompt response. Analysis is focused on the development of recognition factors and protective actions.

These *notional* scenarios are intended to convey general aspects of the approach *without* incorporating technically accurate, facility-specific details necessary for producing a realistic set of recognition factors and protective actions. Thus, details related to facility design, its relationship to other facilities on the site, and the surrounding geographic, economic, and demographic characteristics are not part of the protective actions to be presented later in this section, especially with regard to the longer-term actions.

4.3.1 Source and Release Parameters

The following is the narrative describing the first scenario contained in Appendix A:

> **Accident Scenario 1: Tube Breakage in Centrifuge (release of B. anthracis spores as an aerosol)**
>
> **Incident**: Two 50 ml tubes containing 40 ml each of $1x10^9$ spores/ml of Bacillus anthracis are placed in a centrifuge. A floor model centrifuge is used outside of the Class II BSC. A hairline crack in one of the centrifuge tubes goes unnoticed, causing the test tube to break early in the centrifuge run, releasing the solution. The technician opens the centrifuge door immediately after hearing the tube break, potentially releasing aerosolized spores (0.1 -1% of the solution = 50,000,000 to 500,000,000 spores or 500 to 5000 times ID_{50} value) into the laboratory environment.

Conditions: The biosafety program requires that all centrifuges be used only in a Class II BSC, since the centrifuges in the facility are not equipped with a HEPA filtration system on the exhaust to the environment outside the biocontainment area.

Because the centrifuge was used outside of the Class II BSC and the facility HVAC system does not have a filtered exhaust, an aerosolized solution containing Bacillus anthracis spores may have been released to the environment outside the biocontainment area. The assumed release duration is 30 minutes, based on evaporation, settling, and an air exchange rate of 10 room-air-exchanges per hour.

Recognition: The possible release of a biological agent into the external environment outside the biocontainment area is the basis for declaring an OE. Recognition indicators include:

- Laboratory personnel observe or discover damage to the test tube and release of the solution of *Bacillus anthracis* spores.

- The centrifuge is used outside the Class II BSC, in violation of laboratory biosafety procedures.

Incident is intended to describe the source, form, activity, *initial* barrier (physically closest to the material), and initiator of the event. Conditions are expected to provide details of other containment barriers or mitigating factors that will fail and subsequently release the material to the environment. Specific transport mechanisms are also indicated. Recognition provides the candidate set of indicators that will represent scenario-specific criteria, which, if satisfied, will result in categorization of the event as an OE.

The eight scenarios from Appendix A are summarized in **Table 4-1** (at the end of this Chapter), which identifies the information/data needed in the key areas that each scenario should identify as part of the EPHA process (from Figure 3-1). Tables in this section are presented to demonstrate a process for collecting and structuring information for analyzing each scenario. ***They do not represent the only acceptable way to collect, organize, and analyze information used to develop recognition tools and initial protective actions.***

4.3.2 Recognition Factors

Recognition of *observed* releases will occur at the facility as the result of direct indicators of the release (e.g., initiating event, barrier failure). In contrast, *unobserved* releases (e.g., unreported infected host, contaminated vectors) could remain undetected for a substantial period of time following the actual facility event. Indirect detection of these events can occur as the result of the employee medical surveillance program or identification of a disease cluster *above expected norms* in the local population by the medical and/or public health community.

Table 4-2 (at the end of this Chapter) contains recognition factors related to the example scenarios in Appendix A. Most of the scenarios relate to *observed* releases. However, as indicated in Appendix A, failure to check operability of a specific system during a facility accident/incident or to identify correlations between observables in some scenarios could result in facility staff not recognizing that a release has actually or potentially occurred and, hence, the event could remain an *unobserved* release. Criteria for *unobserved* releases to be used in epidemiological aspects of the onsite medical surveillance program or for offsite disease surveillance activities are not addressed in this Guide; this task should be addressed at each DOE/NNSA biosafety facility.

A facility-specific analysis will lead to a more definitive set of OE criteria resulting in an OE declaration that would provide the facility with higher level of confidence that an actual or potential release to the environment has occurred. In addition, a *reliable* and *timely* monitoring and detection capability would further enhance the level of confidence.

4.3.3 Initial Protective Actions

Many of the protective actions implemented in radioactive and chemical hazardous materials incidents/situations are generally effective in response to biological agents/toxins releases. Protective action examples in this section address primarily onsite workers in collocated facilities and the offsite public. These examples differ from the agent/toxin-specific medical protective measures (e.g., treatment availability, vaccinations), which are developed at each facility.

Initial protective action examples for biological releases have been defined in Section 3.10, above, to include:

1. Access control
2. Sheltering/shelter-in-place
3. Evacuation
4. Medical surveillance
5. Quarantine
6. Decontamination
7. Vector control
8. Control/disinfection of contaminated water supplies
9. Control of contaminated food products
10. Changes in livestock and agricultural practices

Some of these protective actions, such as vector control, control/disinfection of contaminated water supplies, control of contaminated food products, and changes in livestock and agricultural practices, are generally longer-term measures where *planning can begin in the initial time frame*. Protective actions to be implemented for each scenario will depend on the expected transport mechanisms in the environment. In the

table below, the most commonly implemented protective actions for the biological agent release (using the numbering scheme given above) are identified. The three transport mechanisms in the environment are: 1) Environmental dispersion (i.e., airborne, waterborne); 2) Release via an infected host; and 3) Release via a contaminated person or object. Example initial protective actions and potential longer-term measures (***italics***) are provided for each transport mechanism, as follows:

Transport Mechanism in the Environment	Protective Actions
• Environmental Dispersion	
- Airborne	1 2 3
- Waterborne	1 ***8***
• Infected Host	
- Human	4 5
- Vector	1 3 ***7***
• Contamination	
- Human	6
- Vector	1 3 ***7***
▪ Medium/Objects	
▪ Soil	1 3 6
▪ Water	1 3 ***8***
▪ Agricultural products	***9 10***
▪ Equipment	1 6

The table provides selected protective actions that may be implemented or recommended for the set of scenarios in Appendix A. The protective actions for scenarios presented in **Table 4-3** (at the end of this Chapter) are derived from the above lists. Actual facility-specific protective actions for the set of scenarios would reflect the real situation onsite and offsite (e.g., distances, directions, collated facilities, geographical features, agricultural enterprises).

Note that in some instances, groups of initial protective actions within the set assigned to the scenarios in Table 4-3 appear multiple times. This provides the opportunity to implement generic subsets of initial protective actions (consisting of a number of measures) for a variety of scenarios. This use raises the possibility of developing a simpler and more effective protective action strategy, especially for facilities that may be involved with several agents.

Examples of generic scenario characteristics are presented in **Table 4-4** (at the end of this Chapter). A common **Standard Initial Protective Actions** set is defined in Table 4-4 (a) and two example airborne release scenarios are given in Table 4.4 (b). Associated with each airborne release scenario are candidate protective actions. In the first scenario, the agent is assumed <u>not</u> transmissible and protective actions are based on the Standard Initial Protective Actions. Because the agent is transmissible in the second example

scenario, protective actions include the Standard Initial Protective Actions plus additional measures to be considered as shown in Table 4-4 (b). These examples of initial protective actions are presented for two cases of an airborne release of a biological agent in order to demonstrate the dependence of protective actions on agent characteristics.

Methods presented in this section for developing and implementing protective actions for biological OEs are intended to focus on general concepts and convey a structured process for analysis. ***However, biosafety facility emergency planners should implement an approach best suited for their hazards, the facility, and the emergency management program in place at their location***.

Table 4-1. Source and Release Parameters

Source						Failure(s)			
Scenario	**Agent/Toxin**	**Quantity**	**Form & Activity**	**Containment Barriers**	**Procedures/ Protocols**	**Initiating Event(s)**	**Barrier (Initial)**	**Failure Mode(s)**	**Release Condition(s)**
1	*Bacillus anthracis*	2 tubes with 1 x 10^9 spores each	Spores in solution; being centrifuged	Class II BSC with HEPA filter; PPE; facility design	Centrifuge procedures, Biosafety Program	Failure to follow centrifuge safety protocols	Vial containing spores in solution	Spill/drop caused by the centrifuge tube break	Facility HVAC system picks up aerosolized material then exhausts them to the environment.
2	*Yersinia pestis*	Unknown	Infected laboratory animals in cages	Pest Control Program (e.g., cages, traps, pesticides, training); facility design	Pest Control Procedures, Change Control Procedure	Failure to train contract workers on Pest Control Program	Pest Control Program	Construction personnel fail to cap new cable entries	Uncapped cable entries; feral rodents enter facility, contact infected rodents, fail to be trapped, and escape to environment
3	*Clostridium botulinum* toxin	300 ml with 1 x 10^9 cells per ml	Production of *Botulinum* toxin from spores in solution	Anaerobic jar; Class II BSC with HEPA filter; HEPA filter on HVAC exhaust; PPE; facility design	Procedures for using anaerobic jar in BSC II	Wire capsule is not placed around catalyst causing the anaerobic jar to explode	Anaerobic jar	Shattering of the anaerobic jar	HEPA filter in Class II BSC fails or is not in use; HEPA filter on HVAC exhaust fails or is not in use; air-handling systems on the BSC and the facility draw air from laboratory space and exhaust to the environment.

