DRAFT

Planning Guidance for Recovery Following Biological Incidents

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Planning Guidance for Recovery Following Biological Incidents

Biological Decontamination Standards Working Group

Subcommittee on Decontamination Standards and Technology
Committee on Homeland and National Security

National Science and Technology Council

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Executive Summary

This guidance describes a general risk management framework for government and nongovernmental decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective of this guidance is to provide Federal, State, local and tribal decision makers with uniform Federal guidance to protect the public, emergency responders, and surrounding environments and to ensure that local and Federal first responders can prepare for an incident involving biological contamination. This guidance was developed by an interagency working group of the White House Subcommittee on Decontamination Standards and Technology (SDST).

Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation/cleanup and restoration phases of a response. This guidance is intended to achieve effective cleanup following a biological incident while minimizing the expected total social cost, which includes human health costs, ecological and environmental damage, loss of site utility, and the economic costs of the actions taken. The guidance does not address critical public health (such as antibiotic distribution) or public safety (security) aspects of the First Response portion of Crisis Management. This guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs.

This document follows principles developed within the context of *Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents* – which is final and was released by the U.S. Department of Homeland Security (DHS) on August 1, 2008. Those protective action guides introduced the overarching concept of optimization. Optimization is a flexible, multi-attribute decision process that seeks to weigh many factors. Optimization analyses are qualitative and quantitative assessments applied at each stage of site remediation decision-making from evaluation of decontamination options to implementation of the chosen alternative.

This guidance applies to characterization, decontamination, clearance, and restoration/reoccupancy of a variety of public facilities, drinking water infrastructure, and open areas. Principal topics include the unique characteristics and hazards of biological agents, a risk management framework for responding to a biological incident, and all remediation and restoration activities. A process is identified for making timely and effective decisions despite incomplete data and uncertainties associated with potential risks posed by biological agents.

Chapter 1 summarizes the purpose, audience and scope of this document.

Chapter 2 focuses on pathogenic microorganisms and biotoxins considered likely threats and the unique aspects of each relevant to cleanup. There is no consensus-based methodology for evaluating human health risks posed by environmental exposure to biological agents, or standard cleanup goals to be employed after biological attacks. Risk assessments for most biological agents are qualitative and inherently contain significant uncertainty and variability. This document emphasizes that judgments concerning the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of all risks arising from a particular contamination incident.

Hazard information on the virulence and drug resistance of organisms may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals or those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination. In the face of potentially serious consequences from contamination, judgments regarding risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of risks arising from a particular contamination incident.

Because of the extremely broad range of potential impacts that may occur from biological agents, a pre-established numeric guideline might limit the ability of decision-makers to take important factors into account. Rather, a process should be used to determine the societal objectives for expected land or structure uses and the options and approaches available to select the most acceptable criteria. The goal is to balance achievable and practical results. This process or approach is known as optimization and is recommended to identify successful cleanup options.

Chapter 3 is the framework for decision-making, which consists of four principal components:

(1) A risk management process: Risk management is the process of identifying, evaluating, and implementing actions to reduce risk to human health and ecosystems.

(2) A clear delineation of roles and responsibilities of relevant agencies and responders: The National Response Framework (NRF) establishes a comprehensive, all-hazards approach to manage domestic incidents and delineates the roles and responsibilities of the numerous agencies that work together during incidents.

(3) The phases of response: The basic phases of response to a biological incident are notification, first response, characterization, followed by decontamination, clearance and restoration, which incorporates site-specific optimization into the response effort. (Figure 3).

(4) A decision tree that defines key decision points and actions for decision-makers.

Chapter 4 explains the decision process, namely, all actions required during response to a biological incident. Beginning with notification and screening environmental sampling, each step in the decision-making process is described, and the various actions are explicitly linked to numbered boxes in a five-page decision-tree flowchart (Figure 4).

An important step in the decision process is setting a clearance (or cleanup) goal for determining whether a remediation is successful and the treated area may be returned to normal use. No formula is available for setting a clearance goal for biological agents. The collective, professional judgment of experts, considered within the context of the concerns of a broad range of local, regional, and Federal stakeholders should be used to set a clearance goal appropriate to the site-specific circumstances. A practical clearance goal is to reduce residual risk to levels acceptable by employing an optimization process. The aim of such a process is to reduce exposure levels as low as is reasonable while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability. After the remediation is carried out, a clearance decision is made based on a judgment whether decontamination verification criteria

and the clearance goals have been met. This judgment is based on a thorough analysis of all sampling, processes, and other pertinent data.

This document focuses on the decision making framework in response to a biological event; it is designed to be consistent with the NRF and our scientific understanding of the characteristics of biological agents. Neither of these areas are static. We expect both our response planning and our scientific understanding of the characteristics of biological agents to evolve over time.

In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site specific optimization. Because of the response details contained in these scenarios, they are sensitive and contained in a separate, Official Use Only document.

1. Introduction

The Homeland Security Act of 2002 (PL 107-296 Section 301) directs DHS, in partnership with other Federal agencies, to develop and implement countermeasures to prepare for and respond to chemical, biological, radiological and nuclear threats. *Homeland Security Presidential Directive - 10: Biodefense for the 21st Century*, describes the interagency activity required to meet this charge. This document is part of a series of guidance being prepared by the Federal government. The first in the series was *Planning Guidance for Protection and Recovery Following Radiological Dispersal Device (RDD) and Improvised Nuclear Device (IND) Incidents* by DHS/FEMA on August 1, 2008.

Response and recovery following an incident involving a biological agent is likely to be a complex, resource-intensive, and challenging undertaking. Biological contamination presents a unique cleanup challenge because of the ability of pathogenic microorganisms to infect and replicate in a host or in the environment. Clear, consistent Federal decontamination guidance is needed to address all phases and activities involved in response and recovery following a biological incident (GAO, 2003). The National Science and Technology Council (NSTC) is the principal means by which the President coordinates science, space, and technology policies across the Federal government.

To develop coordinated Federal guidance, the NSTC Committee on Homeland and National Security convened a Subcommittee on Decontamination Standards and Technologies (SDST). The Subcommittee chartered an interagency Biological Decontamination Standards Working Group (BDSWG) to develop risk management guidance for safe recovery from an incident involving biological contamination in a domestic, civilian setting. The interagency working group included participants from the Departments of Homeland Security, Agriculture, Commerce, Defense, Energy, Labor, Health and Human Services, Transportation, and the Environmental Protection Agency.

This guidance describes a general risk management framework and activities for decision-makers, at all levels, in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. The objective is to provide uniform Federal guidance that enhances the ability of Federal, State, local and tribal emergency responders and decision makers to prepare for and respond to an incident involving biological contamination. This guidance is not intended to impact site cleanups occurring under other statutory authorities such as the Environmental Protection Agency's (EPA) Superfund program, or other Federal and State cleanup programs.

In developing the guidance, the Federal government recognized that experience and scientific knowledge from existing programs such as EPA's Superfund and research programs, from multi-agency cleanups of sites contaminated with *Bacillus anthracis* spores (EPA, 2002), and from other national recommendations will be useful in planning response and recovery efforts following a biological incident. This guidance allows the consideration and incorporation, as appropriate, of any or all of this existing experience and knowledge, and does not alter existing programs. It is sufficiently flexible to address the extremely broad range of situations that can occur under various biological contamination scenarios, which is larger than most existing programs or recommendations address. Finally, this guidance will enable State and local officials, working with Federal counterparts, to make informed decisions with the best available information to decide what is best for their community.

1.1 Purpose

This document provides guidance that focuses primarily on remediation and restoration activities associated with a domestic, civilian site that has been contaminated, intentionally or otherwise, with a biological agent. Note: Because this guidance document covers disease outbreaks and intentional or accidental releases of biological agents, henceforth the term "biological agents" will be used rather than "biological warfare agent" (BWA). Throughout the overall response and recovery process, remediation activities conducted to clean up facilities take place in parallel with other activities such as risk communications and addressing public health issues. The document explains the unique characteristics and hazards of biological agents (i.e., pathogenic microorganisms and biotoxins); provides a risk management framework for responding to a biological incident in a domestic, civilian setting; and addresses the environmental remediation and restoration activities necessary for successful cleanup and reoccupation.

Most importantly, this document describes the process for making timely and effective decisions despite incomplete data and uncertainties associated with characterizing the potential risks posed by biological agents. An optimization process is recommended to guide the choice of targets during the remediation and restoration phases of the response, thus providing the best opportunity for decision-makers to gain public confidence through the involvement of stakeholders.

1.2 Audience

The intended audience for this document is Federal, State, tribal, and local government officials, as well as nongovernmental decision-makers, involved in conducting or overseeing response and recovery operations at a site contaminated by a biological agent.

1.3 Scope

This document describes a general risk management framework for decision-makers to use in planning and executing the many activities required for response and recovery from a biological incident in a domestic, civilian setting. The guidance applies to significant incidents involving natural outbreaks or intentional or accidental releases of biological agents, including unknown and genetically modified organisms. Contamination via air and water is considered in this document. Food production and distribution systems are excluded since they are covered adequately in another guidance document (USDA/FSIS, 2006). Decision-makers should use this guidance as a supplement to existing regulations and in the context of National Response Framework (NRF) policies and procedures outlined in the Emergency Support Function Annexes (ESF) #8, Public Health and Medical Services Annex, and ESF #10, Oil and Hazardous Materials Response Annex, the Worker Safety and Health Support Annex, and the Biological Incident Annex of the NRF (DHS, 2008).

Although an overall risk management framework covers all phases of a response to a biological incident, this document emphasizes the remediation and restoration phases of a response. For each activity in this component, the decision-making processes and scientifically based methods, practices, and procedures are described, and references are provided as applicable. Each biological incident will have unique, site-and organism-specific characteristics associated with remediation. Thus, even though a general framework can be used, final decision-making will be done on a case-by-case basis using an optimization process. Planning and preparedness, critical components of effective site response and recovery, are described elsewhere [e.g., in the National Academies of Science (NAS) study (NRC, 2005); Lawrence Livermore National Laboratory (LLNL) airport guidance (Carlsen et

al., 2005)], but are not described in depth in this document.

The guidance in this document is applicable to:

- Enclosed facilities and objects, such as commercial and residential buildings, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, and treatment facilities, and wastewater infrastructures.

A full discussion of all possible scenarios is beyond the scope of this document. This guidance emphasizes the scalable principles of optimization, in which the extent of cleanup efforts and range of considerations will largely be determined by the location, nature and severity of the biological incident. The processes and decisions employed in the cleanup of a building or facility will differ from that used to cleanup a large area, like a neighborhood or city.

This document emphasizes a framework and activities for decontaminating the first two types of settings because most incidents involving contamination with biological agents to date have involved enclosed and partially enclosed areas. However, this document is also designed to provide basic guidance for contaminated outdoor sites and water-related facilities. Unique problems presented by outdoor contamination pose significant challenges and include: (1) the dynamic and continuing meteorology effects on transport and spread of aerosol, (2) how to deal with intentional contamination given the potential presence of naturally occurring biological agents such as *Bacillus anthracis* spores, (3) decontamination of biological agents deposited on common materials such as car metal surfaces, street lights, concrete sidewalks and brick building surfaces, paved roadways, and bridges, (4) decontamination of subsurface and difficult to access infrastructure, and (5) how to deal with potentially very large quantities of contaminated water (see *Interim Guidance on Developing Consequence Management Plans for Drinking Water Utilities*, EPA, 2008). Additionally, waste disposal continues to be a difficult perception problem even if wastes have been treated and cleared; there are no easy answers in this arena.

Currently, there are other efforts in the Federal government that address the capability gaps in wide-area remediation as well as protecting responders under that scenario.

Current methodologies for assessing the degree of exposure to and potential risks from biological agents of concern can be used to determine the appropriate degree of cleanup based on the characterization phase and the best available scientific data. However, significant uncertainties exist regarding agent effects and fate, sampling and detection limits, and decontaminant effectiveness (Raber et al., 2001, 2004). Processes for dealing with such uncertainties are emphasized. Guidance is presented in the context of currently available information; as new data are obtained, that information will be incorporated into this decision-making guidance.

1.4 Organization

This document is organized into four chapters:

1. Introduction.
2. Background on Biological Agents.
3. Framework for Decision-Making.
4. Key Activities for Decision-Making.

Chapter 1 provides background on the purpose, audience, scope, and organization of this document. Chapter 2 describes the types and characteristics of biological agents and explains why cleanup of biological contamination substantially differs from cleanup of chemical or radiological contaminants. Chapter 3 describes the risk management framework, roles and responsibilities, phases of a biological response, and a "decision tree" for decision-making. Chapter 4 provides "how-to" guidance for each of the key activities required for a successful cleanup and recovery effort and includes references for further scientific or expert guidance. In addition to the guidance presented here, there are two scenarios that have been developed to illustrate the principles and application of site specific optimization. Because of the sensitive response details contained in these scenarios, they are available as a separate, For Official Use Only document.

1.5 References

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2. Background on Biological Agents

2.1 Types of Biological Agents

Biological agents considered to be likely threats are classified as pathogenic microorganisms (pathogens) and biological toxins (biotoxins). Microorganisms can replicate and are grouped into categories according to their structure and method of replication. Biotoxins are molecules of biological origin that cannot replicate. Some additional information on specific contaminants and general guidance for response and clean-up is available at the websites of the National Response Team (*http://www.nrt.org/*) and the Centers for Disease Control and Prevention (*http://www.cdc.gov/*). Specific contaminant information is available in the NRT's Quick Reference Guides (QRG's) located at: *http://www.nrt.org/Production/NRT/NRTWeb.nsf/AllPagesByTitle/P-BiologicalHazards?Opendocument* (EPA 2006).