Table 4-1. Source and Release Parameters (cont'd)

Source						Failure(s)			
Scenario	***Agent/Toxin***	***Quantity***	***Form & Activity***	***Containment Barriers***	***Procedures/ Protocols***	***Initiating Event(s)***	***Barrier (Initial)***	***Failure Mode(s)***	***Release Condition(s)***
4	*Bacillus anthracis*	1 gram ($1x10^{12}$ spores/g)	Experimentation conducted with B. anthracis dry spores in a single container	Container	Facility Biosafety Program, DOE Safety Analysis Program	Earthquake	Container	Container is broken due to shock effects of the earthquake	Loss of power and other damage renders HVAC and BSCs inoperable; loss of building integrity; failure to decontaminate due to perceived danger of collapse
5	*Clostridium botulinum* toxin	0.5 gram	Experimentation conducted with *Clostridium botulinum toxin* as dry powder in a single container	Container	Biosafety Program, DOE Fire Protection Program	Facility fire	Container	Container is broken due to shock effects of being dropped	Facility HVAC system is unfiltered; airborne material is vented to the environment; fire protection system (water) is activated; wastewater discharged through outfall.

Table 4-1. Source and Release Parameters (cont'd)

Source						*Failure(s)*			
Scenario	***Agent/Toxin***	***Quantity***	***Form & Activity***	***Containment Barriers***	***Procedures/ Protocols***	***Initiating Event(s)***	***Barrier (Initial)***	***Failure Mode(s)***	***Release Condition(s)***
6	*Yersinia pestis*	Unknown	Multiple experiments being conducted with *Yersinia pestis* Bacteria in solution	Test tubes and flasks; facility design	Biosafety Program	Explosion of propane truck near facility	Test tubes and flasks	Test tubes and flasks break due to shock effects of the blast	Loss of power and other damage renders HVAC inoperable in BSCs, loss of building integrity (i.e., openings)
7	*Crimean-Congo hemorrhagic fever virus*	Unknown	Infected host being transported	Biosafety cage and transport vehicle	Transportation procedures for infected laboratory animals; protocols for blood borne pathogen protection	Transportation accident	Biosafety cage and transport vehicle	Damage to the transport vehicle and cage, injures the infected laboratory animal causing it to bleed	Responders come into contact with infected blood and violate bloodborne pathogen protection procedures; vectors feed on blood and excrement at scene and become infected

Table 4-1. Source and Release Parameters (cont'd)

Source						*Failure(s)*			
Scenario	***Agent/Toxin***	***Quantity***	***Form & Activity***	***Containment Barriers***	***Procedures/ Protocols***	***Initiating Event(s)***	***Barrier (Initial)***	***Failure Mode(s)***	***Release Condition(s)***
8	*Bacillus anthracis*	Container with 1 gram (approximately $1x10^{12}$ spores)	Dried *Bacillus anthracis* spores in a container set up in a BSC for an experiment	Class II BSC with HEPA filter; PPE; facility design	Centrifuge procedures, Biosafety Program	Malevolent act, disgruntled employee smashes container and discards PPE outside of biocontainment are	Container	Airborne release caused by Malevolent Act Contamination caused by employee violating contamination control procedures	Facility HVAC system picks up aerosolized material then exhausts them to the environment. Contaminated PPE discarded outside of the biocontainment area.

Table 4-2. Recognition Factors

Scenario (Agent/Toxin)	Transmissibility	Transport to Environment	Recognition Factors
1. Tube Breakage in Centrifuge [release of *B. anthracis* spores as an aerosol]	**No (inhalation pathway)**	Airborne dispersion via the ventilation system	The experimenter or other laboratory personnel observe or discover the damage to the test tube and the release of the solution of *Bacillus anthracis*. The centrifuge is used outside the Class II BSC.
2. Failure in Pest Control Program [release of *Y. pestis* bacteria via infected host]	**High**	Infected Host (vector)	Discovery of trapped feral mice within the facility (indicating a potential failure in the pest control program). Discovery of unsealed cable penetrations, which could allow rodents and other vectors direct access to the interior of the facility.
3. A naerobic Jar Explosion [*C. botulinum* bacteria and toxin released as an aerosol]	**No**	Airborne dispersion via the ventilation system	The anaerobic jar explodes in the Class II BSC The HEPA filters in the Class II BSC are non-operational. The HEPA filters in the HVAC system are non-operational
4. Earthquake [release of dried *B. anthracis* spores; airborne, contaminated personnel and fomite transfer]	**No (inhalation pathway)**	Airborne dispersion and transfer of contaminated material	Earthquake occurs and causes significant damage to the facility structure (including creating openings to the environment). The container holding dried Bacillus anthracis spores was reported by personnel involved to have been spilled, releasing the contents to the environment. HEPA filters (Class II BSC, HVAC) are inoperable due to the loss of ventilation flow. Emergency evacuation of personnel from laboratory spaces without following the standard decontamination and disrobing procedures.
5. Facility Fire [airborne and contaminated water release of *C. botulinum* toxin]	**No**	Airborne dispersion through the ventilation system, and water borne release through building outfall	The fire detection system activates fire alarms and the fire suppression system. The researcher handling the toxin reports the spill of the material after exiting the room. Water runoff from the activation of the sprinklers is discharging through the outfall.

Table 4-2. Recognition Factors (cont'd)

Scenario (Agent/Toxin)	Transmissibility	Transport to Environment	Recognition Factors
6. Explosion [release of *Y. pestis* bacteria; personnel contamination and infected host]	**High**	Airborne dispersion Transfer of contamination Infected Host (Human)	The explosion causing visible damage to the facility structure including creating openings to the environment The tubes/beakers containing solutions of *Yersinia pestis* bacteria break and release their contents. The loss of electrical power to the Class II BSCs ventilation and associated HEPA filters.
7. Transportation Accident [arthropod and animal to human transmission of a viral pathogen (*Crimean-Congo hemorrhagic fever virus*)	**Moderate**	Contamination from infected host (animal)	Initial responders initiating protective actions at locations beyond the immediate/affected area
8. Malevolent Act [Disgruntled employee releases dried *B. anthracis* spores]	**No (inhalation pathway)**	Airborne dispersion via the ventilation system Contamination from discarded PPE	Returning laboratory personnel find the discarded PPE outside the containment area. Laboratory personnel discover the smashed container inside the containment area, approximately 30 minutes after the employee leaves the work area. Facility HVAC system is *operating* when the incident is discovered; no mitigative actions took place prior to the arrival of coworkers.

Table 4-3. Example Protective Actions

Scenario (Agent/Toxin)	Transport to Environment	Stability of Agent/Toxin in the Environment	Transport to Receptors	Candidate Protective Actions for Collocated Workers & the General Public
1. Tube Breakage in Centrifuge [release of *B. anthracis* spores as an aerosol]	Airborne dispersion via the ventilation system	The spores are very stable and may remain viable for many years in soil and water. They resist sunlight for varying periods. [High stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Contamination	**1 3 6** *7 8 9 10*
			Infected host (insects, food animals, pets)	**1 3** *7 10*
2. Failure in Pest Control Program [release of *Y. pestis* bacteria via infected host]	Infected Host (vector)	At near freezing temperatures, it will remain alive from months to years but is killed by 15 minutes of exposure to 55°C. It also remains viable for some time in dry sputum, flea feces, and buried bodies but is killed within several hours of exposure to sunlight. [Moderate stability in the environment]	Infected host (insects, food animals, pets)	**1 3** 7 10
			Contaminated animal droppings	**1** 6 *9 10*
3. Anaerobic Jar Explosion [*C. botulinum* bacteria and toxin released as an aerosol]	Airborne dispersion via the ventilation system	The stability of botulinum toxin is not equal in all environments. It is most stable in neutral or alkaline foods. Aerosolized botulinum toxin is estimated to degrade at a rate of 1% to 4% per minute. [High stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Contamination	**1 3 6** *7 8 9 10*
4. Earthquake [release of dried *B. anthracis* spores; airborne, contaminated personnel and fomite transfer]	Airborne dispersion and transfer of contaminated material	The spores are very stable and may remain viable for many years in soil and water. They resist sunlight for varying periods. [High stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Contamination	**1 3 6** *7 8 9 10*
			Infected host (insects, food animals, pets)	**1 3** *7 10*

Table 4-3. Example Protective Actions (cont'd)