Pathogens. Pathogens are disease-causing agents that invade a host and replicate. They are diverse and range from non-cellular organisms (i.e. the viruses) to cellular life forms within both the eukaryotic (protozoa, fungi and animals) and prokaryotic (bacteria) kingdoms. The pathogens of greatest concern in airborne exposures are viruses, bacteria (including Rickettsiae), and fungi (including molds). In waterborne contamination, protozoa and helminths may also be of concern. Some microorganisms have developed specialized life stages designed to resist periods of environmental stress. In general, these are more difficult to disinfect than those microorganisms that have not developed these life cycle stages. Appendix 1 shows a general scheme for hierarchy of environmental resistance and difficulty of disinfection.

Bacteria. Many bacterial species are pathogenic to other organisms. Unlike viruses, the majority of pathogenic bacteria (excluding Rickettsiae and some others) are capable of reproducing outside living cells. A typical bacterial cell is small—approximately 1–2 microns in diameter and approximately 2–10 microns in length (1,000 microns = 1 millimeter). By comparison, a human hair is about 100 microns wide. Bacterial diseases may respond to treatment with antimicrobials, but antimicrobial-resistant bacteria are common. Vaccines are available for some bacteria (e.g., *Bacillus anthracis*), (CDC, 2004b; Dennis et al., 2001; Inglesby et al., 1999, 2000).

Viruses. Viruses are a large group of non-cellular infectious particles that can only multiply within a living cell. Viruses are much smaller than the majority of bacteria, generally ranging from 0.02–0.2 microns, and generally do not respond to antimicrobials. Certain viruses may respond to antiviral compounds. Vaccines are available for certain viral illnesses (e.g., smallpox) (CDC, 2004a; Henderson et al., 1999).

Fungi and molds. Pathogenic fungi and molds are unique organisms in terms of their cellular structure and biochemistry. This highly diverse group of organisms is widely dispersed in the environment. Many molds and fungi are resistant to environmental conditions that kill bacteria, such as sunlight, desiccation, and heat. Many molds and fungi also have life-cycle stages that are environmentally resistant and readily aerosolized. Some organisms in this category are disease-causing agents, including *Coccidioides immitis* and *C. posadasii*, which can cause systemic or lung infections. Specific anti-fungal drugs are available; however, the infections can be difficult to treat. Currently there are no approved vaccines for human use against any fungi or mold.

Protozoa and helminths. Pathogenic protozoa are single-celled organisms, whereas helminths (flatworms and roundworms) are multicellular. Both include many parasitic forms. In their

infectious stages, protozoa and helminths are generally larger than bacteria, ranging from 2 to 100 microns in diameter. Because of their large size, they are typically only considered a threat to water supplies. Due to their large size, many protozoa and helminths are unlikely to be inhaled deeply enough into the lungs to cause an infection. Thus, aerosol dissemination of these pathogens would be an ineffective means of exposure; however, ingestion of these organisms, for example in contaminated water, may be an effective means of dissemination. Many of these organisms are highly resistant to chemical disinfection, and although drug treatment is available for some protozoa and helminths, many infections are difficult to treat. No human vaccines are available for these organisms.

Biotoxins. Biotoxins are toxic substances that are either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals. Although biotoxins can be transferred from person to person on contaminated objects, they are not communicable like the flu and do not replicate within an individual. Biotoxins can be more toxic than most chemical warfare agents (CWA). Biotoxins are categorized into groups according to molecular weight and composition or origin. Among biotoxins of concern is the Category A botulinum toxin, which is produced by *Clostridium botulinum*. There are other toxins of concern as well, including other bacterial toxins (e.g., Staphylococcus enterotoxin B), fungal toxins, also known as mycotoxins (e.g., trichothecenes), and toxins produced by plants and animals (e.g., ricin and tetrodotoxin). Biotoxins may be formulated in a variety of ways, as either liquids or powders. The natural pathway of transmission for most toxins is through contaminated food or water. However, it may be also possible to spread these toxins by aerosol, through hand to mouth exposures, and by direct injection. The symptoms of exposure may vary greatly depending on the toxin and the route of exposure. Medical treatments and vaccinations are available for some toxins, but for many biotoxins, specific treatments or vaccinations have not yet been identified.

2.2 Characteristics of Biological Agents

2.2.1 Pathogens

This section describes the general characteristics of pathogens.

Infectivity. Pathogens act by infecting and replicating within a susceptible host. The infectivity of a pathogen reflects the relative ease with which microorganisms establish themselves and cause disease in a host. Once an individual is infected, the pathogen multiplies, making a dose–response assessment difficult.

Infectious dose. In theory, infectious dose is the number of organisms required to cause an infection. A pathogen is considered highly infective when relatively few organisms can cause disease. Conversely, when numerous pathogens must be present to cause disease, the pathogen is considered to be of low infectivity. High infectivity, the speed of disease onset and severity of illness are not necessarily related. A minimum infectious dose is the minimum number of organisms required to cause an infection. For most high-consequence pathogens, the minimum infectious dose for some proportion of the population may be a single organism (NRC, 2005). Most pathogens considered to be likely biological weapons are highly infectious with some requiring fewer than 100 organisms to infect an individual.

Infectious dose is the result of complex interactions between host and microorganism, and involves many variable factors. Infectious dose is highly dependent on route of exposure, and may be dependent on the method of preparation of the infectious agent as well. The environmental persistence of various

microorganisms is also highly variable. For example, *Yersinia pestis* has been shown to have very limited survival (only minutes) under certain laboratory conditions, yet has been shown to persist in water for days or weeks. In addition, it can be difficult to ascertain whether an infection is present, how an individual has been exposed to a defined dose of microorganisms, or if an exposed individual is either particularly susceptible or resistant to infection. Furthermore, little information is available on cumulative exposures. Because of these and other considerations, the National Research Council (NRC) of the National Academies of Science (NAS) concluded that infectious doses for harmful biological agents cannot be determined with confidence (NRC, 2005). In a jointly developed white paper, the American Biological Safety Association (ABSA) and the Occupational Safety and Health Administration (OSHA) conclude that there is no clear and universally acceptable definition of the term "infectious dose" (Johnson, 2003). They note that there is no single, standard protocol for testing infectious doses in laboratory animals, making legitimate and controlled comparisons of study results difficult. They also find that extrapolation of infection and toxicity data among animal species and from animals to humans is unreliable for most biological agents (Haas et al., 1999a, 2000).

Viability of pathogens and activity of biotoxins. Pathogens can be present in the environment in both viable and nonviable forms, but they must be viable to exert a pathogenic effect. Toxins, particularly large-protein toxins, also need to be in the appropriate structural configuration (active form) to exhibit toxicity. A pathogen-contaminated environment may be cleaned by pathogen removal or by rendering the pathogens nonviable. Physical removal of pathogens can be done by removing contaminated objects and materials, or by direct removal of the contaminant itself by methods such as wet washing or vacuuming (Weis et al., 2002). Disinfection, inactivation, or decontamination can be accomplished by rendering the contaminant nonviable or incapable of infecting or causing disease through the use of disinfectants such as oxidants, through the application of heat, or by other means. Removal and inactivation of pathogens or toxins can be accomplished together through activities such as wiping an area with a disinfectant-saturated cloth. The effectiveness of efforts to remove pathogens or toxins can be evaluated by monitoring for the presence of their signatures or footprints. The effectiveness of disinfection or inactivation must be monitored by methods that test for not only the presence but also the viability or activity of the pathogen or toxin in question. For some contaminants, such as viruses, viability tests are difficult to conduct.

Routes of exposure and infection. Microorganisms must enter a host organism to infect and cause disease. The major routes of exposure to pathogens are inhalation, ingestion, dermal contact, mucous membrane contact, and direct injection by a vector (e.g., mosquito) (Raber et al., 2001). Intentionally introduced contaminants might exploit routes of exposure that are not usually observed in naturally occurring disease incidents.

For example, a pathogen that is usually ingested might be inhaled after being disseminated as an aerosol. People exposed to a pathogen through a novel pathway may experience effects that are uncharacteristic for the typical disease course of that pathogen. Residuals remaining from a release or attack can pose dermal contact, ingestion, or reaerosolization hazards (Weis et al., 2002) that are not normally present in natural disease outbreaks. When reaerosolization (Ferro et al., 2004; Long et al., 2000; Rodes et al., 2001) is a hazard, the potential for reaerosolization from surfaces can depend on a variety of factors, including contaminant formulation, method of dissemination, and the nature of the surfaces involved. Potential exposures to various routes of infection must be considered when planning for decontamination efforts.

Method of dissemination. Dissemination presents pathogens to victims through an intended route of infection. Pathogens may be disseminated in wet and dry forms, through contamination of food and water supplies, by release of infected vectors, through aerosol-generation devices, in the mail, or by other novel methods. Dry preparations can range in dispersibility from large, chunky powders with low dispersibility, to finely milled homogenous and highly dispersible powders. Flow-enhancing agents and charge-neutralization techniques can also enhance the dispersibility of dry preparations (Brown et al., 2007). Liquid preparations are easy to manage from a production standpoint and may be used to generate aerosols with a variety of properties ranging from mixed droplet sizes, to evenly dispersed and homogenous controlled droplets, or dried particles, depending on the dispersion devices employed. Aerosols can be created with either dry or liquid formulations, and aerosol delivery systems can generate particulate clouds that can remain suspended for long periods and spread over large areas. Contaminated water moving through a water-distribution system can carry a contaminant into a large number of inhabited structures in a city. In the past, pathogens have been intentionally disseminated on contaminated objects or by dispersal of infected vector insects (Kolavic et al., 1997; Carus, 2001; Wheelis, 2004; Torok et al., 1997; Smithson and Levy, 2000). Such methods could be used again in the future. However, certain pathogens are not amenable to particular methods of formulation or dissemination. Methods of dissemination can also create unexpected environmental contamination sites. For example, an outdoor release of agent might contaminate indoor areas or the food supply, and a waterborne release of agent might contaminate indoor areas. The scale and type of remediation for pathogens or biotoxins is determined in large part by the method of formulation and dissemination.

Pathogenicity and virulence. These two related concepts concern a pathogen's ability to cause disease (low to high pathogenicity) and the severity of disease that is produced (low to high virulence). Some pathogens rapidly cause death; others incapacitate individuals. Some disease agents have short courses of infection; others cause illness lasting months, years, or a lifetime. Some diseases are associated with conditions that occur long after initial exposure to the infectious agent.

Availability and effectiveness of prophylaxis and treatment. Some diseases are readily treatable by antimicrobials, antivirals, or other chemotherapeutic agents. In some cases, prophylaxis that provides protection against the disease can be given to individuals before exposure (pre exposure) or before the onset of symptoms (post exposure). Drug treatments and vaccines exist for several of the diseases of concern. However, drug resistance and vaccine failure are widely known, and engineering drug resistance into bacteria is a standard protocol for certain organisms. In any incident, the existence or lack of effective vaccination, prophylaxis, and treatment will influence decisions on worker protection and other aspects of decontamination efforts.

Communicability. Diseases can be transmitted directly from person to person (e.g., by coughing, sneezing, talking or touching), indirectly through the environment, or through a vector. Microorganisms that are readily transmitted directly from person to person can multiply the effect of an attack. In military terms, most communicable pathogens that are developed as biological warfare agents are considered strategic weapons because they are capable of sustained transmission that could cause long-term debilitation of a population, and it is difficult to prevent spread among one's own forces. Infections caused by certain pathogens of concern (e.g., smallpox) can be readily transmitted person-to-person after initial dissemination; some can only do so when the disease is in certain forms (e.g., pneumonic plague as opposed to bubonic plague); and others are generally not transmitted person-to-person (e.g., anthrax).

Availability. Pathogenic microorganisms are naturally occurring, and some are intentionally cultivated. Many can be cultivated using technology that has been available for more than 50 years (Pepper and Gentry, 2002).

Incubation period. The time from exposure and infection to onset of a pathological effect is the incubation period. There may be a delay between exposure to a pathogen and the development of a symptomatic infection that is capable of being transmitted. This delay is often termed the latent period. In addition, there may be a delay between exposure and the ability to detect the pathogen in a host, which is termed the pre-latent period. Finally, in some cases exposed individuals may never exhibit symptoms and yet may still be able to pass a disease agent on to others. These cases are called asymptomatic carriers. Delays between exposure and the recognition of infection or the presence of disease agent may range from hours to days, to weeks or more. Such delays may enhance the ability of terrorists to launch a covert attack or multiple attacks. The delay between exposure and recognition that an exposure has occurred also has implications for the remediation required. Because some pathogens do not persist in the environment, the time that may elapse from an initial biological incident to the onset of disease in exposed individuals may mean that viable (i.e., infectious) pathogenic microorganisms are no longer present in the initially contaminated area by the time exposure becomes evident. Alternatively, delayed diagnoses due to long incubation periods or confusion with other more common diagnoses, along with related challenges in detecting a contamination incident, may allow some environmentally persistent pathogen preparations to spread beyond the initially contaminated area.