Scenario (Agent/Toxin)	Transport to Environment	Stability of Agent/Toxin in the Environment	Transport to Receptors	Candidate Protective Actions for Collocated Workers & the General Public
5. Facility Fire [airborne and contaminated water release of *C. botulinum* toxin]	Airborne dispersion through the ventilation system, and water borne release through building outfall	The stability of botulinum toxin is not equal in all environments. It is most stable in neutral or alkaline foods. Aerosolized botulinum toxin is estimated to degrade at a rate of 1% to 4% per minute. [High stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Waterborne	**1** *8*
			Contamination	**1 3 6** *7 8 9 10*
6. Explosion [release of *Y. pestis* bacteria; personnel contamination and infected host]	Airborne dispersion Transfer of contamination Infected Host	At near freezing temperatures, it will remain alive from months to years but is killed by 15 minutes of exposure to 55^0 C. It also remains viable for some time in dry sputum, flea feces, and buried bodies but is killed within several hours of exposure to sunlight. [Moderate stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Contaminated animal droppings	**1** 6 *9 10*
			Infected host (insects, food animals, pets)	**1 3** *7 10*
			Infected host (human)	**1 3 4 5 6**
7. Transportation Accident [arthropod and animal to human transmission of a viral pathogen (CCH)]	Contamination from infected host	The virus is rather fragile and does not survive well outside the host. It is rapidly killed by ultraviolet light. It is very stable in the tick vector and infected ticks remain infected throughout their lives. [No stability in the environment]	Contamination caused by direct contact with fluids from an infected host	**1 4 5 6**
			Infected host (insects, food animals, pets)	**1 3** *7 10*
8. Malevolent Act [Disgruntled employee releases dried *B. anthracis* spores]	Airborne dispersion via the ventilation system Contamination from discarded PPE	The spores are very stable and may remain viable for many years in soil and water. They resist sunlight for varying periods. [High stability in the environment]	Inhalation through airborne dispersion	**1 2 3**
			Contamination	**1 3 6** *7 8 9 10*
			Infected host (insects, food animals, pets)	**1 2 3** *7 10*

Table 4-4. Examples of Generic Initial Protective Actions

(a) Standard Initial Protective Actions

Standard Initial Protective Actions
Access control: Control of personnel access to areas of potential exposure and/or contamination outside the biocontainment area to prevent unnecessary exposures and minimize the spread of contamination. Access control is most effective when implemented immediately upon recognizing that an area has been, or will be, affected by a hazardous material release.
Sheltering/Shelter-in-place: Directing people to seek shelter inside a building or similar location and to remain inside until the threat of exposure at dangerous levels passes. Shelter-in-place means directing people to stay inside at their current locations until the threat of dangerous exposure passes. Sheltering/shelter-in-place is used when evacuating collocated workers and/or the public would cause greater risk than staying where they are, or when an evacuation cannot be performed.
Evacuation: Moving all people from a threatened area to a safer place. To perform an evacuation, there must be enough time for people to be warned, to get ready, and to leave an area. If there is enough time, evacuation is the best protective action. Evacuees should be sent to a definite place, by a specific route, far enough away from the incident site so they will not have to be moved again if the wind shifts.
Decontamination: The removal of hazardous material from personnel and equipment to the extent necessary to prevent potential adverse health effects. Contaminated clothing and equipment should be removed after use and stored in a controlled area until cleanup procedures can be initiated. Decontamination also applies to removal of hazardous materials that may have been deposited on the ground and on other structures in the vicinity of the release.

(b) Airborne Release Scenarios

1. Airborne Release of a biological agent; the agent is <u>not</u> transmissible.
Standard Initial Protective Actions
2. Airborne Release of a biological agent; the agent is transmissible.
Standard Initial Protective Actions
Quarantine: Separation and restriction of movement of persons, who while not yet ill, have been exposed to a transmissible biological agent and therefore may become infectious. Since quarantine may sometimes require long periods of time pending definitive laboratory results, considerations for support of personnel may include food, water and diversionary activities.
Medical Surveillance: Immediate and active medical surveillance activities, including a process to *identify*, *screen, test, and assess* people who are most likely to have been exposed. Based on medical surveillance results, identify candidates for monitoring and/or treatment.

5. EMERGENCY MANAGEMENT PROGRAM FOR BIOSAFETY FACILITIES: *PROGRAMMATIC ELEMENTS*

The technical details necessary for establishing programmatic activities for developing, implementing, and maintaining the emergency management program depend on the documented "technical planning basis" contained in the Hazards Survey and EPHA described in the previous chapter. Guidance in this chapter will emphasize integration of the requirements of the Select Agent Rules with DOE/NNSA programmatic requirements (i.e., planning, preparedness, and readiness assurance) for hazardous biological materials and with an existing site emergency management program. Documentation of these program elements in the Emergency Plan or program descriptions should clearly characterize the role of tailoring in applying commensurate with hazards.

5.1 Program Administration

DOE O 151.1C directs that effective organizational management and administrative control of a facility emergency management program be provided by establishing and maintaining authorities and necessary resources commensurate with the associated responsibilities to plan, develop, implement, and maintain a viable, integrated, and coordinated program. This program administration element identifies the functions and activities that should be implemented and effectively maintained to ensure that emergency management programs at facilities/sites comply with both ***Base Program*** and ***Hazardous Material Program*** requirements contained in DOE O 151.1C.

Contractors at all DOE/NNSA facilities must designate a qualified individual to administer the emergency management program. This administrator should develop and maintain the emergency plan, develop related documentation, develop the Emergency Readiness Assurance Plan (ERAP) and annual updates, develop and conduct training and exercise programs, coordinate readiness assurance assessment activities, and coordinate emergency management resources.

An individual or entity (facility) required to register under the Select Agent Rules also must designate an individual to be the ***Responsible Official (RO)*** with the authority and control to ensure compliance with the Select Agent Rules. According to the Select Agent Rules, the RO should:

- Have authority and responsibility to act on behalf of the entity.
- Ensure compliance with the requirements of the Select Agent Rules.
- Ensure that annual inspections are conducted for each facility/laboratory where Select Agents or Toxins are stored or used in order to determine compliance with the Rule requirements. Results of each inspection should be documented and any deficiencies identified during an inspection should be corrected.

In order to facilitate the seamless integration of CDC/APHIS incident response requirements with DOE/NNSA biosafety facility emergency management requirements and guidance, it is recommended that the designated **RO** also have overall responsibility for implementing and maintaining the emergency management program as the biosafety facility emergency management program administrator. As such, the designated administrator/official has responsibility for program administration tasks that involve compliance with Select Agent Rule requirements and existing DOE/NNSA emergency management policy as expressed in DOE O 151.1C, with its companion guidance in the DOE G 151.1-series. This dual responsibility includes:

- Development of a specific integrated comprehensive emergency management and incident response program based upon a graded approach commensurate with the hazards. An integrated response program should include response to incidents involving hazardous biological materials as well as response to other identified site hazards.

- Development of an Emergency Plan (including Select Agent Rule ***Incident Response Plan*** requirements) to fully describe facility response to incidents involving "theft, loss, or release of a Select Agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc." The emergency plan should account for hazards associated with Select Agents/toxins and should detail appropriate actions for containing such materials.

- Documentation of the comprehensive emergency management program in the Emergency Plan to describe provisions for biosafety facility response to OEs and, specifically, provisions for response to an OE involving the release of a biological agent or toxin from the biosafety biocontainment.

- Development of Emergency Plan Implementing Procedures (EPIPs) to describe how the emergency plan should be implemented.

- Development of training, drill, and exercise programs for hazardous biological materials response. These programs should be coordinated and integrated with existing facility/site emergency response programs to prevent conflict with other activities and to ensure that resources are available.

- Oversight by the emergency management program administrator of biosafety program implementation and maintenance, especially ***routine surveillance*** of biosafety protocols and practices, safety equipment, and systems that represent an integral component of the safety and emergency management programs.

Other specific requirements are contained in the Select Agent Rules and DOE O 151.1C.

The primary task of the administrator is to ensure the program is effectively implemented and maintained by directing and monitoring functions/activities. Tasks of the emergency management program administrator can be extensive, covering the breadth of the

program. However, delegating functions and activities or integrating them with site-wide emergency management programs may satisfactorily accomplish these requirements.

The administrator should ensure that DOE/NNSA biosafety facilities review all emergency preparedness documents, such as plans, procedures, scenarios, and assessments for classified information using current classification guidance. If documents such as EPHAs do not contain classified information, the emergency management program administrator reviews them to determine if the documents contain Official Use Only (OUO) information.

Additional guidance related to general aspects of Program Administration can be found in DOE G 151.1-3, Chapter 1.

5.2 Training and Drills

DOE O 151.1C directs that a comprehensive, coordinated, and documented program of training and drills be developed as an integral part of the emergency management program to ensure that preparedness activities for developing and maintaining program-specific emergency response capabilities are accomplished. The program should apply to emergency response personnel and organizations the facility/site expects to respond. Emergency-related information needs to be available to offsite response organizations.

Training and drill tasks for DOE/NNSA facilities/sites with biological agents and/or toxins involve integration of Select Agent Rule training requirements with existing emergency management training policy given in DOE O 151.1C. For those DOE/NNSA biosafety facilities registered under the Select Agent Rules, facilities containing biological agents/toxins should provide incident response information and training to each individual approved for access to the facility. All workers required to take protective actions (e.g., assembly, evacuation, shelter) are to be provided the appropriate hazard-specific training for their responsibilities and periodic drills. Training should address particular needs of the individual, the work they will do, and risks posed by the Select Agents or Toxins. Symptom-specific awareness training should be provided for all personnel.

Routine surveillance of experience and skill levels of personnel in at-risk positions, such as laboratory technicians/workers and maintenance, housekeeping, and animal care personnel, needs to be maintained. Monitoring of biosafety facility activities will identify additional training and education necessary to ensure the safety of persons working at each BSL. Establishment of a regular education/recertification process is essential to ensure the safety of all personnel at the location/activity.

Refresher training should be provided annually. A record of the training provided to each individual working in biosafety facilities should be maintained, including name of the individual, date and description of the training, and means used to verify that the employee understood the training.

Training and drills for hazardous biological agents/toxins should be hazard-specific, and address two generic response scenarios. The first is the *observed* release scenario based on observed facility accidents and initiating events. The second is the *unobserved* release scenario based on recognition through medical surveillance. Training and drills for both should involve onsite medical personnel; offsite public health officials and community medical personnel should be invited to participate regularly.

General guidance for developing, conducting, and recording training and drills activities can be found in DOE G 151.1-3, Chapter 2.

5.3 Exercises

DOE O 151.1C requires all elements of an emergency management program be validated over a multi-year (5 years) period through a formal exercise program. The exercise program validates facility- and site-level emergency management program elements by initiating response to simulated, realistic emergency events/conditions replicating an integrated emergency response to an actual event as nearly as possible. Planning and preparation should use a structured approach that includes documentation of specific objectives, scope, timelines, injects, controller instructions, and evaluation criteria for realistic scenarios. Each exercise should be conducted, controlled, evaluated, and critiqued. A critique process should be established to include gathering and documenting observations of participants. Corrective action identified in the critique process should be incorporated into the emergency management program.

Similarly, the Select Agent Rules require that drills or exercises be conducted at least annually to ***test and evaluate*** effectiveness of the emergency plan. A lessons-learned and corrective actions program should also be implemented if no site-wide program is available. After any drill, exercise, or incident, the emergency plan should be reviewed and revised as necessary. Further guidance related to evaluations, lessons learned, and corrective actions can be found in DOE G 151.1-3, Chapter 4, *Readiness Assurance*.

As part of a site-wide emergency management program, DOE/NNSA biosafety facilities should conduct annual building evacuation exercises consistent with Federal regulations, local ordinances, and National Fire Protection Association (NFPA) Standards. Communications systems should also be tested at least annually with DOE Headquarters, Cognizant Field Element, and offsite agencies. Site-level emergency response organization elements and resources need to participate in a minimum of one exercise annually. For multiple-facility sites, the biosafety facility should be the basis for the site exercise, in its turn, as part of the rotation among facilities; the integration of its response to hazardous biological releases with the site-wide emergency program should be tested and demonstrated.

Each biosafety facility needs to exercise its emergency response capability annually and include at least facility-level evaluation and critique. Evaluations of annual facility exercises by Departmental entities should be performed periodically so that each facility has an external Departmental evaluation at least every 3 years.

The exercise program for DOE/NNSA biosafety facilities should be hazard-specific and address the two generic types of scenarios, *observed* and *unobserved* releases. These exercises should involve onsite medical personnel and, if possible, offsite public health officials and community medical personnel. Although DOE O 151.1C only requires offsite response organizations be invited to participate in site-wide exercises once every 3 years, the essential role of the offsite response in the case of biological releases suggests that more frequent participation is desirable and should be encouraged.

Further guidance for developing and conducting exercises can be found in DOE G 151.1-3, Chapter 3.

5.4 Readiness Assurance

As required by DOE O 151.1C, a Readiness Assurance program for emergency management provides a framework and associated mechanisms to assure emergency plans, implementing procedures, and resources are adequate and sufficiently maintained, exercised, and evaluated (including assessments and appraisals). The Order requires appropriate and timely improvements to be made in response to needs identified through coordinated and comprehensive emergency planning, resource allocation, training and drills, exercises, and evaluations.

As indicated in Section 6.3, below, the Select Agent Rules require that drills or exercises be conducted to ***test and evaluate*** the effectiveness of the emergency plan. In addition, the HHS Secretary is allowed to inspect any biosafety facility at which activities regulated by the Select Agent Rules are conducted. Prior to issuing a certificate of registration to an individual or facility (entity), the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with the Rules.

A Readiness Assurance program consists of evaluations, improvements, and ERAPs. The biosafety facility emergency management program is subject to internal and external program and exercise evaluations. Routine surveillance of biosafety protocols and practices, safety equipment, and systems provides assurances that required maintenance, equipment tests, certifications, inspections, reviews, and other activities intended to maintain laboratory control measures at high performance levels, are accomplished as required. Skill level and training for at-risk personnel should also be monitored to provide assurances that a high level of performance is maintained and to ensure the safety of laboratory personnel. A structured and comprehensive approach to these surveillance activities can provide an effective tool for sustaining a continuous process of self-assessment.

Other components of a Readiness Assurance program involve reliable improvement and lessons-learned programs. Of particular importance for biosafety facilities is a system for incorporating and tracking lessons learned from internal training, drills, and actual responses, as well as from external sources. Mutual sharing of lessons-learned among similar BSL laboratories in DOE/NNSA, academic institutions, and private industry is expected to increase, as biosafety emergency management becomes a more mature discipline.

Other topics such as performance indicators, No-Notice Exercises, and ERAPs are discussed in detail in the guidance contained in DOE G 151.1-3, Chapter 4.

6. EMERGENCY MANAGEMENT PROGRAM FOR BIOSAFETY FACILITIES: *RESPONSE ELEMENTS*

The technical details necessary for establishing programmatic activities for developing, implementing, and maintaining the emergency management program depend on the documented "technical planning basis" contained in the Hazards Survey and EPHA described in Chapter 4. Guidance in this chapter will emphasize integration of the requirements of the Select Agent Rules with DOE/NNSA response requirements for hazardous biological materials and with an existing site emergency management program. Documentation of these program elements in the Emergency Plan or program descriptions should clearly characterize the role of tailoring in applying commensurate with hazards.

6.1 Emergency Response Organization (ERO)

The Emergency Response Organization (ERO) is a structured organization with overall responsibility for the initial and ongoing response to and mitigation of OEs at DOE/ NNSA facilities/sites or activities. Positions and associated functions of the ERO response structure are based on capabilities needed for each specific emergency situation. The ERO establishes effective control at the event/incident scene and integrates local agencies and organizations providing onsite response services. An adequate number of experienced and trained primary and alternate response personnel should be available on demand for the timely and effective performance of ERO functions.

The emergency management program administrator [e.g., Responsible Official (RO)] at a DOE/NNSA biosafety facility should be responsible for establishing and maintaining the facility-level component of the site-wide ERO. This is not meant to suggest that the RO has overall responsibility for the site *response* during a biological OE. This site-specific ERO responsibility during an emergency response [e.g., Emergency Director (ED)] should be determined locally.

Select Agent Rules require incident response plans to contain personnel roles and lines of authority for the biosafety facility incident response, information necessary for the development of the biosafety ***facility-level*** component of an ERO structured to respond to a biological release. A facility with biological agents and toxins will require positions and roles for personnel from the biological health and safety program and an expanded role for the site medical staff. The integration of these facility-level ERO positions with the site-level ERO will require that position qualifications and personnel requirements be formalized and responsibilities and authorities of each be detailed in the site emergency plan and procedures for response to OEs. These positions are added to the ERO call lists for response to biological releases.

Personnel from the biological health and safety program and laboratory personnel (i.e., facility personnel such as microbiologists and toxicologists) who are familiar with the facility and the hazards should be available to provide their technical and subject

matter expertise as members of the ERO. The onsite medical staff should be part of the established medical surveillance program, utilized to detect and recognize symptoms of illnesses and toxic effects on workers and/or the public following a biological release. This staff will ultimately partner with the Tribal, State and local medical and public health agencies to support initial and ongoing activities during a response. Depending on the local situation and agreements, a position on the ERO might be considered for the offsite public health authority. The medical staff will provide the technical expertise that supports the Consequence Assessment Team (CAT) similar to the support provided by health physics and industrial hygiene staff in response to a radiological or chemical release.

Further detailed guidance related to ERO organizational structure, roles, and responsibilities is contained in DOE G 151.1-4, Chapter 1.

6.2 Offsite Response Interfaces

DOE O 151.1C requires effective interfaces be established and maintained to ensure that emergency response activities are integrated and coordinated with Federal, Tribal, State, and local agencies and organizations responsible for emergency response and the protection of workers, the public, and the environment. In addition, the Select Agent Rules require that incident response plans include planning and coordination with local emergency responders.

In the case of hazardous biological materials, offsite response interfaces should be established with first responders [e.g., hazardous material (HAZMAT) teams] and external agencies that have public health and/or agricultural incident response roles. Agencies and organizations may include but are not limited to HHS/CDC, USDA/APHIS, and State and local public health or agricultural organizations, and, in some cases, local medical providers and veterinarians. Depending on specific arrangements for the DOE/NNSA site, local HAZMAT responders and/or fire and medical resources may provide primary or backup response to site emergencies. In either situation, interfaces need to be established and plans developed for coordination during an onsite response. All offsite response agencies expected to respond to a biological OE should also be offered the opportunity to participate in facility/site drills and exercises that involve potential releases of hazardous biological materials.

Local initial responders should be informed of the presence of hazardous biological materials at DOE/NNSA facilities, as is routinely done with all classes of hazardous material. DOE emergency planners should provide specific information (specific, but within the constraints of security) and/or offer training on the nature and characteristics of the specific biological agents and/or toxins present at the DOE/NNSA facility. Local responders should be informed whether vaccines are available as a prophylaxis against facility-specific hazardous biological materials. They should be informed of appropriate PPE, provided information on effective decontamination methods, and provided information for contacting experts on the agents/toxins.