Environmental persistence. Some disease agents rapidly die when not in a suitable environment or a host. Others are adapted for existing long-term in an infectious state in the environment. Heat, humidity, dryness, and ultraviolet radiation are all known to kill many microorganisms in the environment; however, certain microorganisms are less susceptible to these conditions than others. The environmental persistence of a particular pathogen or toxin is an important factor in selecting the type and extent of remediation activities. Pathogens that are exceptionally fragile and persist in some environments for only minutes or hours may require only minimal intervention for decontamination. However, it would still be necessary to confirm that natural attenuation of the pathogen had taken place as expected. The most environmentally persistent agents in dry environments on the Center for Disease Control and Prevention's (CDC, 2005) list of agents of concern for bioterrorism are *Coxiella burnetti* and *Bacillus anthracis* spores. In water-distribution systems, many bacteria, protozoa, and helminths can create a persistent contamination problem, necessitating thorough disinfection of the system.

Zoonotic potential and environmental reservoirs. Certain pathogens infect domestic or peri-domestic animals, or replicate within particular environments. Many of the CDC pathogens of concern, such as *Yersinia pestis* (Inglesby et al., 2000) and *Burkholderia mallei*, cause zoonotic illnesses, which are naturally transmitted from animals to humans. Some zoonotic pathogens, such as *Francisella tularensis* (Dennis et al., 2001) and *Burkholderia pseudomallei*, can survive and replicate outside of a host organism in a free-living state in specific environmental habitats. Microorganisms with the potential to become established in animal hosts or to multiply directly in the environment require special consideration during remediation.

Resistance to decontamination. Disease agents vary considerably in their resistance to decontaminants; some are particularly resistant to disinfection. *Bacillus anthracis* spores, for

example, are known to be highly heat resistant. In a water environment, *Cryptosporidium parvum* is resistant to chlorination, and some strains of *Burkholderia pseudomallei* may be resistant to routine chlorination (Howard and Inglis, 2003.). Even though a particular pathogen might be generally susceptible to a type of disinfectant, specific strains of a pathogen can be more resistant to a disinfectant than expected under certain conditions. This principle is well understood in the field of water disinfection, where some organisms that are generally susceptible to chlorine disinfection may be highly resistant under some conditions (Morris et al., 1996.). Although less well studied, it is likely that this phenomenon exists in surface contaminants as well. In addition, it is possible that a contaminant could be intentionally formulated to increase resistance to decontamination. Thus, it is necessary to test the expected susceptibility of a disease agent to a disinfection regimen by using the actual organism from an attack, in the state and condition in which that organism is to be disinfected. Appendix 1 shows the relative resistance of several organisms to inactivation by certain chemical disinfectants. (see Rutala, 1996).

2.2.2 Biotoxins

Biotoxins are the products or by-products of living organisms. They are nonvolatile, odorless, tasteless, and generally do not affect the skin, with notable exceptions such as T-2 mycotoxin. Unlike pathogens, biotoxins cannot replicate within the body, therefore the toxic dose of a biotoxin must be delivered by exposure. Non-lethal doses of biotoxin may also have severe medical effects, depending on the biotoxin. Biotoxins may be metabolized and removed from the body at some rate; alternatively, their effects may be cumulative or irreversible. In toxicology, the dose makes the toxin; that is, a critical dose must be ingested or taken in through some route of exposure for it to have a toxic effect. The critical dose, however, may be extremely small and related to the route of entry. Some biotoxins act rapidly; others act over longer times or are progressively incapacitating.

On a weight-for-weight basis, biotoxins tend to be more toxic than chemicals, and because of their diversity in structure and function, they can have more varied adverse effects than chemical agents. Nevertheless, risk assessments of biotoxin- and chemical-contaminated environments can be done in a similar manner.

Small-molecular-mass biotoxins are considerably more environmentally stable than large, globular protein toxins. As such, they may also be resistant to some of the means of inactivation or physical removal that are effective against larger biotoxins. Large-molecular-mass biotoxins are generally more susceptible to heat inactivation, and because of their size, some can be removed from liquid phases by appropriate filtration.

2.2.3 Biological Agents of Concern

Numerous lists of pathogens and biotoxins of concern have been developed for different purposes and according to the needs of various organizations. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA) have published lists of microorganisms and biotoxins that are regulated as "Select Agents" (see 42 C.F.R. Part 73, 7 C.F.R. Part 331, and 9 C.F.R. Part 121). The CDC has published a list of Select Agents, dividing them into categories A, B, and C (Rotz et al., 2002). Burrows and Renner (1999) present a more thorough discussion on water-safety threats. Another way to determine likely threat agents is to examine their history of use. Carus (2001) and Ecker et al. (2005) have examined pathogens and toxins known or suspected to have been used in bioterrorist, criminal, or warfare incidents. The U.S. Army handbook, *Medical Management of Biological Casualties*, provides several lists of agents and includes a large amount of useful information on each (Darling and Woods, 2004). Intelligence

documents and scientific literature contain additional information concerning potential threat agents. It may be important to consider potential novel threat agents from these and other sources, particularly if they might present challenges to a remediation strategy.

2.3 Unique Aspects of Biological Agent Cleanup

Many characteristics of microbial contaminants make them unique from chemical contaminants. The following principles apply primarily to pathogens rather than biotoxins, which are more like chemical contaminants in terms of risk assessment and risk management.

2.3.1 Availability

Pathogens occur naturally, and many are cultivated as a part of routine human or veterinary diagnostic activities. Techniques for obtaining and propagating pathogens are widely known, practiced, and taught for legitimate purposes. Stock material can be harvested from the environment or from human disease cases in hospitals or veterinary clinics worldwide. The availability of many highly pathogenic microorganisms makes them unique from CWAs. Important considerations include the following:

- Most CWAs are uniquely toxic compared to the more widely available toxic industrial chemicals (TICs); therefore, CWAs are generally unavailable to individuals without access to sophisticated chemical manufacturing facilities. Potential biological warfare agents (BWA), on the other hand, because they are not solely created as BWAs per se, have been cultivated in laboratories using standard laboratory techniques for more than a hundred years in some cases. Good laboratory equipment and biosafety practices are required for safe manufacture, and both are readily available.

- A few CWAs can be synthesized in field-expedient laboratories, but these are exceptions. In contrast, BWAs can be generated readily in field-expedient laboratories.

- Available information suggests that CWAs have never been found to occur naturally. CWAs are synthesized from precursor materials that must be generated or purchased. Many of the unique and required precursor chemicals for CWA production are controlled under the Chemical Warfare Convention (CWC) and are difficult to obtain. In contrast, BWAs are much more widely available. At any given time, multiple outbreaks of moderate and high-risk pathogens are occurring somewhere in the world. Outbreaks often occur in areas where terrorist organizations have resources. Natural outbreaks can provide seed material for BWA production.

- CWAs are distinguished by treaty as chemicals with no legitimate civilian purpose; there is no legitimate reason for CWAs to exist outside a closely controlled, treaty-regulated purpose. CWAs must be manufactured under closely monitored conditions in compliance with the CWC, or covertly. Such restrictions should hamper the ability to produce CWAs. On the other hand, BWAs are naturally occurring public health threats, and their creation for offensive purposes may be conducted under the cover of legitimate public health activities.

BWAs may be as readily accessible as TICs, and are as hazardous as, or more hazardous than, CWAs. Their widespread natural occurrence and accessibility make BWAs unique as potential threat agents. [Note: Because this guidance document covers disease outbreaks and intentional or accidental releases of biological agents, henceforth the term "biological agents" will be used rather than "BWA."]

2.3.2 Mechanisms of Dissemination

A significant impact can result from a release of much smaller quantities of biological agent than chemical agent (Rubin, 1987). However, unlike many chemicals, biological agents in a liquid state do not readily aerosolize or vaporize, so some form of dissemination device is usually required.

2.3.3 Delayed Effects

In many scenarios, the first indicator of an incident involving contamination with a biological agent would be an increased number of patients presenting with clinical features caused by exposure to the pathogen (Darling and Woods, 2004). The time from exposure to onset of clinical signs is generally much longer for pathogens than for acute toxic doses of chemical agents. Onset of clinical signs and symptoms may occur days, weeks, or more after exposure to a pathogen. The result may be delayed identification of a covertly disseminated pathogen, and exposed individuals may unknowingly incubate and disperse the agent if it is capable of human-to-human transmission. This delay in identification that an attack has occurred has wide ramifications to the decontamination process. This may affect the exposure assessment, the design and implementation of the sampling plan, the choice of sampling methods and locations, and other elements of contamination analysis.

2.3.4 Difficulties in Identification

The following difficulties are associated with identifying biological agents:

- Many infectious agents tend to initially produce nonspecific symptoms that mimic more common diseases (e.g. flu-like symptoms, gastrointestinal distress, etc.) thus complicating diagnosis.

- Biological agents are endemic to many environments and, as a result, cause naturally occurring disease outbreaks, complicating recognition of an intentional versus natural biological agent infection.

- Because pathogens can naturally occur in the environment, recovery of specific pathogens or their signatures (e.g., antigens, DNA traces) from an environmental sample may not indicate the presence of an introduced contaminant or the source of an environmentally acquired infection.

- Even when pathogen signatures are present, viability assessments on environmental samples can be time consuming and difficult. Viability information is critical for risk management decisions.

- Many current collection and analytical methods are not capable of distinguishing small but biologically significant quantities of pathogens.

- Some current collection and analytical methods are not specific enough to distinguish between organisms that are human pathogens and those closely related species that produce no human disease.

- Constituents of environmental matrices and, in some instances, constituents of sampling devices may inhibit detection of organisms in the environment. It is not possible to predict all such interactions in advance.

- Techniques that may be applicable for producing pathogens that are difficult to detect are readily available to scientists around the world and have been used and taught in universities for decades.

2.3.5 Potential for Amplification and Significant Numbers of Casualties

Certain biological agents spread via contagion. Person-to-person transmission may lead to rapid, geometric increases in the number of victims and facilities or areas that require decontamination. Most contagious diseases are spread directly from person to person, and most contagious pathogens do not persist in the environment for extended periods of time, with significant exceptions such as noroviruses and Methicillin-resistant *Staphylococcus aureus*, or MRSA. However, the causative agents of some of these diseases could be treated or disseminated in a manner to cause environmental contamination. The occurrence of person-to-person transmission arising from an initial environmental contamination may give impetus to conducting additional, unwarranted environmental decontamination activities. Conversely, recognition of person-to-person spread may result in a failure to appropriately recognize the role of environmental transmission, leading to an unwarranted lack of environmental decontamination activities. It is important to recognize that mass casualties can also arise from incidents involving dissemination of non-contagious pathogens such as *B. anthracis*.

2.3.6 Public Fear

Increased public fear can be anticipated from potential exposures to biological agents, particularly because exposures are not generally immediately detectable. While rapid, portable contamination detectors are available for radiological and chemical contaminants, the detection technologies currently available for biological agents have severe limitations (Fitch et al., 2003). Moreover, since a biological attack or exposure to a biological agent may have occurred days before its recognition, there may be nothing the public can do to prevent themselves from becoming victims, resulting in a sense of helplessness in the wake of the attack or outbreak.

2.3.7 Control Measures

For naturally occurring disease outbreaks, many public health interventions already suffice to control and decontaminate environmental reservoirs for disease agents (e.g., insecticidal spraying for mosquitoes that carry equine encephalitis, West Nile virus, etc.). However, deliberate attacks using biological agents as weapons may differ from these naturally occurring outbreaks. For example, these agents may have been manipulated to be more easily dispersed, or more environmentally resistant. Biological agents used as weapons might also be present in locations or scenarios that are unlikely or impossible for the naturally occurring disease agents. For example a toxin normally associated with food contamination may have been sprayed in the air. For these reasons, the control measures for naturally occurring diseases may not be sufficient, and novel control measures may be required for the control of biological agents used in an attack by an adversary.

Sampling, analysis, and decontamination of biological agent incidents may not be achieved as predicted in selected environments. Factors influencing these elements of a response could include the presence of a biofilm (an encapsulated

community of microorganisms attached to a living or inert surface), interaction of the surface with the sampling technique or decontamination agent, or the characteristics of exposed surfaces (e.g., an environmental surface may be presumed to be hard, but is in fact functionally porous). These factors could cause unpredictable failures or discrepancies in persistence, sampling, analysis, and decontamination.

2.3.8 Replication

Since chemicals and biotoxins do not replicate within an individual, the dose of a chemical or biotoxin is directly related to its toxic impact. Within limits, exposure to greater or lesser amounts of a chemical or biotoxin will predictably have greater or lesser impacts on the health of the exposed individual. This property is used to create safety guidelines, such as permissible exposure limits and acute exposure levels. In contrast, pathogens can replicate (or multiply) within an infected individual, and therefore risk assessments for microorganisms are entirely different from chemical or biotoxin risk assessments. This unique aspect of biological organisms must be considered along with other information to conduct an appropriate assessment of the risk of residual contamination from biological contaminants in the environment.

2.4 Risk Assessment

To make an effective risk management decision, risk managers and other stakeholders need to know what potential harm the situation poses and how likely it is that people or the environment will be harmed. This is accomplished through risk assessment.

Risk is the probability that a substance or situation will produce harm under specified conditions. Risk assessment is gathering and analyzing information on what potential harm a situation poses and how great the likelihood is that people or the environment will be harmed. (See Section 2.4.1 for a more detailed explanation of risk assessment in the specific context of biological agents.) The nature, extent, and focus of risk assessment are guided by risk management goals. The results of a risk assessment, along with information about public values, statutory requirements, benefits, costs, and cost effectiveness, are used to decide whether and how to manage the risks. Risk assessment can be controversial, reflecting the important role that both science and judgment play in drawing conclusions about the likelihood of effects on human health and the environment. For the reasons described in Section 2.3, risk assessment for biological incidents is highly problematic.

The following are the most salient risk analysis principles from the 1997 Commission report that need to be considered by decision-makers as they plan for and carry out a response to a biological incident:

- Clarify the factual and scientific basis of risks posed by the problem, treating health and ecological risks both qualitatively and quantitatively, where possible.
- Describe the nature, severity, reversibility, or preventability of adverse effects.
- Identify who is at risk and when they are at risk, and explain the possibility of multiple effects.
- Evaluate the weight of the scientific evidence, and identify the primary sources of uncertainty. For ecological risks, consider indirect effects on human health through disruption of the environment and possible effects on future generations.
- With input from the problem/context stage, place the specific risks posed by the problem into their multi-source,

multimedia, multi-chemical, and multi-risk contexts.

- Identify stakeholder perceptions of the risks posed by the problem (Burger, 2002; Jones, 2004; NRC, 1996; Till and Meyer, 2001).

- Combine information on scientific and contextual aspects of risks posed by the problem into a characterization of the problem's risks to human health or the environment.

2.4.1. Risk Assessment in the Context of Biological Agents

Live microorganisms pose a unique challenge because risk assessment of environmental contamination cannot be done with reasonable certainty (NRC, 2005; Canter, 2005). As described earlier, quantitative dose-response assessment is a particular problem. The minimum number of organisms necessary to initiate disease has not been well defined for the various infectious threat agents and depends on many factors related to the agent itself, the person (host) exposed, and environmental influences.

Although some methodologies exist for this purpose, in many cases it is not possible to conduct a scientifically sound, quantitative risk assessment to adequately characterize the risks to people from intentional exposures to pathogens. This is especially true when the pathogens themselves or the routes of exposure are novel and may not occur in nature (e.g., exposure to *B. anthracis* spores in the mail) (NRC, 2005). Usually, risks can only be characterized qualitatively and, as such, may be accompanied by significant uncertainty. Nevertheless, sound risk management decisions can be made from qualitative risk assessments by following the risk management framework described in Chapter 3 and the guidance in Chapter 4 when setting clearance goals and determining an appropriate decontamination strategy. Additionally, efforts should still be made to evaluate these risks quantitatively, and to conduct uncertainty analysis if necessary, which may illuminate areas where additional information could be collected to increase the value of a quantitative assessment if time permits.

Fundamental principles for conducting risk assessments are found in the NAS Risk Assessment/Risk Management Paradigm developed in the late 1970s. Since the development of this paradigm, several enhancements have been made to the initial methods, and new methods have been developed to characterize uncertainties and increase the utility of the resulting quantitative analyses (examples include cancer risk assessment methods, reproductive and developmental toxicity assessment methods, mutagenicity risk assessment methods, and methodologies to assess chemical mixtures).

Using the NAS paradigm, quantitative risk assessment should include four components: **hazard identification**, **exposure assessment**, **dose–response assessment**, and **risk characterization**. The methodology used to assess human risk from chemical exposures and to develop standards and guidelines for chemicals may also be used to assess the health effects associated with exposures to biotoxins. However, there is no consensus-based methodology for evaluating human risks specifically posed by environmental exposure to biological agents, and there are no established cleanup goals after biological attacks.

The World Health Organization (WHO) and the International Life Sciences Institute (ILSI) have developed frameworks to be used as guides in developing risk assessments for pathogens. These frameworks have been used for assessing the risk of exposure to harmful pathogens in certain

contexts such as microbial hazards in food safety, drinking water quality, and hospital isolation practices. However, data are lacking to support quantitative risk assessment for pathogens that might be used as biological weapons (NRC/NAS, 2005). A more thorough discussion of the issues is provided in the report *Reopening Public Facilities After a Biological Attack: A Decision-Making Framework* (NRC/NAS, 2005; see Executive Summary and chapters 5–8).

Although the basic NAS paradigm was originally developed for chemical risk assessments, it may still be generally followed when assessing risks to humans from environmental exposure to pathogens and biotoxins. Guidance on factors to be considered in each step of the risk assessment paradigm is outlined below.

For biotoxins, the tools currently available for chemical risk assessment may be more relevant. Guidance such as the EPA's Exposure Factors Handbook (USEPA 1997), Risk Assessment Guidance for Superfund (RAGS) (USEPA 1989 and 1991), and other guidance for chemical risks and remediation should serve as excellent resources for information on biotoxin remediation. Therefore, the discussion below is focused on pathogens.

2.4.2 Hazard Identification

The first step in determining the risk associated with a biological incident is hazard identification; that is, identifying the pathogen or biotoxin, how the contamination occurred, and the potential adverse health effects to humans through potential routes of exposure to the pathogen or biotoxin. These health effects may have different endpoints. The diseases resulting from exposure to some pathogens have mortality rates approaching 100%. Meanwhile, exposures to other pathogens or biotoxins may result in far lower mortality rates but have high morbidity rates causing a significant burden on the health care system and the economy. The military divides pathogens into lethal and incapacitating agents, with incapacitating agents requiring perhaps more medical intervention than lethal agents. The effect of certain lethal agents may also be reduced by long-term or significant medical interventions. Data are often readily available on the efficacy and cost effectiveness of various medical responses for infected individuals. Hazard identification is initially a matter of identifying the agent used in an attack. Such information may be derived from clinical, epidemiological, forensic, or environmental sampling data. The hazard assessment must also consider the potential route of exposure for the pathogen or biotoxin. In some cases, novel exposures may cause a change in the hazard inherent from a biological agent. For example, a toxin which is normally ingested may cause much more severe disease if inhaled. These novel pathways of exposure may lead to hazards that would be unanticipated from an examination of natural disease occurrence. Methods for the identification of specific contaminants of concern in biological terrorist incidents may be found in the EPA's *Standard Analytical Methods* document (EPA, 2007).

2.4.3 Exposure Assessment

Exposure assessment is an evaluation of the number of people who have—or could—ingest, inhale, or otherwise come in contact with a pathogen and at what level and frequency. If a pathogen's or biotoxin's formulation is easily dispersible or readily aerosolizable, it poses a risk of aerosol exposure. The characteristics of pathogen and biotoxin preparations change over time and with environmental conditions, making it nearly impossible to quantify each of the characteristics in a given situation. Many pathogens and biotoxins also have several routes of infection. *B. anthracis* causes disease from ingestion, dermal contact, and inhalation

exposures. Even though inhalation anthrax is the greatest concern posed by this particular pathogen, measures taken to reduce the inhalation risk may not fully address the other risks of exposure and infection. The infectious or toxic dose also varies by the route of exposure. For example, the infectious dose for anthrax by ingestion is considerably higher than through inhalation. Similarly, many pathogens cause different diseases from exposures through different routes of infection. Thus, the route of exposure is an important factor in both hazard identification and subsequent exposure assessment.

Characterizing the viability of a pathogen or activity of a biotoxin is an important aspect of exposure assessment. Exposure to nonviable pathogens and inactive toxins poses little or no risk. Pathogens die and biotoxins may become inactive in the environment at different rates, but the specific environmental conditions that result in die-off vary. Methods of preparing a pathogen or biotoxin can also affect the survival in the environment. Thus, determining viability for many pathogens or activity of a biotoxin is exceedingly difficult. In most cases, the ultimate viability test is the ability to cause an infection or toxic effect in a suitable animal or cell culture. In addition, the collection of viable pathogens from the environment is difficult because of such factors as organism die-off between the release period and the identification of disease, limitations in field collection and transport techniques, and the presence of other co-contaminants in the environment which may inhibit the growth of the pathogen of interest.

If a pathogen is present in a state such that it will not result in exposure to a susceptible individual or initiate infection that is likely to cause disease, then it is not a threat to human health. Similarly, an inactive biotoxin may not be a human health risk. The identity and formulation of the agent, and interactions with environmental media, make determining exposure difficult, even in the presence of a known quantity of agent. For example, even if the precise amount of viable or active contaminant present on a floor were known, it would be difficult to predict how much of the contaminant is released in a manner that may result in exposure through inhalation, ingestion, or exposure to broken skin or mucous membranes. It may be possible to design a sampling plan to answer some important exposure questions, but because the variables are so numerous, some of the information must be estimated.

The distribution of contaminants is another crucial variable for exposure assessment. The nature of a large-scale contamination incident may lend itself to developing conceptual distribution models through various modeling tools and an adequate sampling plan. The sampling plan is executed to test the distribution of contaminant. If the distribution is understood, then the information can be used in risk management decision-making. Even though information on the distribution of a contaminant is necessary to understand the potential for exposure, such information alone does not constitute exposure assessment.

Finally, it is likely that not all pathogens or biotoxins will be detectable in environmental samples. For example, pathogens may no longer be in a sample by the time their presence is suspected, their presence might be masked by other environmental microorganisms, or the methods used for detection may not be sensitive enough to identify pathogens present at low but biologically significant levels. The inability to detect environmental pathogens or biotoxins should not be interpreted as the absence of these. Other sources of information, including epidemiological and forensic evidence, should be interpreted in the context of what is known about the pathogen or biotoxin in question to form a hypothesis about the distribution and concentration of contamination. Such information can then be used to inform the exposure assessment.

2.4.4 Dose–Response Assessment

Dose–response relationships for pathogens are difficult to characterize and describe. Linear relationships in which smaller doses lead to less severe responses cannot be assumed. There may theoretically be some doses of some pathogens that are incapable of causing infection in a given host. There also may be doses of a pathogen that lead to infection (when the organism multiplies within the host) but are unable to cause disease due to elimination of the organism by the host. In other cases, exposure to a small dose may cause an infection leading to a disease state only after sufficient time has elapsed for the number of pathogenic microorganisms to multiply to some threshold level. In such cases, exposure to a higher initial dose may cause an earlier onset of symptoms and more rapid disease progression, but there may be no dose-dependent difference in the final outcome.

There is also a significant and complex interrelationship between dose-response and host factors such as age, immune status, and the presence of other disease conditions. For instance, in some cases, an altered immune status may not change the infectious dose (Miller et al., 2006), but may cause a change in the observable course of the disease (Miller and Schaefer, 2007). Thus the immune status of a given host may make that individual more or less susceptible to infection, or more or less likely to experience a severe outcome from a disease, independent from the infectious dose. Inherent differences in many pathogens may also affect the dose-response relationship. Various strains of the same pathogen may exhibit differences in infectious dose (Messner et al. 2001) or pathogenicity (Welkos et al. 1993). The resulting relationship between the immune status of exposed individuals and the strain or strains to which they are exposed are complicating factors that must be considered in any assessment of dose-response. Most microorganisms that could be used as weapons are not widespread causes of naturally-occurring disease in the U.S.; thus, there may be limited specific immunity in the population.

Estimates of the infectious dose of a specific pathogen can be used to inform risk management decisions related to pathogen remediation. However, infectious dose values are subject to significant uncertainties, and the assumptions defining infectious dose must be taken into consideration. Nevertheless, infectious dose may be useful to roughly predict illness in exposed individuals and to serve as a rationale for setting initial clearance goals.

Given the numerous uncertainties regarding published infectious doses for pathogens, it is extremely important to carefully examine what the numbers actually represent, as well as the routes of exposure and the animal species used in the underlying laboratory studies. Risk managers should not assume that an infectious dose estimate reflects a "safe" level, that is, the dose below which few people are likely to become ill. Even pathogens that have an infectious dose of 10,000 organisms for 50% of the population may cause infection in 1% of the population with as few as 10 organisms (Peters and Hartley, 2002). The dose response assessment for biotoxins is more similar to that conducted for chemicals.

2.4.5 Risk Characterization

Hazard information on the virulence and drug resistance of organisms, or toxicity of a biotoxin, may be collected from clinical isolates and epidemiological evidence. Exposure information may be collected from clinical samples taken from people who are thought to have been near exposed individuals, or those present before or after a presumed exposure incident. Law enforcement and intelligence information may also provide information about the potential for environmental contamination. In the face of potentially

serious consequences from contamination, judgments as to the assessment of risks should be based on a weight-of-evidence approach that reflects a qualitative assessment of risks arising from a particular contamination incident.

The risk characterization synthesizes all available evidence about a hazard to address the needs of decision-makers and interested parties (NRC, 1996; NRC/NAS, 2005). In some cases, it is not possible to directly measure environmental contamination. In other cases, direct measurements of environmental contamination may not be related to exposure. Therefore, even though it is imperative to attempt to estimate exposure potential and other elements to inform a risk assessment, it may be necessary to make decisions from a variety of sources of information. This is known as a weight-of-evidence approach.

An overarching goal in any risk assessment is to reduce uncertainty and variability. Because risk assessments for most pathogens are usually qualitative, they inherently contain more uncertainty and variability than quantitative risk assessments performed for chemicals. Nevertheless, following the basic risk assessment principles described above, and collecting and evaluating all relevant information on the pathogen or biotoxin, should provide a sound risk assessment (even if qualitative) that can be used by decision-makers to determine the nature and extent of cleanup needed after a biological incident.

For biotoxins, the tools currently available for chemical risk assessment may be more relevant. Guidance such as the EPA's *Exposure Factors Handbook* (USEPA 1997), *Risk Assessment Guidance for Superfund (RAGS)* (USEPA 1989 and 1991), and other guidance for chemical risks and remediation should serve as excellent resources for information on biotoxin remediation.