State and local agencies and organizations responsible for the identification of public health emergencies may ultimately take the lead in response, especially if the emergency becomes an offsite public health emergency or involves an agricultural incident. Many of these agencies have developed emergency plans and response procedures that relate to bioterrorism or naturally occurring epidemics but do not contain specific reference to local biosafety facilities. DOE facilities/sites that have biological agent/toxins should interface with these agencies and coordinate their planning activities; especially to:

- Provide guidance for detecting disease outbreaks or toxic effects by identifying the symptoms (presented by people or animals) associated with the facility-specific agents and toxins.

- Establish a mutual understanding of response measures to be implemented by the facility/site in anticipation of involvement of local and State public health agencies or agricultural authorities.

Local medical and academic communities may provide a backup capability for responding to an outbreak. A DOE/NNSA biosafety facility may develop this capability by contacting the appropriate local infectious disease physicians, veterinarians, and/or agricultural expertise to identify personnel who may be willing to respond if needed.

While some of the areas of expertise needed are different than those required for other hazardous materials response, coordination and interface functions are very much the same. Most DOE sites will have an established offsite interfaces organization that will provide the vehicle for implementing and maintaining additional biological-specific interfaces. DOE/NNSA facilities with select biological agents and/or toxins can find further general guidance for developing and maintaining interfaces in DOE G 151.1-2, Chapter 2.

6.3 Emergency Facilities and Equipment

DOE O 151.1C requires that facilities and equipment adequate to support emergency response be available, operable, and maintained. Specifically, DOE/NNSA sites are responsible for ensuring that an adequate and viable command center is available, as necessary, and PPE are available and operable to meet the needs of the responders. A command center dedicated solely to biological OEs is ***not*** necessary, but an identified command center onsite should be fully prepared to respond to a hazardous biological release. Also, provisions should be established for the use of an alternate location if the primary command center is not available. If a Hazardous Material Program is in place at the site, then a command center and alternate have already been established/designated.

Select Agent Rules require that the incident plan provide lists of PPE and emergency equipment and their locations. Response equipment and facilities need to support actions to contain hazards associated with facility-specific agents or toxins. Medical treatment and decontamination equipment should also be available for supporting the response. These requirements are entirely consistent with the expectations of DOE O 151.1C requirements and guidance.

All DOE/NNSA biosafety facilities should provide and maintain equipment to notify its employees of an emergency to facilitate their safe evacuation from the workplace, immediate work area, or both. Communications equipment should be kept in operational condition and tested at least annually. Biosafety equipment should be monitored and maintained regularly to ensure it will provide barriers and containment intended to prevent unacceptable releases to the environment. Routine surveillance of safety equipment and systems provides assurances that required maintenance and equipment tests are accomplished as required.

Note that it is ***not*** the intent of this section to support the purchase of new equipment or capabilities, if the current situation adequately supports the needs of emergency response *commensurate with the hazards*. DOE/NNSA facilities with Select Agents/Toxins can find further general guidance for identifying, implementing, and maintaining emergency facilities and equipment in DOE G 151.1-4, Chapter 3.

6.4 Emergency Categorization and Classification

DOE/NNSA biosafety facilities that have quantities of Select Agents/Toxins could experience major events or conditions involving or affecting these inventories that have the potential to cause serious health and safety impacts to collocated workers or the public. Unlike events involving other types of hazardous materials, OEs declared for release of hazardous biological agents and toxins will not be classified as Alert, Site Area Emergency, or General Emergency. They will, however, be categorized as OEs. Event categorization initiates the dissemination of information about an OE so that proper response actions can be initiated at all levels of DOE/NNSA and other Federal, Tribal, State, and local organizations and authorities. The capability needs to exist at a biosafety facility to perform categorization promptly and reliably for actual or potential releases to the environment.

All DOE/NNSA biosafety facilities should establish criteria or indicators for determining quickly if an event is a biological release OE. An OE will reflect the condition that the release is outside of the biosafety facility, defined as outside the secondary barriers of the biocontainment area. This definition is applicable for either the *observed* or *unobserved* release.

The onsite medical surveillance program for facility workers should be closely tied to the biosafety program and should have ready access to data related to agents/toxins in the biocontainment and to the associated criteria for recognizing OE based on disease characteristics/symptoms or toxic effects. Offsite surveillance activities, on the other hand, will require that the biosafety facility share similar criteria (or recognition factors) related to the agents/toxins being stored or used onsite. These indicators should be available at the offsite surveillance location to initiate prompt notifications back to the facility/site if a possible outbreak might be traced to a release from the facility. An OE would then be declared by the facility based on this communication from offsite. Discretionary criteria for declaring a biological OE should be available to the person with categorization authority. Such criteria will enable the authority to declare an OE based

on circumstances that are not covered under the existing program technical planning basis.

Predetermined conservative onsite protective actions and offsite protective action recommendations should be associated with the categorization of these OEs. Further general guidance related to recognition and categorization is available in DOE G 151.1-4, Chapter 4.

6.5 Notifications and Communications

Upon recognition of an OE, DOE O 151.1C requires that prompt, accurate, and effective initial emergency notifications be made to workers and emergency response personnel/ organizations, including appropriate DOE/NNSA elements, and other Federal, Tribal, State, and local organizations and authorities. Accurate and timely follow-up notifications should also be made when conditions change or the emergency is terminated. Continuous, effective, and accurate communications among response components and/or organizations should be reliably maintained throughout an OE.

The authorized official needs to notify the Cognizant Field Element Emergency Operation Center (EOC) and Headquarters Operations Center within 30 minutes of the declaration of an OE. In addition, notifications should be made to local, State, and Tribal response organizations within 30 minutes or as established in mutual agreements with these entities. For biological OEs, the local and State response organizations should include local and/or State public health organizations, based on prior agreements.

According to the Select Agent Rules, upon discovery of a release of an agent or toxin causing occupational exposure or release of a Select Agent or Toxin outside the primary barriers of the biocontainment area, an individual or entity needs to immediately notify CDC or APHIS. Since a release outside primary barriers of the biocontainment area precedes a release outside of secondary barriers, the above notifications to CDC/APHIS apply to the associated OEs.

At a minimum, emergency notification to the Headquarters Operations Center should consist of a phone call providing as much information as is known at the time. The verbal notification to Headquarters must be accompanied (before or after) by written or electronic (fax or e-mail) notification containing the same information. The following is an example initial notification format for a biological release OE that incorporates both DOE O 151.1C and CDC/APHIS requirements:

1. An **Operational Emergency** has been declared;

2. Description of the **Operational Emergency** –

   - Name of the Select Agent or Toxin and any identifying information (e.g., strain or other characterization information);

   - Estimate of the quantity released;

- Duration of the release;
- Environment into which the release occurred (e.g., in building or outside of building, waste system);
- Location (building, room) from which the release occurred; and
- Hazards posed by the release.

3. Date and time the emergency was discovered;
4. Damage and casualties or the number of individuals potentially exposed at the facility (entity);
5. Whether the emergency has stopped other facility/site operations or program activities;
6. Protective actions taken and/or recommended;
7. Notifications made;
8. Weather conditions at the scene of the emergency;
9. Level of any media interest at the scene of the emergency or at the facility/site; and
10. Contact information of the DOE/NNSA on-scene point of contact.

All DOE/NNSA biosafety facilities should include communications planning for an OE in the Emergency Plan (*Incident Response Plan*). Additional notification and communication requirements can be found in DOE O 151.1C and further general guidance is contained in DOE G 151.1-4, Chapter 5.

6.6 Consequence Assessment

DOE O 151.1C requires that biosafety facilities establish provisions to assess the potential or actual onsite and offsite consequences of an OE involving the release of hazardous biological material(s). These assessments, related to the event consequences, should:

1. Be timely throughout the emergency
2. Be integrated with the protective action process
3. Incorporate monitoring of specific indicators and field measurements, as available
4. Be coordinated with Federal, Tribal, State, and local organizations

Traditional activities associated with the consequence assessment program *immediately following an actual or potential release* and *continuing during an OE* are usually based on determining the area impacted by different levels of either doses or concentrations for

airborne radioactive or toxic chemical releases, respectively. The consequence assessment process provides the means for updating estimates of consequences as additional information is obtained. The full process is normally focused on OEs that require *classification*. The consequence assessment process needs to be integrated with the classification and protective action process to provide a periodic review of measures implemented to protect workers and the public.

In contrast, calculations for an airborne release of a biological agent/toxin may not be available or reliable. Since there is no unique measure of severity for adverse health effects associated with biological agents, a determination of dose contours (e.g., ID_{10}, ID_{50}) may provide sufficient information to estimate criteria for making safety determinations. The protective action process can be integrated with this assessment method to review the actions taken to protect workers and the public. For some airborne biological sources, calculations may not be possible or reliable and, hence, even infectious dose contours may not be available. In that case, data that influence airborne dispersal of materials should be accessed and best estimates of protective action parameters should be obtained.

For transport mechanisms other than airborne releases, consequence assessment can involve an approach that applies only to biological agents, namely, an analysis of disease outbreaks. In this case, release of a biological agent in a human host could be suspected because of control failure indicators or there may be no reason to suspect a release. In either case, an *unobserved* release may not be confirmed or discovered until symptoms caused by the released biological material begin to appear in persons presenting themselves for treatment at site or local health care facilities. Efficient discovery of a possible release involves methods of detection that rely on epidemiological modeling and medical expertise, which are normally conducted by local and State public health departments. As discussed in Section 4.2, above, to ensure a prompt response, the local public health agencies and DOE/NNSA biosafety facility should agree to pre-determined criteria that would initiate prompt notification of the facility in the event that a local outbreak is detected and the facility is potentially the source of the release.