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3. Framework for Decision-Making

This chapter describes basic principles and concepts that provide a sound framework for managing a response to a biological incident. The framework is designed to help decision-makers and officials at the Federal, State, tribal and local levels achieve defensible decisions. Key parts of the framework include a brief description of the overall risk management process, a summary of roles and responsibilities of government agencies and others under the NRF, an overview of the phases and activities involved in responding to a biological incident, and a "decision tree" that outlines key decision points and actions for decision-makers. Key to any decision-making is the application of the site specific optimization process which is described in this chapter.

3.1 A Starting Point: Presidential / Congressional Commission's Risk Management Framework

In 1997, a Presidential/Congressional Commission on Risk Assessment and Risk Management issued a landmark document entitled *Framework for Environmental Health Risk Management* (Presidential/Congressional Commission, 1997). The Commission's Risk Management Framework is intended to:

- Provide an integrated, holistic approach to solving public health and environmental problems in context.
- Ensure that decisions about the use of risk assessment and economic analysis rely on the best scientific evidence and are made in the context of risk management alternatives.
- Emphasize the importance of collaboration, communication, and negotiation among stakeholders so that public values can influence risk management strategies.
- Produce risk management decisions that are more likely to be successful than decisions made without adequate and early stakeholder involvement.
- Accommodate critical new information that may emerge at any stage of the process.
- Following salient risk management principles from the 1997 Commission report should be considered by decision-makers as they plan for and carry out a response to a biological incident.
- Base risk management decision-making on a careful analysis of the weight of the scientific evidence that supports conclusions about a problem's potential risks to human health and the environment.
- Make decisions after examining a range of regulatory and non-regulatory risk management options.
- Reduce or eliminate risks in ways that:
  - Are based on the best available scientific, economic, and other technical information.
  - Account for their multi-source, multimedia, multi-chemical, and multi-risk contexts.
  - Are feasible, with benefits reasonably related to costs.

  - Maximize net-benefits. Such approaches should:
  - Give priority to preventing risks, not just controlling them.
  - Use alternatives to command-and-control regulation, where applicable.
  - Be sensitive to social, legal, and cultural factors.
  - Include incentives for innovation, evaluation, and research.
- Implement decisions effectively, expeditiously, flexibly, and with stakeholder support.
- Implement decisions shown to have a significant impact on the risks of concern.
- Revise and change decisions when significant, new information becomes available, but avoid "paralysis by analysis."

The Commission's Framework defines a six-stage process for risk management that can be applied to any public health or environmental hazard. As shown in Figure 1, the six stages are:

1. Define the problem, and put it in context.
2. Analyze the risks associated with the problem in context.
3. Examine options for addressing the risks.
4. Make decisions about which options to implement.
5. Take actions to implement the decisions.
6. Conduct an evaluation of the actions .

The level of effort and resources invested in using the Framework can be scaled to the importance of the problem, potential severity and economic impact of the risk, level of controversy surrounding it, and resource constraints. As such, the Framework is particularly appropriate for the type of clean-up decisions associated with the aftermath of intentional attacks.

Figure 1. Risk management process.

Every stage of the Framework relies on three key principles:

Broader contexts. Instead of evaluating single risks associated with single chemicals in single environmental media, the Framework puts health and environmental problems in their larger, real-world contexts. The goal of considering problems in their context is to clarify the impact that individual risk management actions are likely to have on public health or the environment and to help direct actions and resources where they will do the most good.

Stakeholder participation. Involvement of stakeholders—parties who are concerned about or affected by the risk management problem—is critical to making and successfully implementing sound, cost-effective, informed risk management decisions. For this reason, the Framework encourages stakeholder involvement to the extent appropriate and feasible during all stages of the risk management process.

Iteration. Valuable information or perspective may emerge during any stage of the risk management process. This Framework is designed so that parts of it may be repeated, giving risk managers and stakeholders the flexibility to revisit early stages of the process when new findings made during later stages shed sufficiently important light on earlier deliberations and decisions. ("The Importance of Iteration" on page 47 provides more information.)

The objectives of the Presidential/Congressional Commission's Risk Management Framework and the central role of the stakeholder dovetail with the principles inherent in the optimization processes that currently underlie many State, Federal, and international risk management programs. In the next section we discuss the optimization approach.

3.2 Optimization Approach

Broadly speaking, optimization is a flexible, multi-attribute decision process that seeks to consider and balance many factors. Optimization analyses are qualitative and quantitative assessments applied at each stage of site remediation decision-making from evaluation of decontamination options to implementation of the chosen alternative. The evaluation of cleanup alternatives, for example, should factor in all relevant variables, including areas impacted (e.g., size and location relative to population), types of contamination (chemical, biological, and/or radioactive), human health, public welfare, technical feasibility, costs and available resources to implement and maintain remedial options, short-term effectiveness, long-term effectiveness, timeliness, public acceptability, and economic effects (e.g., on residents, tourism, and business and industry).

Optimization is a flexible approach, under which applicable dose and/or risk benchmarks may be identified from State, Federal and other sources (e.g., national and international advisory organizations), such information may be useful in supporting assessments of site-specific circumstances and balancing other relevant factors. If information from other sources has an optimization process built into it, those processes could be considered during the development of final cleanup levels. The optimization process is further described in Section 3.1.

The principles of site-specific optimization can be applied during several phase of a response to a biological incident. The site-specific optimization process includes quantitative and/or qualitative assessments applied at a particular stage of site cleanup decision making, such as conducting characterization environmental sampling, establishing clearance goals, and selecting decontamination options. The optimization process should consider all of the factors relevant to the issue, such as:

- Areas impacted (e.g., size, location relative to population)
- The identity and characteristics of the contaminant
- Other hazards present
- Human health risk
- Public welfare
- Ecological risks
- Actions already taken
- Projected land uses
- Preservation or destruction of places of historical, national, or regional significance
- Technical feasibility

- Wastes generated and disposal options and costs
- Costs and available resources to implement and maintain remediation options
- Potential adverse impacts (e.g., to human health, the environment, and the economy) of remediation options
- Short-term effectiveness
- Long-term effectiveness
- Timeliness
- Public acceptability, including local cultural sensitivities
- Economic effects (e.g., on employment, tourism, and business)
- Intergenerational equity

The site-specific optimization process provides an opportunity for decision makers to gain public confidence through the involvement of stakeholders. The goals of site-specific optimization are:

(1) Transparency—The basis for cleanup decisions should be publicly available.

(2) Inclusiveness—Representative stakeholders should be involved.

(3) Effectiveness—Technical subject matter experts should analyze available options and assess various technologies in order to identify optimal solutions.

(4) Shared accountability—The final decision to proceed will be made jointly by Federal, State, and local officials.

3.3 Roles and Responsibilities

The NRF establishes a comprehensive, all-hazards approach to enhance the ability of the United States to manage domestic incidents (DHS 2008). It forms the basis for how Federal departments and agencies will work together during incidents and how the Federal Government will coordinate with State, tribal and local governments and the private sector. DHS is the overall Federal coordinator for incidents involving biological terrorism, but many other Federal agencies play key roles in coordinating activities within their areas of expertise. Figures A2-1 and A2-2 in Appendix 2 provide additional information about the structure of the NRF. Table 1 in Appendix 2 shows the roles of individual Federal agencies in decontaminating biological agents. The reader is encouraged to refer to the most current version of these overarching documents, which are available at *http://www.fema.gov/nrf/*.

Under the NRF, technical and policy issues are addressed at the lowest possible organizational level. In most cases, this is at the level of the Incident Command or Unified Command (IC/UC). Issues that cannot be resolved at the IC/UC level may be elevated to the Joint Field Office (JFO) Unified Coordination Group for resolution. The JFO Unified Coordination Group may also wish to review and provide input on decisions related to extensive contamination (and remediation costs) and in situations where it may be necessary to set priorities among multiple contaminated sites.

In the event of accidental or intentional biological contamination of a facility or area, the appropriate local authority (e.g., fire department, police department, or public health representative) would establish and run an Incident Command, and other local, State and Federal agencies would join, as needed. As emergency response operations are completed,

the lead for remediation/cleanup activities would then be taken by the party responsible for the property involved. For example, the owner of a private building (depending on his/her resources) could oversee the cleanup and restoration of his/her own facility. However, the local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority (such as by issuing a quarantine for the affected area) to assure that their cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

The response process will be managed by the IC/UC, who ultimately determines the structure and organization of the Incident Command Post, but the discussion below provides one recommended approach for managing the cleanup process within a NIMS ICS response structure. Decisions will be informed by scientific and technical analyses conducted by the Environmental Unit within the Planning Section of the Incident Command Structure. The Environmental Unit, shown in Figure 2, may be comprised of experts in sampling, decontamination technologies, industrial hygiene, public health and risk assessment, environmental engineers, and waste management. For complex or controversial remediation, the IC/UC or Environmental Unit leader may choose to convene a technical working group (TWG) of additional experts to provide multi-agency, multi-disciplinary input to planning and implementing the remediation, including setting clearance goals. The TWG may include representatives from Federal, State, local, and tribal agencies, and experts from the private sector or universities. The IC/UC or Environmental Unit leader should also meet with representatives of residential communities, building owners, and workers in nearby communities to ensure that they are fully informed about the remediation and their issues are addressed. The IC/UC might also consider convening a Stakeholder Work Group to make use of local knowledge and ensure that community concerns are addressed during remediation. The IC/UC command structure shown in Figure 2 is intended to be flexible and expandable in accommodating the groups necessary to address a particular incident. The IC/UC has a number of options available for managing the optimization process: the Environmental Unit, the Scientific Support Coordinator, or a separate unit under the Planning Section (e.g., a Long-Term Cleanup Planning Unit). The unit with this responsibility will coordinate the work group processes and interactions and report the results of the optimization analysis and working efforts to the IC/UC through the Planning Section Chief. See the National Incident Management System (2004) for further discussion of the roles and responsibilities of entities identified in Figure 2.

3.4 Overview of a Response to a Biological Incident

Effective and timely decision-making in responding to a biological incident first requires a broad understanding of all the phases and activities involved. Figure 3 provides such an overview and shows the phases and activities, starting with initial notification of a potential or actual biological incident and ending with the completion of restoration/reoccupancy operations that allow a contaminated site to be returned to normal use. Figure 3 has been developed specifically for use in this document, and the terms are defined in the Appendix 9 Glossary based either on existing definitions or on the meaning that best fits within the context of this document. Although the same terms may be defined differently elsewhere, the multi-agency review and approval of this document provides a strong basis for the definitions.

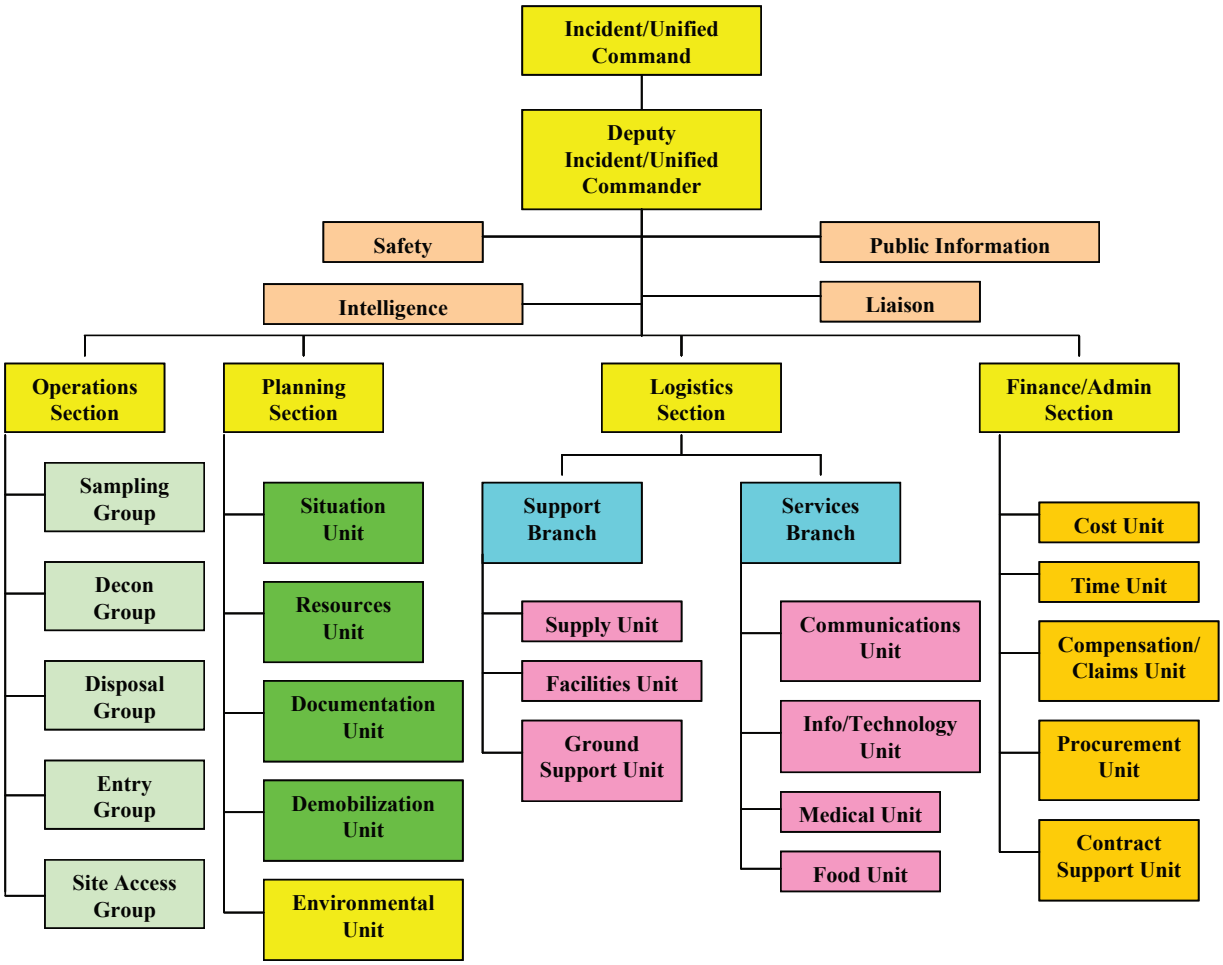


Figure 2. Incident/Unified Command Structure (adapted from DHS, 2008)

As shown in Figure 3, Crisis Management and Consequence Management are the two basic phases of response to a biological incident. Crisis Management consists of Initial Response, which can be further subdivided into Notification and First Response. These phases of response to a biological incident are not emphasized in this document, but are the focus of other guidance that is under development. Consequence Management consists of Remediation/Cleanup (which can be further subdivided into Characterization, Decontamination, and Clearance) and Restoration/Reoccupancy. As mentioned previously (Section 1.3), this guidance document emphasizes the remediation and long-term site recovery/restoration phases of a response to a biological incident.

Figure 3 also identifies the principal activities that take place under each of the above categories. For example, under Notification the activities listed are: Receive information on biological incident, Identification of suspect release sites, and Notification of appropriate agencies. Such activities are briefly described below. It is important to note that these activities do not necessarily occur in sequential order, but may start at different times, run concurrently, or occur outside the phase in which they are listed in Figure 3.

3.4.1 Notification

A biological incident may be detected by an active environmental detection system, medical surveillance, or epidemiologic investigation. That

Response and Recovery*					
Crisis Management		**Consequence Management**			
Notification	**First Response**	**Remediation/Cleanup**			**Restoration/ Reoccupancy**
		Characterization	**Decontamination**	**Clearance**	
Receive information on biological incident Identification of suspect release sites Notification of appropriate agencies	Initial threat assessment HAZMAT and emergency actions Forensic investigation Public health actions Screening sampling Determination of agent type, concentration, and viability Risk communication	Characterization of biological agent Characterization of affected site Site containment Continue risk communication Characterization environmental sampling and analysis Initial risk assessment Clearance goals	Decontamination strategy Remediation Action Plan Worker health and safety Site preparation Source reduction Waste disposal Decontamination of sites or items Decontamination verification	Clearance environmental sampling and analysis Clearance decision	Renovation Reoccupation decision Long-term environmental and public health monitoring
* The optimization decision process is applicable to any phase					

Figure 3. Basic phases of response and recovery to a biological incident.

information will then likely be reported to or collected by a Federal, State or local agency. The responsible person(s) assesses the credibility of information and the degree to which a response is needed. If incoming information of a possible biological incident appears credible and requires a response, the responsible receiving person(s) relays key information to appropriate agencies (e.g., police, fire, public health, Hazmat teams, FBI, and DHS). Suspect release sites are identified, and people are dispatched to the scene to initiate a First Response (Meehan et al., 2004).

3.4.2 First Response

First-response activities are described briefly in this document (see Section 4.2) to emphasize that such actions will have an effect on remediation activities. Hazmat and emergency actions take place when first responders arrive on the scene to address any immediate threats to life or valuable property necessary for public welfare (e.g., critical infrastructure) and to establish control of the situation. They set up a command post, initiate any needed rescue operations, mitigate any life-threatening or hazardous conditions (e.g., fire or explosion), and conduct preliminary tests to determine whether the threat substance is organic or likely to be a hazard. They also contact law enforcement and other personnel as needed.

To initiate risk communication, a Joint Information Center (JIC) should be established as soon as notification of a biological incident is received to coordinate all public-affairs activities and media releases. Communication activities continue throughout the response (Section 4.6).

If preliminary tests indicate the likely presence of a biological agent, the FBI will likely commence a forensic investigation to identify the agent and determine its specific genetic, physical, and chemical properties; search for other types of evidence; establish a possible source of the contamination; and determine the responsible party. If a crime scene is established, environmental sampling must be done with

explicit approval of the FBI. Initial samples are sent to a Laboratory Response Network (LRN) (CDC, 2005b) laboratory for analysis and to confirm the identity of the contaminant.

If the laboratory analytical results confirm the presence of a biological agent, the responsible public health agency involved in the response will commence appropriate public health actions, such as treatment (CDC, 2004c) and decontamination of potentially contaminated individuals, distribution of prophylaxis, and medical examinations.

In some instances, environmental screening sampling will commence during First Response to obtain information on the presence of an agent. Initial environmental sampling may also be conducted to begin collecting information on agent type, concentration, and viability. These activities may continue in more depth under Characterization.

3.4.3 Characterization

During Characterization, additional screening sampling and analysis is performed to determine the identity of the biological agent and approximate location(s) of contamination (Section 4.2). Further detailed characterization of a biological agent includes obtaining viable agent, confirming its identity, determining the formulation, and understanding its relevant characteristics (Section 4.3).

Characterization of an affected site includes describing its size, construction, heating, ventilation and air conditioning (HVAC) systems, ambient environmental conditions (such as temperature and relative humidity), structural materials, stored materials, and contents. If decontamination is warranted, the characteristics of the site and its contents may affect selection of a decontamination strategy (Section 4.10) as well as the efficacy of decontamination agents (Section 4.4).

Containment is the set of actions taken to prevent the spread of a contaminant from a particular zone or its movement within the zone (Section 4.5). Workers who exit a contaminated area (the Exclusion Zone or Hot Zone) pass through a decontamination unit erected in a neutral area (Contamination Reduction Zone or Warm Zone) so that they can be decontaminated prior to entering a "clean" area (Support Zone or Cold Zone).

A Characterization Environmental Sampling and Analysis Plan (SAP) is developed to characterize the distribution of biological agent within a facility and to obtain semi-quantitative estimates of its concentrations at specific locations. The SAP also assesses the potential of an agent to aerosolize as evaluated by its presence on or in ceiling air ducts, on top of light fixtures, and in other locations (Section 4.7). In case of a water contamination, the SAP would evaluate the source and location of the spread of the contaminant in the water distribution system.

A risk assessment (either qualitative or quantitative) is conducted to determine potential risks posed by a biological agent at a specific site. Risks need to be assessed to assist decision-making about setting clearance goals, formulating a decontamination strategy, and developing a SAP.

There is no simple formula for setting clearance goals. This is especially true for biological agents, which do not have established reference values (like some radiological or chemical agents) or exposure guidelines. The collective, professional judgment of experts, tempered by concerns of the people affected, and other factors, are used to set a clearance goal appropriate to the site-specific circumstances (Section 4.9) (EPA, 1997; NRC, 2005). The successful establishment of clearance goals will incorporate optimization (referred to earlier in this chapter).

3.4.4 Decontamination and Clearance

An overall decontamination and clearance strategy is developed through the optimization process and uses agent- and incident-specific information (Section 4.10). After the strategy is determined and the decontamination agent(s) is selected, a Remediation Action Plan (RAP) is prepared that lays out an overall strategy for decontaminating the contaminated site and its contents (Section 4.11).

The OSHA Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65) requires a written Worker Health and Safety Plan (HASP) to among other things, protect employee health and safety during Remediation/Cleanup activities (Section 4.12).

Before decontamination can proceed, site preparation is necessary (Section 4.13). Source reduction involves removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal. The remaining items and site surfaces may need to be cleaned prior to the main decontamination activity (Section 4.14). Waste disposal runs concurrently with source reduction, but continues throughout the entire decontamination process. In addition to materials or items that are removed from the site as waste, other wastes are created by the decontamination processes themselves, such as water used to rinse personal protective equipment (PPE), employee shower water, and scrubber wastewater (Section 4.15). Source reduction and waste disposal are significant factors that may affect the overall decontamination strategy. Some decontamination methods allow items to be left in place while others do not, and some methods generate waste products themselves.

Once a determination is made that decontamination is necessary to mitigate a biological agent incident, the evaluation, selection, and use of the most appropriate decontamination methods for the biological agent and affected site(s) and item(s) can be carried out (Section 4.16). Decontamination processes are monitored as they are carried out and are evaluated as to whether they have been conducted successfully (Section 4.17).

Clearance sampling and analysis is performed as the ultimate test of whether a remediation process is successful (Section 4.18). The IC/UC or property owner and/or responsible local/State agency (e.g. public health) makes the ultimate clearance decision. This decision is a judgment as to whether the criteria for decontamination verification and clearance have been met (Section 4.19). The local or State agencies with authority for protecting public health and/or the environment would also likely exert their regulatory authority during the response/recovery and cleanup phases (such as by issuing a quarantine for the affected area) to assure that the cleanup and restoration efforts are acceptable. In addition, local, State, tribal, or Federal agencies would have authority for remediating a public building or any private building should the owner not have the resources to remediate it.

3.4.5 Restoration/Reoccupancy

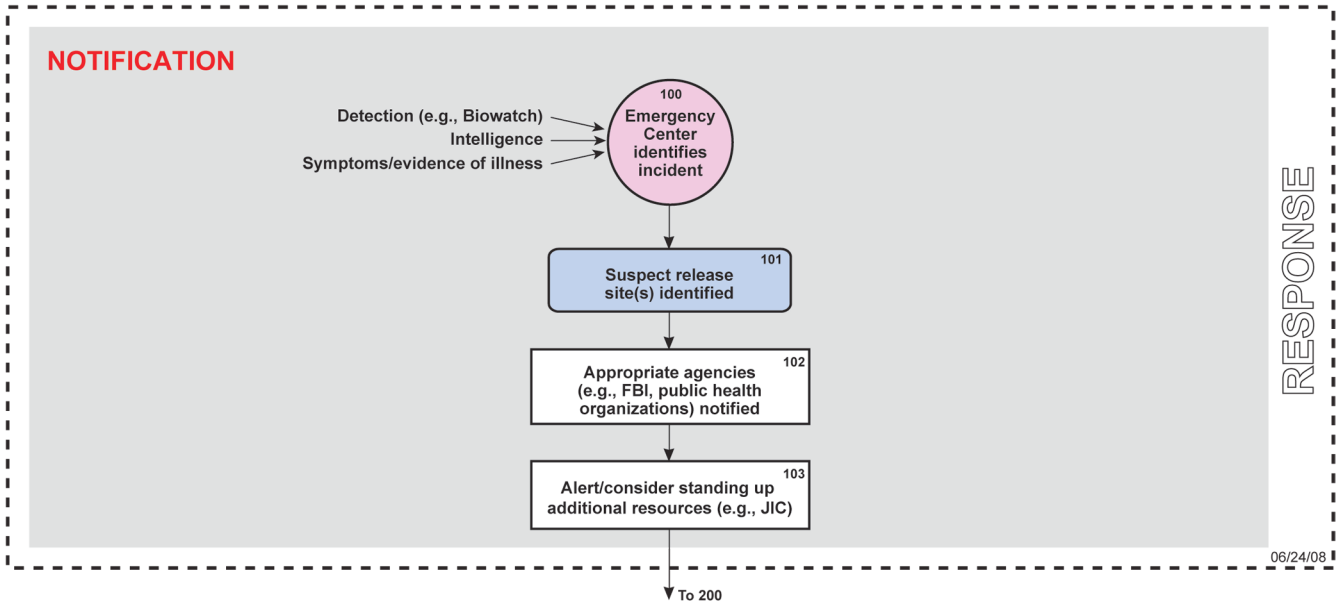
Once a building is cleared for re-use by workers and others without the need for PPE, it may still require extensive work prior to reoccupation by employees and the general public. Site-specific restoration plans, generated through the optimization process would detail any necessary renovations, reoccupancy and reuse criteria. Renovations can include refurbishment, system testing, and inspection before the building is returned to normal use. Upgrading a facility may also take place to make it less vulnerable to future biological agent attack or incident

(e.g., installation of biohazard detection systems in U.S. Postal Service Processing and Distribution Centers) (Noller, 2005). Reoccupancy and reuse criteria aimed at longer-term environmental and public health monitoring can vary dramatically depending on who will occupy the site and the extent of the potential residual contamination (Section 4.20). After renovations are completed and monitoring indicates that the established criteria have been met, a reoccupancy decision is made about whether to permit residents and employees to return.

3.5 Biological Agent Incident-Response Decision Process

The flowchart shown in Figure 4 highlights the critical steps that must be taken during the phases of response to a biological incident (Raber et al., 2002). Whereas Figure 3 in the previous section lists the basic activities that comprise a response, Figure 4 arranges the response activities in a specific sequence and provides the decision-maker (e.g., IC/UC) with a guide to key decisions (diamonds) and tasks (rectangles) that need to be accomplished during a response. The activities in the flowchart are described in more detail in Chapter 4. Thus, a decision-maker can use this chart as a general "map," along with Chapter 4 for details, when determining what needs to be done and in what general order to proceed when responding to a particular incident. Key decisions are within the diamond-shaped boxes, key issues or decisions addressed are in blue boxes, activities are in white boxes, and completion is indicated by green circles. Chapter 4 refers to the various flowchart activities by the number within a box. Just as for Figure 3, in Figure 4 it is important to note that the listed activities may not necessarily occur in sequential order, but may proceed in a different order or in parallel.