In most circumstances involving biosafety facilities, the primary role of the consequence assessment process for releases of biological agents will ultimately involve the confirmation that a release to the environment has occurred. Such a role is essential for verifying that the release occurred and for initiating measures onsite to ensure that the release has stopped and the situation that led to the release is corrected. The Timely Initial Assessment (TIA), which provides the initial event and consequence assessment by the CAT, will develop the first description of the event (*observed* event) required for the initial notification of CDC/APHIS. The continuing confirmation process will depend on periodic review of information from the event scene and the results of biological material detection techniques. Unless *direct* detection devices are available, the CAT will depend on laboratory analyses for monitoring the release, which may take an extended period of time. As event information is gathered and the event is reconstructed, the consequence assessment process will combine the event analysis with laboratory results to confirm or deny the release of an agent/toxin.

A general description of the consequence assessment process can be found in DOE G 151.1-4, Chapter 6.

6.7 Protective Actions and Reentry

According to DOE O 151.1C, protective actions should be promptly and effectively implemented or recommended for implementation, as needed, to protect health and safety of workers, the public, or the environment. Protective actions can be implemented individually or in combination to reduce exposures from hazardous materials, are reassessed throughout an emergency, and modified as conditions change. In addition, reentry activities should be planned, coordinated, and accomplished *properly* and *safely*.

All DOE/NNSA facilities should be prepared to execute general protective actions, such as evacuation or sheltering of employees, along with provisions to account for employees after emergency evacuation has been completed. Employees in a biosafety facility collocated with other Operational Emergency Hazardous Material Programs should also be prepared to respond to notifications to implement protective actions in the event of hazardous material releases from other facilities.

Protective actions to be implemented or recommended for biological OEs will likely be a combination of general protective actions and specific measures that depend on the agent transport mechanism, characteristics, and the associated disease. General protective actions might include evacuation, accountability, access control, and sheltering. The Select Agent Rules Emergency Plan (*Incident Response Plan*) requirements include a description of the procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge. (Section 4.7, above, provides an introduction to the determination of initial protective actions for biological OE events.)

Specific protective measures may also depend on characteristics of the agent and associated disease. These protective actions may include PPE, decontamination, quarantine, and medical prophylaxis. Selection of these measures will depend on agent/disease characteristics, including: stability in the environment, transmissibility, and infectivity.

The EPHA will provide release scenarios that can be used to establish ***initial protective actions*** implemented when OE categorization criteria are met. The nature of most biological release scenarios and the lack of a PAC will likely preclude detailed technical consequence estimates traditionally used for establishing areas of possible exposure and contamination. For example, the facility may only develop a best estimate radial distance and use the current wind direction to *focus* initial protective actions for actual or potential airborne releases. These specific *initial protective actions* should be developed with the cooperative involvement of facility and site experts representing a broad scope of interested functions, including Operations, Safeguards and Security (S&S), medical, and safety/biosafety, in addition to emergency management analysts. Of particular importance is the cooperation and active assistance of medical personnel and biosafety experts who provide essential expertise for assessing agent/toxin characteristics.

Planning and development of initial protective actions requires a coordinated effort between DOE/NNSA site medical personnel and offsite public health agencies. Site medical personnel should coordinate protective action planning with the local/State public health agency to ensure that initial measures taken by the site or recommendations for offsite are consistent with the expectations of local/State public health authorities.

Reentry is a planned emergency response activity directed by the ERO to accomplish a specific objective(s). Reentry activities are time-urgent, performed during an emergency response, and include such activities as search and rescue, hazard mitigation, damage control, and accident assessment. Some activities performed during reentry may involve entering a facility or affected area in which hazardous biological materials may have been released. For this reason, reentry has been included with protective actions since the protection of emergency workers involved in the activities is an essential component of reentry planning. The same considerations involving agent/toxin characteristics used in determining protective actions will guide planning for these potentially dangerous activities by the determination of guidelines for controlling exposures in various types of emergency situations. Procedures to be followed in performing these reentry activities should be part of the Emergency Plan according to the applicable Select Agent Rules.

Further policy and guidance related to protective actions and reentry can be found in DOE O 151.1C and in DOE G 151.1-4, Chapter 7.

6.8 Emergency Medical Support

DOE O 151.1C requires that medical support be available and provided to injured workers (potentially) contaminated by hazardous biological materials. Arrangements with offsite medical facilities to transport, accept, and treat contaminated, injured personnel should be established and documented.

Both onsite and offsite medical organizations need to develop plans and procedures for responding to OEs involving hazardous biological agents and/or toxins. The following are key recommendations for these plans and procedures:

- Identify responsibilities for medical surveillance and reporting
- Develop surveillance plans for detecting unusual medical events
- Involve the veterinary profession in surveillance activities, as appropriate
- Establish key indicators and medical surveillance baselines for each agent/toxin
- Enhance epidemiological capability to detect and respond
- Enhance training for health care professionals regarding the biological agents/toxins present
- Install an information system for patient monitoring, management, and tracking

- Ensure that procedures are in place for rapid and effective communications among public health officials, emergency rooms, law enforcement, and emergency management officials about unusual biological events

- Provide symptom specific awareness training for all personnel and coordinate a central reporting process for ongoing medical surveillance

During an event involving the release of hazardous biological material, medical personnel will assume a primary role as responders. Medical personnel will assist in release detection/confirmation, consequence assessment, and development of protective actions. A key to an effective medical response for health safety is advance knowledge of personnel susceptibility and on-hand or rapid access to both treatment and prophylactic doses. An ongoing active medical surveillance system onsite tied into the local health community and including a method for post-OE exposed personnel tracking and testing, with rapid pharmaceutical administration, is essential. Depending upon the lethality of the virus involved, an aggressive ongoing surveillance program can positively affect morbidity and mortality rates post-exposure in an OE.

Stopping or preventing the spread of a rare disease in the first hours after it is detected in the community or after exposure of site personnel to the agent may require rapid access to vaccines, antibiotics or other specialized medicines and supplies. Sources for these specific materials (regional medical centers, national stockpiles, etc.) and the means for obtaining them (points-of-contact, release protocols, etc.) should be detailed in the Emergency Plan to ensure that they can be accessed without delay in an emergency.

Further requirements and guidance related to emergency medical support following OEs involving hazardous biological materials can be found in DOE O 151.1C and DOE G 151.1-4, Chapter 8.

6.9 Emergency Public Information

DOE O 151.1C requires that accurate, candid, and timely information be provided to workers, the news media, and the public during an emergency to establish facts and avoid speculation. Emergency public information efforts should be coordinated with State, Tribal, and local governments and are part of Federal emergency response plans, as appropriate. Workers and the public should be informed of emergency plans and planned protective actions before emergencies occur.

The same guidance regarding the development of emergency public information for other hazardous material classes will apply to biological agents and toxins. Medical and biosafety personnel should be involved in development of materials to be used in news releases to ensure that characterization of the hazard is conveyed accurately. The role of emergency public information in ensuring that the public has a clear understanding of protective actions and subsequent public health activities suggests that pre-planning activities between emergency public information, site medical officials, the Responsible Official, and local/state public health authorities (as appropriate) are essential for an effective response.

The appropriate official should review public announcements in areas involving classified or unclassified controlled information before release. However, in situations involving classified or unclassified controlled information, the official should provide sufficient publicly releasable information to explain the emergency response and protective actions required for health and safety of workers and the public.

DOE/NNSA facilities/sites with hazardous biological agents and/or toxins should follow the policy in DOE O 151.1C and guidance in DOE G 151.1-4, Chapter 9.

6.10 Termination and Recovery

According to DOE O 151.1C, an OE is terminated only after a predetermined set of criteria is met and the termination is coordinated with offsite agencies. Recovery from a terminated OE involves communication and coordination with State, Tribal, local, and other Federal agencies; planning, management, and organization of the associated recovery activities; and ensuring health and safety of workers and the public.

Termination is the declared conclusion of an OE. Formal termination of emergency response should be considered when conditions at the incident scene and other impacted areas are sufficiently well defined and stable that the capabilities of the entire ERO are no longer needed to manage the situation. The decision to terminate emergency response and the subsequent notification of all involved Federal, Tribal, State, and local organizations mark the beginning of ***recovery***.

Termination criteria for hazardous biological material release OEs will be similar to OEs that require classification (i.e., as Alert, Site Area Emergency, and General Emergency), such as the release of toxic or radioactive materials. The decision to terminate a biological OE will be based on the ***perceived need for the ERO to remain fully active to monitor and manage the situation***. In this case, termination is essentially a declaration that the full ERO is no longer needed and the ERO may now begin to reduce its support.

The decision to terminate emergency response should be made with the concurrence of the principal participating response organizations. General criteria should be developed that, when met, will allow the authorized official to declare the emergency response phase terminated and to initiate accident recovery. For biological agents and toxins, the decision to terminate an emergency and begin recovery planning will involve active participation of onsite medical personnel and offsite *public health agencies*.

Recovery from a biological release OE can involve significant coordination with local and State public health organizations, and possibly with CDC/APHIS.