Biological Agent Incident-Response Decision Process (1 of 5)



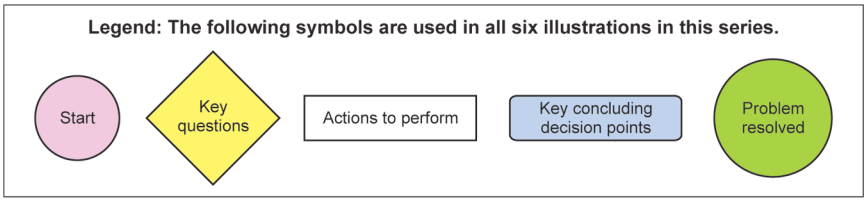


Figure 4. Biological agent incident-response decision process (1 of 5).

Biological Agent Incident-Response Decision Process (2 of 5)

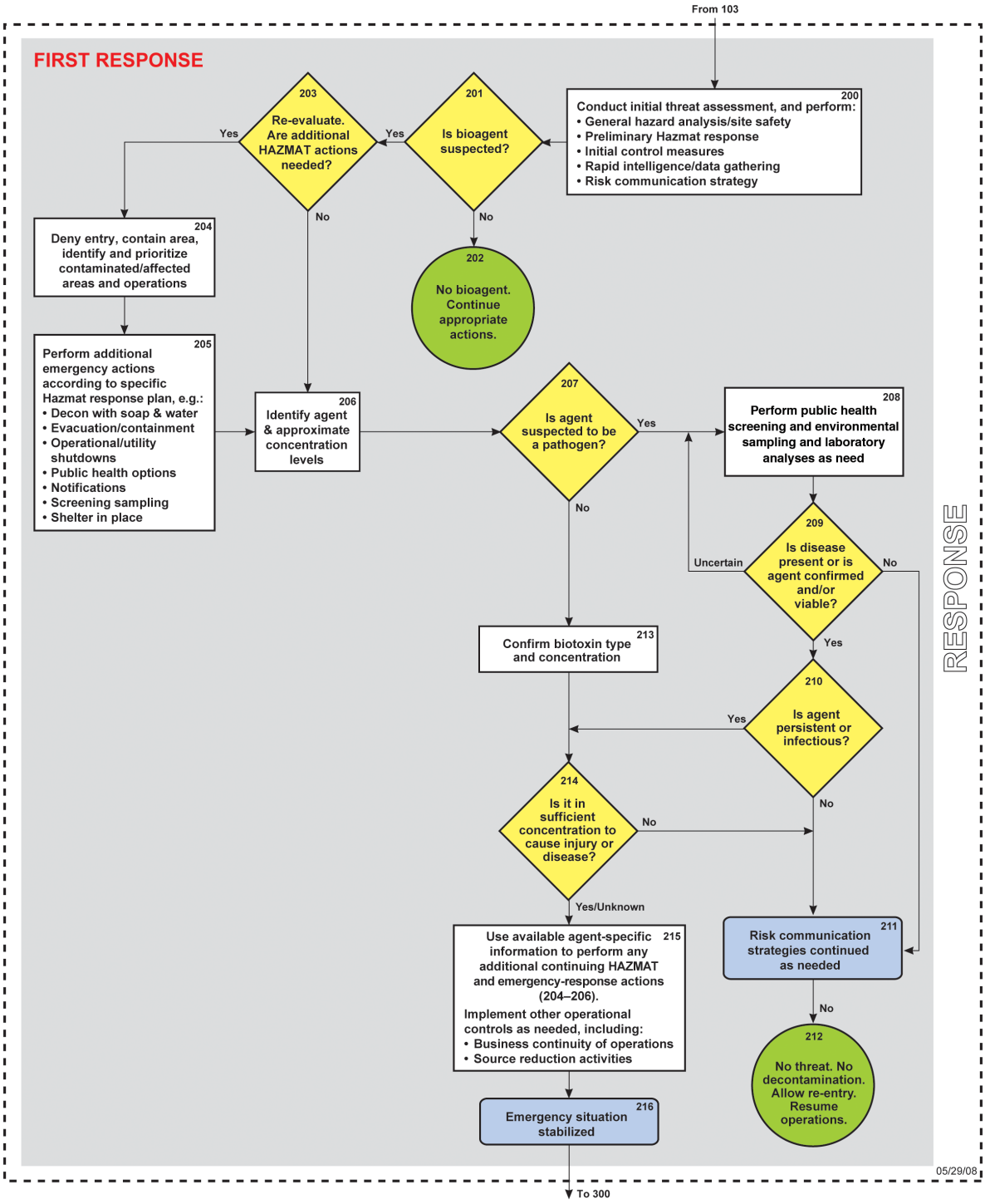


Figure 4. Biological agent incident-response decision process (2 of 5).

Biological Agent Incident-Response Decision Process (3 of 5)

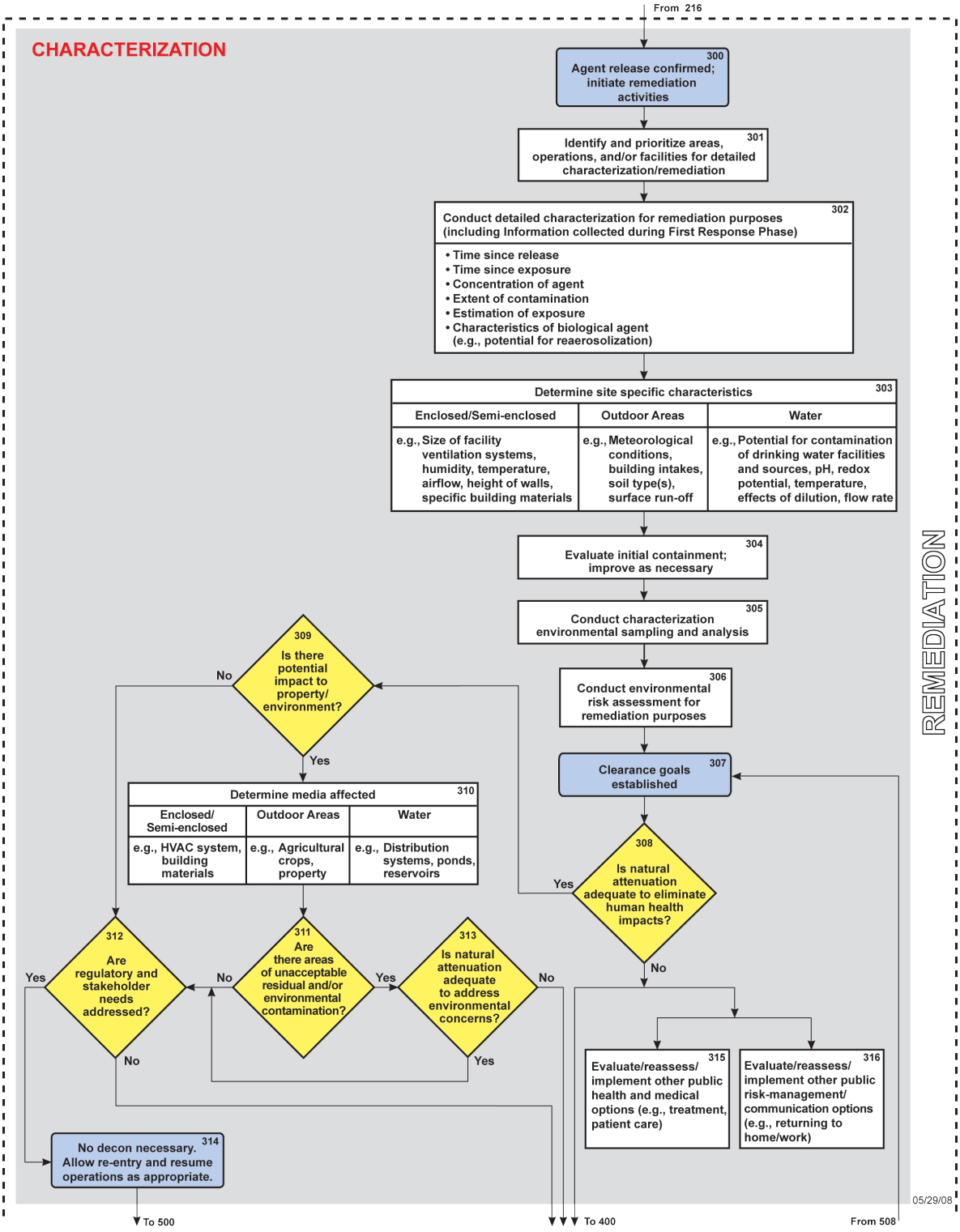


Figure 4. Biological agent incident-response decision process (3 of 5).

Biological Agent Incident-Response Decision Process (4 of 5)

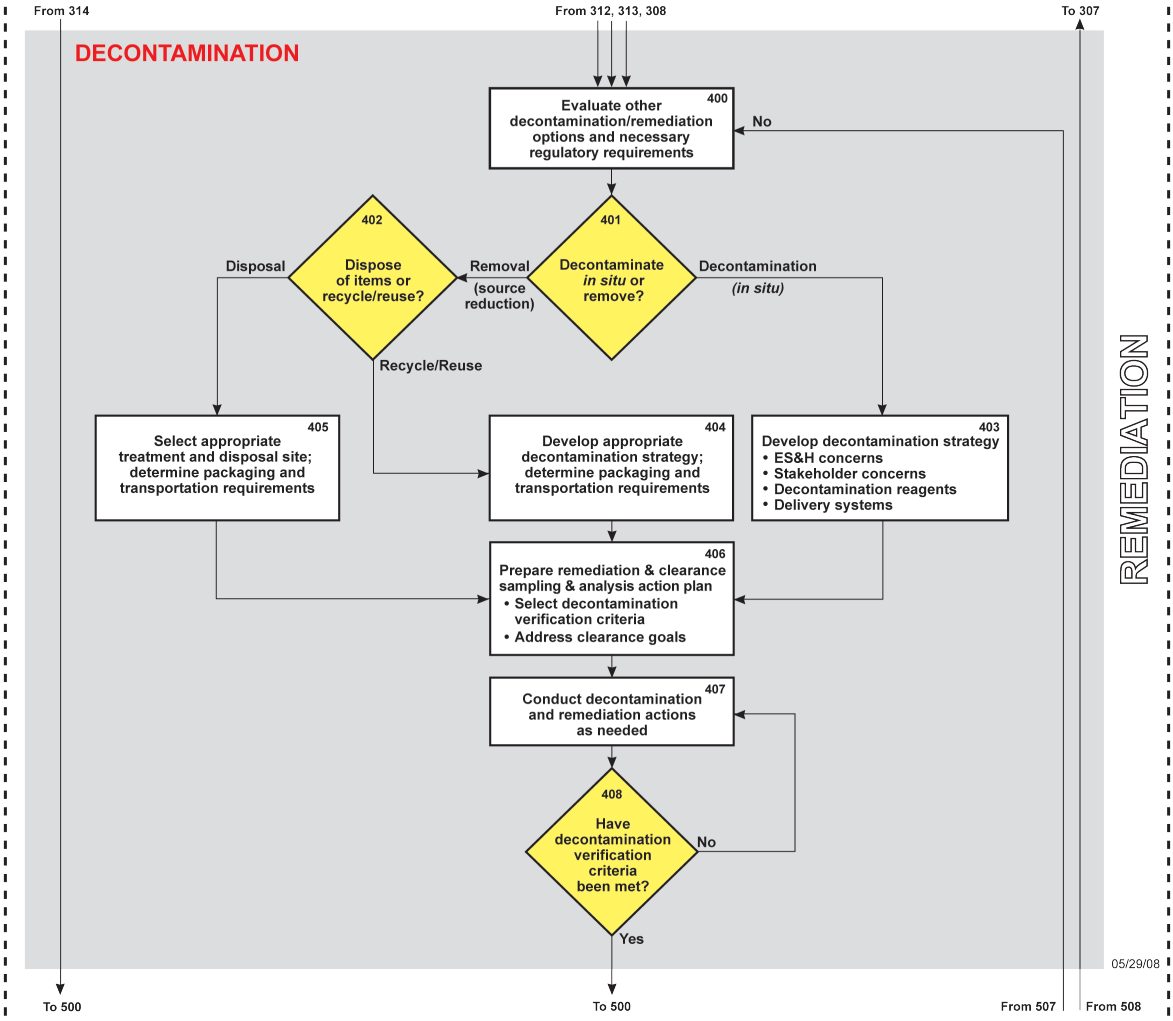


Figure 4. Biological agent incident-response decision process (4 of 5).