Further requirements related to termination of and recovery from an OE will be found in DOE O 151.1C and DOE G 151.1-4, Chapter 10.

APPENDIX A. Operational Emergency Scenarios for Biosafety Facilities

The purpose of this appendix is to provide a number of example biological OE scenarios to illustrate an approach that develops an *integrated description* of scenarios (see Section 4.2.4, above) for analyzing biological agent releases. These notional scenarios and associated summary tables should not be interpreted as an exact model to follow at all DOE/NNSA biosafety facilities. These tools are not required, but represent a suggested thought process that may assist analysts in development of facility-specific release scenarios in EPHAs and in application of EPHA results to develop categorization criteria and associated initial protective actions.

The Select Agents used in these scenarios were identified in the **BMBL**, and either BSL 2 or 3 conditions were recommended. The general assumption for all of the scenarios is that the facilities described are designated as BSL-3 facilities. It is assumed that the facility biosafety program requires laboratory personnel to wear PPE when working with infectious material. When a Class II BSC is equipped with an operable HEPA filter, it is assumed that no release to the laboratory or the environment occurs (in accordance with the **BMBL**) when material is released in the Class II BSC, either accidentally or as the result of an activity being performed.

The scenarios presented below focus on one set of parameters that describe an event and subsequent release. Each event described might lead to one or several different conclusions, depending on the observables acquired and used to determine whether the event should be categorized as an OE. In several of the scenarios given below, conditions stated for detecting/recognizing the OE release might not be investigated and available to the staff personnel for various reasons, including:

- Failure to recognize that safety systems were not operable or were compromised at the time of the release (e.g., HEPA filter inoperable).

- Failure to identify appropriate correlations among observed indicators of a release (e.g., activities conducted during the period of a failed safety system).

- Failure to recognize limitations of secondary containment barriers when some indicators may not provide definitive conclusions on the possibility of a release (e.g., trapping of feral mice in a facility results in detected potential release, while no trapped mice provides no information on whether a release occurred).

If any of these types of conditions (or others) exist, then the release may only be recognized indirectly. Observables that may be used to recognize an OE indirectly can include:

- Agent/toxin is found during routine environmental sampling and analysis.

- Medical Surveillance program detects infected individuals.

- People (or animals, for overlap agents) are found to have manifested symptoms of infection consistent with the incubation period, either onsite or offsite.

If the agent found by an environmental monitoring program is not naturally occurring in the local area and is on the facility inventory, then an OE is declared mobilizing resources to determine if a release did occur from within the facility. If the agent was naturally occurring, then the OE would not be declared based on the environmental monitoring program alone; additional confirmation would be needed. If public health authorities report an outbreak of the associated infection above expected norms, then an OE may be declared. If an agent of concern is discovered during routine environmental sampling and analysis that is **not** naturally occurring and is **not** on the facility inventory, then an investigation should be conducted to determine the source and take appropriate actions.

The Select Agent Rules require registered laboratories to develop incident response plans that address:

> **". . . theft, loss, or release of a select agent or toxin, inventory discrepancies, security breaches (including information systems), severe weather and other natural disasters, workplace violence, bomb threats, suspicious packages, and emergencies such as fire, gas leak, explosion, power outage, etc."**

The following scenarios were developed to address OE events, such as natural phenomena (e.g., severe weather, earthquake), accidents within the facility, external accidents, and malevolent events to assist in the development of incident response plans using the EPHA process to establish a technical planning basis. The operations and agents described in the scenarios are not necessarily representative of DOE/NNSA biosafety facilities but are presented to illustrate the approach suggested in this Guide.

A.1 Accident Scenario 1 – Tube Breakage in Centrifuge (release of *B. anthracis* spores as an aerosol)

Incident: Two 50 ml tubes containing 40 ml each of $1x10^9$ spores/ml of *Bacillus anthracis* are placed in a centrifuge. A floor model centrifuge is used outside of the Class II BSC. A hairline crack in one of the centrifuge tubes goes unnoticed, causing the test tube to break early in the centrifuge run, releasing the solution. The technician opens the centrifuge door immediately after hearing the tube break, potentially releasing aerosolized spores (0.1 -1% of the solution = 50,000,000 to 500,000,000 spores or 500 to 5000 times the ID_{50} value) into the laboratory environment.

Conditions: The biosafety program requires that all centrifuges be used only in a Class II BSC, as the centrifuges in the facility are not equipped with a HEPA filtration system on the exhaust to the outside of the biocontainment area.

Because the centrifuge was used outside of the Class II BSC and the facility HVAC system does not have a filtered exhaust, an aerosolized solution containing *Bacillus anthracis* spores may have been released to the environment outside the biocontainment

area. The assumed release duration is 30 minutes, based on evaporation, settling and an air exchange rate of 10 room-air-exchanges per hour.

Recognition: The possible release of a biological agent into the external environment outside the biocontainment area is the basis for declaring an OE. Recognition indicators include:

- Laboratory personnel observe or discover damage to the test tube and release of the solution of *Bacillus anthracis* spores.

- The centrifuge is used outside the Class II BSC, in violation of laboratory biosafety procedures.

A.2 Accident Scenario 2 – Failure in Pest Control Program (release of *Yersinia pestis* bacteria via infected host)

Incident: The facility is undergoing an information systems upgrade. The work requires installation of new communications cables. At the end of the workday, openings for the new cables are left uncapped. Additionally, during the day, workers discard food waste in the area of the cable entries. Attracted by the food, local feral mice enter the facility through the open cable runs and enter the room where rodents infected with *Yersinia pestis* and that have exhibited the symptoms for pneumonic plague are housed. The cages have an open mesh that allows direct contact between the feral mice and the laboratory animals. The feral mice are infected with plague by their close contact through the cage mesh.

Infected feral mice leave the laboratory avoiding the rodent traps and go back into the wild before the open entryway is found and closed. Once back in the wild, the fleas on the feral mice become infected by feeding on the infected mice. The infected fleas then transmit the bacteria to other mice. Coyotes and cats catch and feed on the infected mice and become infected in turn. The bacteria are spread by fleas of the infected hosts and continue to multiply in the mammal and insect populations, eventually infecting humans.

Conditions: The facility conducts experimental work with laboratory animals infected with *Yersinia pestis*. Workers handling infected animals are required to use PPE designed to prevent direct transmission. Caging systems are used to contain infected animals. An Integrated Pest Control Program, as defined in the **BMBL**, is in place. Treatment of laboratory animals with a pesticide/repellent and daily flea infestation inspection is part of the program to prevent the spread of the plague bacteria from laboratory animals to workers. Workers installing the cables were not briefed on the facility pest control program.

Recognition: The OE would be declared based on the ***potential*** that feral mice avoided the traps and may spread the disease outside the biocontainment area. Recognition indicators used as the basis for an OE event declaration may include:

- Discovery of trapped feral mice within the facility (indicating a potential failure in the pest control program)

- Discovery of unsealed cable penetrations, which could allow rodents and other vectors direct access to the interior of the facility

A.3 Accident Scenario 3 – Anaerobic Jar Explosion (*C. botulinum* bacteria and toxin released as an aerosol)

Incident: An experiment is set up using a 2 liter flask with 300 ml of *Clostridium botulinum* bacteria at a titer of approximately $1x10^9$ cells per ml in liquid medium contained in an anaerobic jar. The jar creates an artificial anaerobic environment (devoid of oxygen) permitting the growth of anaerobic bacteria. The anaerobic environment is achieved using a chemical reaction to generate hydrogen gas. In the presence of a catalyst (e.g., palladium), the hydrogen gas reacts with free oxygen in the air to form water. This reaction removes the oxygen from the sealed atmosphere. The bacterial culture is then incubated at the desired temperature. A wire capsule is normally placed around the catalyst as a safety measure. On day 6 of the experiment, the catalyst is replaced. The wire capsule is not used and the anaerobic jar, and flask inside, explodes. As required by laboratory procedures, the anaerobic chamber is used in a Class II BSC.

Conditions: The Class II BSC in this facility exhausts directly to the HVAC system rather than to the laboratory space. The facility has installed a HEPA filter on the HVAC system ensuring that all of the exhaust streams are filtered prior to exiting the facility. A release to the environment from an anaerobic jar exploding in the Class II BSC requires that the HEPA filters in the Class II BSC and in the HVAC system are both non-operational at the same time. If the jar were outside of the Class II BSC, then just the HEPA filters in the HVAC would have to be non-operational for a release to the environment.

Recognition: Possible release of a biological agent into the external environment is the basis for declaring an OE. Recognition indicators used as the basis for an OE event declaration may include:

- Anaerobic jar and flask inside explodes in the Class II BSC

- HEPA filters in the Class II BSC are non-operational

- HEPA filters in the HVAC system are non-operational

NOTE: Although the release is similar to A.1, this scenario was included to emphasize redundancy in biosafety design.

A.4 Accident Scenario 4 – Earthquake (release of dried *Bacillus anthracis* spores; airborne, contaminated personnel and fomite transfer)

Incident: An earthquake occurs and seriously damages the facility (e.g., openings are created in the building structure). At the time of the earthquake, an experiment is being conducted with dried *Bacillus anthracis* spores. A container with approximately a gram ($1x10^{12}$ spores/g or $1x10^{7}$ ID_{50}) of *Bacillus anthracis* spores is thrown about, releasing respirable spores.

The research staff is in the vicinity of the containers that are broken when the earthquake occurs, and a number of these individuals are exposed to aerosolized spores. Contaminated personnel exit the building without going through normal decontamination and disrobing process, due to falling debris within the building and the perceived danger of building collapse. These individuals are in danger of infection from inhalation of aerosolized spores, contact with their eyes, noses or mouths, or from bacteria entering through cuts or breaks in their skin caused by broken glass and falling debris. They remove their overgarments after exiting the building and discard them in the open. *Bacillus anthracis* spores released from the building, or carried out on exposed persons or discarded protective garments, could be dispersed by the wind, or could contaminate unwitting persons attempting to provide assistance to affected workers.

Conditions: The impact of the earthquake causes internal building damage and falling debris. Exterior walls of the facility are cracked, and openings to the environment develop. Once released, spores are blown through the facility and out into the environment through openings in the structure. The assumed release duration is 12 hours or more, based on movement of air through the openings in the building blowing suspended spores out into the environment. Additional personnel and environmental contamination may occur as a result of contact with contaminated laboratory personnel and garments. Involved laboratory personnel, and persons who come into contact with them, should be tracked; medical monitoring and prophylactic antibiotic treatment should be started as a precaution.

Recognition: Release of a biological agent into the external environment is the basis for declaring an OE. Recognition indicators used for an OE event declaration may include:

- Earthquake occurs and causes significant damage to facility structure (including creating openings to the environment).
- Container holding dried *Bacillus anthracis* spores was reported by personnel involved to have spilled, releasing the contents to the environment.
- HEPA filters (Class II BSC, HVAC) are inoperable due to loss of ventilation flow.
- Emergency evacuation of personnel from laboratory spaces occurs, without following the standard decontamination and disrobing procedures.

A.5 Accident Scenario 5 – Facility Fire (airborne and contaminated water release of *Clostridium botulinum* toxin)

Incident: A researcher is conducting experiments with *Clostridium botulinum* toxin. The researcher is carrying a container holding 0.5 grams of toxin (one nanogram [$1x10^{-9}$ g] per kg of body weight to kill 50 percent of the animals studied) to a BSC in the laboratory, when a short in the electrical system causes a fire to break out in the laboratory. The researcher is startled by the fire alarm and drops the container. The container opens on impact with the floor, releasing the toxin. As a result, the toxin is temporarily airborne and is released into the laboratory environment. The facility HVAC system does not have a HEPA filter on its exhaust. Some of the toxin is carried out of the room by the HVAC system. Sprinklers are activated shortly after the toxin is spilled and it is washed out of the air and off of surfaces by the sprinkler water. Contaminated sprinkler water runoff is discharged through the facility outfall to the environment.

Conditions: The facility has a fire protection system, including alarms and sprinklers that reduce the spread of the fire.

Recognition: Release of a biological agent into the environment is the basis for declaring an OE. Recognition indicators used as the basis for an OE event declaration may include:

- The fire detection system activates fire alarms and the fire suppression system.
- The researcher handling the toxin reports the spill of the material after exiting the room.
- Water runoff from activation of the sprinklers is discharging through the outfall.

A.6 Accident Scenario 6 – Explosion (release of *Yersinia pestis* bacteria; personnel contamination and infected host)

Incident: A propane truck has an accident near the facility, causing an explosion. At the time of the explosion, experiments are being conducted in the facility with solutions containing *Yersinia pestis* bacteria. Test tubes and flasks in several Class II BSCs containing *Yersinia pestis* bacteria in solution are broken from the shaking and movement of the building and projectiles created by the blast wave. Splashing of the solution creates aerosolized droplets, contaminating skin and mucous membranes of the workers conducting the experiment. Personnel evacuating the laboratory follow prescribed exit procedures and remove all contaminated PPE prior to exit.

Conditions: Although laboratory personnel followed the prescribed exit procedure and removed their PPE, they were exposed to the *Y. pestis* bacteria via inhalation of the aerosolized droplets and contact with their eyes and mucous membranes. Inhalation of *Yersinia pestis* bacteria usually manifests as Pneumonic Plague and is highly transmissible. These employees need to be thoroughly decontaminated as soon as possible, subjected to close medical monitoring, and started on prophylactic antibiotic treatment. Additional personnel and environmental contamination may occur because of contact with contaminated laboratory personnel and garments. These persons should be

tracked and started on medical monitoring and prophylactic antibiotic treatment as a precaution.

Recognition: Release of a biological agent into the breached laboratory environment is the basis for declaring an OE. Recognition indicators used as the basis for an OE declaration may include:

- Explosion causing visible damage to the facility structure, including creating openings to the environment
- Test tubes and flasks containing solutions of *Yersinia pestis* bacteria break and release their contents
- Loss of electrical power to the Class II BSCs ventilation and associated HEPA filters.

A.7 Accident Scenario 7 – Transportation Accident [arthropod and animal-to-human transmission of a viral pathogen (CCH)]

Incident: A non-human primate was injected with the virus, causing Crimean-Congo hemorrhagic fever (CCH) approximately 30 days before being transported from the CDC to a DOE facility in a biosafety cage on a transport truck. Relocation is due to tornado damage suffered at the primary laboratory. While at the DOE facility gate waiting for clearance into the facility, another truck runs into the rear of the transport truck, severely damaging the transport truck and the biosafety cage.

The driver of the transport truck, the transporting crew, and the non-human primate are all injured and rendered unconscious. DOE emergency responders are notified of the accident and go to the scene. On arrival, they see the biohazard placards on the vehicle and implement protective actions in accordance with the Emergency Response Guidebook (Guide 158), immediately isolating a 25 meter radius around the accident site. Once the responders review the information on the Crimean-Congo hemorrhagic fever virus, they establish a limited access zone around the isolation area of one city block in all directions and request specialized disinfectants to clean up the area and equipment to catch all runoff. The local public health department institutes a sampling program after the accident to determine if insect vectors have picked up the virus.

Conditions: Responding personnel are in typical blood-borne pathogen protective clothing. Initial responders perform injury surveys on the human victims and the bleeding non-human primate. Additionally, mosquitoes and other insects are beginning to congregate on the animal and body excrement in the vehicle and the ground surrounding the vehicle. There are no secondary barriers or mitigative features.

Release of Crimean-Congo hemorrhagic fever virus is through the blood lost by the non-human primate. The virus is transmitted through aerosolized respiratory droplets from infected hosts, bites by infected vectors such as mosquitoes, and human-to-human (or animal-to-human) through contact with blood or other body fluids, as well as viral particles transmitted in fluids. The assumed release duration is 60 minutes, based on time

required to receive critical information regarding necessary steps to disinfect the area properly.

Recognition: An OE is declared based on the following criterion from DOE O 151.1C:

"Offsite DOE Transportation Activities: The following events or conditions represent an actual or potential release of hazardous materials from a DOE/NNSA shipment.

- Any accident/incident involving an offsite DOE/NNSA shipment containing hazardous materials that causes the initial responders to initiate protective actions at locations beyond the immediate/affected area."

Notifications to DOE/NNSA by local responders from the event scene cause the declaration of an OE based on initiation of protective actions at locations beyond the immediate/affected area. Confirmation of human exposure will be determined by isolation and observation of potentially infected personnel.

A.8 Accident Scenario 8 – Malevolent Act (Disgruntled employee releases dried *Bacillus anthracis* spores)

Incident: A disgruntled employee, angry about being disciplined, picks up and throws a container against the wall of the laboratory, smashing the container. The employee is wearing PPE and is alone in the laboratory. He exits the room, discards the PPE, and leaves the site.

The container holds 1 gram (approximately $1x10^{12}$ spores) of dried Bacillus anthracis spores. The entire contents of the container are released into the laboratory environment and, initially, all of the spores (in the 1-10 micron range) are aerosolized. Spores in this size range remain airborne for up to 24 hours. A large number of spores is subsequently released outside of the biocontainment area via the HVAC system. Workers entering the room discover the incident and are exposed to a large concentration of spores; their activity also stirs up particles that have settled.

Conditions: The biosafety program for the facility requires that all work with Select Agents be conducted in a Class II BSC. The facility HVAC system is not equipped with filtration on the exhaust to the outside of the biocontainment area.

Since the container is smashed outside of the Class II BSC, aerosolized Bacillus anthracis spores have been released into the laboratory space. The assumed release duration is at least 24 hours, based on settling of particles in the 1-10 micron range (10 micron particles fall 10 ft in about an hour, 1 micron particles can remain airborne for up to 24 hours) and an air exchange rate of 10 room-air-exchanges per hour. Since the facility HVAC system does not have a filtered exhaust, Bacillus anthracis spores may have been released to the environment outside of the biocontainment area. In addition, unwitting workers who enter the room subsequent to the release are assumed to receive very high doses of spores in the optimal respirable range.

Recognition: The possible release of a biological agent into the external environment outside the biocontainment area is the basis for declaring an OE. Recognition indicators used may include:

- Returning laboratory personnel find the discarded PPE outside the containment area
- Laboratory personnel discover the smashed container inside the containment area, approximately 30 minutes after the employee leaves the work area
- Facility HVAC system is *operating* when the incident is discovered; no mitigative actions took place prior to the arrival of co-workers

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