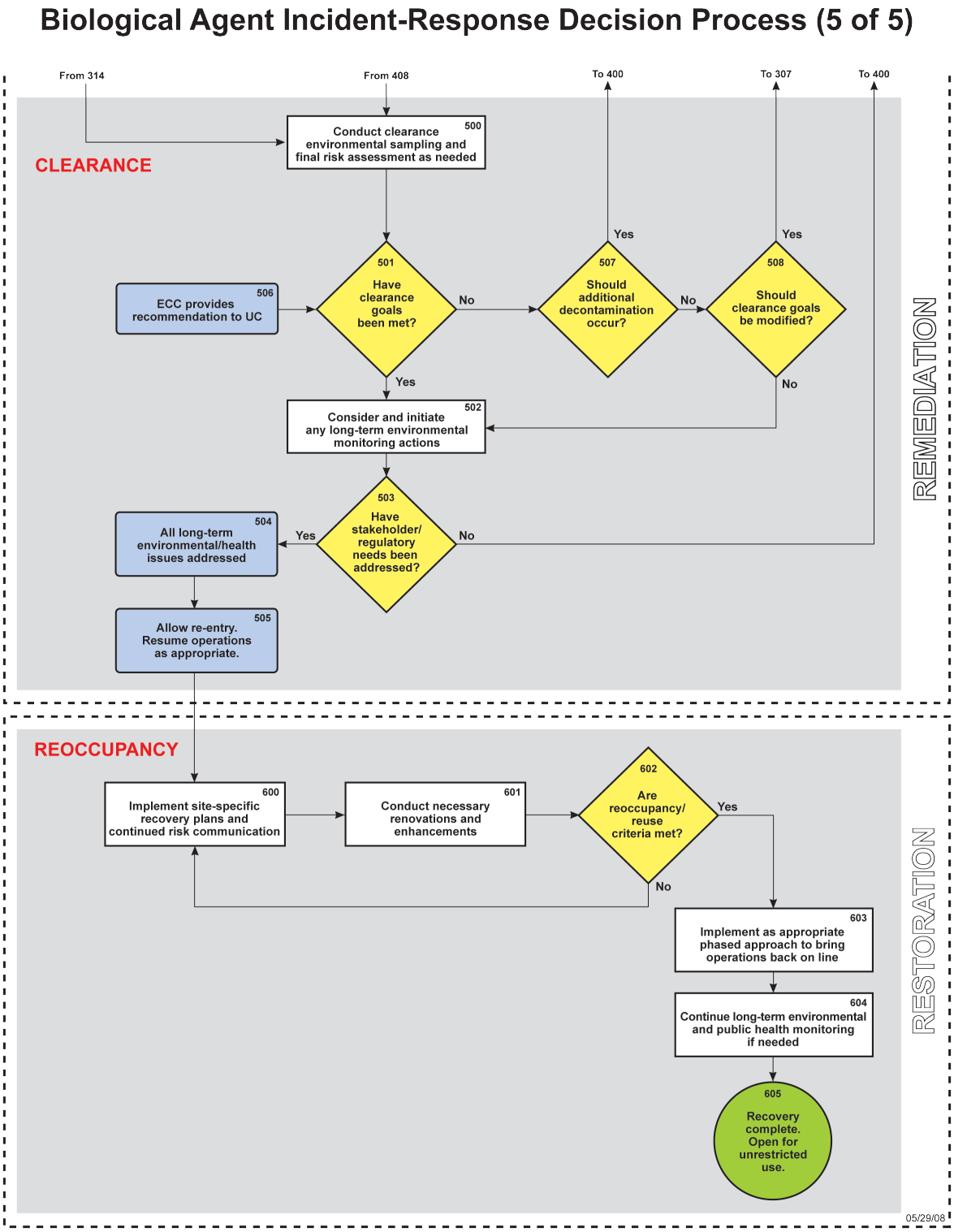


Figure 4. Biological agent incident-response decision process (5 of 5).

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4. Framework for Decision-Making

4.1 Introduction

This chapter describes the activities that occur in domestic, civilian settings during a response to a biological incident (Figure 3) and concepts that guide decision-makers in how to accomplish the activities. In planning and executing activities described in this chapter, decision-makers should generally follow the overarching principles of risk management and optimization described in Section 3.1 and establish the IC/UC system described in Section 3.2. The level of effort and resources invested in using the framework should be commensurate with the significance of the problem, the potential severity and economic impact, the level of controversy surrounding the problem, and resource constraints.

As described in Section 1.3, the scope of this guidance includes natural, intentional, or accidental incidents that involve biological agents. The guidance is intended to apply to:

- Enclosed facilities and objects, such as commercial and residential buildings, aircraft, vehicles, trains, vessels, and their contents.
- Semi-enclosed facilities and objects, such as subways, public transit facilities, and their contents.
- Outdoor areas and objects, such as building exteriors, streets, parks, other open spaces, and items within these areas.
- Drinking water sources, distribution systems, and treatment facilities, and wastewater infrastructures.

Because most experience to date has been with incidents in enclosed and semi-enclosed buildings, much of the guidance pertains to such facilities and their contents. However, as discussed earlier, the framework presented in this document is intended to introduce a scalable cleanup approach based on the principles of site-specific optimization. Where different approaches to response and recovery are needed for outdoor and drinking water facilities or sources, such approaches are discussed in this chapter. In addition, the guidance in this chapter should not prevent the development and use of novel or practical approaches, if those approaches can be implemented safely and effectively. Food production and distribution systems are excluded because they are covered adequately in other guidance (*http://www.fda.gov/oc/bioterrorism/role.html*).

4.2 Notification and First Response (Boxes 100–217)

Notification of a potential biological incident (see Boxes 100–103 in Figure 4) could be triggered by various sources, such as a detection device (e.g., the U.S. Postal Service Biohazard Detection System for *Bacillus anthracis* spores) (Noller, 2005; see also McBride et al., 2003), a suspicious substance such as a white powder, or the occurrence of disease resulting from an airborne release (i.e., inhalation exposure) of known biological agents or consumption of suspect food or water.

An IC is established (Section 3.2) with the arrival on-scene of the first person of authority (e.g., fire department or police department representative), and a UC may be established—depending on the type and scale of incident—with arrival of representatives from other agencies (e.g.,

public health or FBI). The coordination of information and resources to support domestic incident management activities (Box 103) typically takes place at an Emergency Operations Center (EOC), which may be a temporary or a permanently established facility. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, and medical services), by jurisdiction, or some combination. In addition, if a business or government agency has a Continuity of Operations Plan (COOP) prepared for the affected site(s), that plan would be activated.

An initial threat assessment is made of the situation (Box 200). Activities carried out at this early stage would likely include making an initial hazard analysis, performing preliminary Hazmat responses, putting into place control measures, ensuring rapid intelligence and data gathering, and developing a risk-communication strategy. A specific example of such activities would be ruling out an explosive ordnance device. Of paramount importance during this early stage is the fact that emergency responders initially respond with health-protective actions in an effort to save lives.

Once an incident is known to have occurred, hypotheses concerning the characteristics and risks arising from the contamination are developed. Preliminary hypotheses are developed initially from any available information, including epidemiological, intelligence, or other data, and formulated to facilitate testing and analysis. Realistic, evidence-based, first hypotheses are best made by experienced personnel who have direct knowledge of similar situations. Public health and other experts make and deliver initial situation assessments to the IC/UC. Initial sampling (sometimes called screening environmental sampling or screening sampling for short) (Box 205) is undertaken to assess the likelihood of the preliminary hypotheses and to developas complete an understanding of the event as possible.

Screening environmental sampling is the initial collection of a limited number of environmental samples to determine if contamination is present and, if so, determine approximate location(s) of contamination from the biological agent and semi-quantitative estimates of agent concentrations at those locations, where possible. The results of screening sampling provide important data for the IC/UC to use in decision-making on appropriate public health and subsequent remediation actions. The number of samples taken is determined by available resources (collection personnel, equipment, and laboratory surge capacity), the size/complexity/location of the facility, and circumstances. The initial response generally occurs within the first 24 to 48 hours. First responders (Boxes 200–217) in appropriate PPE (National Response Team Technical Assistance Document, 2005) (OSHA Anthrax PPE resource guide, 2008) (CDC Anthrax PPE recommendations, 2001) collect at least the initial sample(s) from any discrete material found and samples from locations of concern based on the information available. Following notification of a presumptive positive result, first responders, industrial hygienists, or others may collect further environmental samples (Box 208), depending on the site. Sampling methods used are appropriate to the site or medium from which samples are taken, such as wet wipes or wet swabs from hard, nonporous surfaces and high efficiency particulate air (HEPA) vacuum samples from porous surfaces within the affected areas of the facility, and water samples from drinking water. Current information on available environmental sampling methods may be obtained from the CDC web site (*http://www.bt.cdc.gov/agent/anthrax/environmental-sampling-apr2002.asp*).

Environmental samples are sent to an LRN laboratory (Box 208), which can provide a definitive determination of the identity of pathogenic microbes (Box 207) and certain biotoxins (Box 213) that may be present (CDC 2005). The LRN laboratory runs an

appropriate analysis of the sample(s), reports positive and negative results, and confirms the identity of the biological agent, if present. The significance of test result to the overall sample characterization process depends on the type of test conducted. For example, the first test run on a suspected sample of *Bacillus anthracis* spores is a polymerase chain reaction (PCR) test, which is based on the presence or absence of DNA. In this case, a PCR test provides evidence of the presence of the bacterium but does not indicate viability (Box 209). In this example, a follow-up, culture-based test together with confirmatory biochemical, molecular, or antigenic testing would provide confirmation that spores are capable of producing viable, vegetative bacteria, as well as other information such as strain and antibiotic susceptibility.

Environmental sampling strategies should always be hypothesis-driven. Sampling should not be undertaken if there is no clear idea of what a "positive" sample would mean, or what actions would be taken if a sample yields a reactive assay. The hypotheses developed pertain to the identity, presence, persistence (Box 210), concentration, probability of contaminant dispersion, likelihood of exposure, and nature of the site, with respect to factors that may have allowed contaminant to migrate to various locations beyond the point of initial release. Such hypotheses are then tested by collecting environmental samples. After decontamination, when no agent can be detected with conventional procedures, more aggressive sampling techniques, such as reaerosolization with a blower or high-volume sampling, may be used (Ferro et al., 2004; LBL, 2004; Rodes et al., 2001; Thatcher and Layton, 1995). Rapid viability determination methodologies for *Bacillus anthracis* are currently under development. However, it may be necessary to conduct other activities, such as engineering studies (i.e., tracer gas or airflow visualization studies in buildings), to better inform the hypotheses. Given an appropriate hypothesis, a testing strategy can be developed that accounts for uncertainties in the sampling and analytical techniques.

Environmental sampling should always be used with other available information, such as clinical sampling (e.g., nasal swabs and blood samples), epidemiologic data (e.g., the occurrence of a disease of concern in humans; see Box 207), and analysis of the original contaminating material to make response and recovery decisions. Clinical sampling can provide definitive identification of the biological agent as well as its characteristics (e.g., virulence and persistence), and epidemiologic data can indicate the possible locations at which persons were exposed to the biological agent. Factors such as viability and agent composition can be obtained from the original material, if it is found. If for some reason environmental sampling cannot be effectively employed for a specific biological agent in the affected area (e.g., because of a lack of sensitivity of available sampling methods for a particular agent), then the decision-maker must rely on these other sources of information to evaluate the nature and extent of contamination.

4.3 Characterization of Biological Agents

(Boxes 206, 208, 209, 210, 213, 214, 302, 308)

Characterizing biological agents includes not only identifying the particular agent (Boxes 206 and 208) and verifying its presence, but also obtaining information about that agent and the risk potential posed by its presence (e.g., Boxes 209, 210, and 214). Identification typically means establishing the genus and species, and potentially the strain or subspecies. In some instances, information on strain or subspecies is necessary to determine the relative risk of illness and transmission of disease. Pathogens may be further tested for virulence, drug resistance, and other conditions that would impact public health recommendations

concerning exposures arising from the contamination. Testing biotoxins (Box 213) can help determine whether a particular toxin is present in an active form or may have been inactivated because of handling or environmental degradation.

The viability of agents (Box 209) is an essential piece of information that is required throughout the agent characterization and sampling processes. Simply identifying agent-specific genetic or antigenic material in a location does not confer sufficient information about risk to human health. Only viability testing can provide this information in the context of appropriate identification.

Some of the information about remediation requirements (Box 302), such as time since release and time since exposure, will already have been collected during first-response activities. Characteristics of a biological agent (Box 302) that are critical to the decontamination effort include the environmental persistence of the agent (Boxes 210 and 308) and its susceptibility to inactivation. It is widely thought that there are few environmentally persistent agents of concern among the agents generally considered to have been formulated into weapons-grade agents. There are, however, exceptions to the hypothesis about environmental persistence. It is possible that a terrorist could use a novel agent that was not considered for inclusion by the weapons programs and that is environmentally persistent as well. Several weapons-grade agents may have the potential to persist in the environment. For example, *Bacillus anthracis* spores have been documented to survive in the environment in endemic areas for years (NRC, 2005; Pepper and Gentry, 2002; Sneath, 1962). Furthermore, given appropriate conditions, *Francisella tularensis*, *Burkholderia mallei*, and *Burkholderia pseudomallei* cause naturally occurring outbreaks. The most likely explanation for environmentally transmitted infections is that they are associated with reservoir animal hosts in the environment. However, it is also possible that these agents may persist in the inanimate environment under proper conditions.

Biological agents may be formulated into more environmentally persistent forms. For example, a commercial technique for stabilizing and drying microorganisms so they can be stored might also be used to increase persistence. The time needed for less-persistent, dried agents to undergo monitored natural attenuation can range from days to months.

4.4 Characterization of the Affected Site

(Boxes 301–306, 309, 310)

Just as the biological agent is characterized as part of the ongoing assessment of health risks, so is the affected site. Site characterization (Boxes 301–305 and 310) is generally based on the results of environmental sampling and provides important inputs into environmental risk assessment for site-remediation purposes (Box 306; see also Section 4.8). Site characterization includes the following activities, as appropriate, for an affected site. Activities that apply to all four types of sites (see Box 303 and Section 1.3 Scope)—namely, enclosed facilities, semi-enclosed facilities, outdoor areas, and drinking water facilities and water sources—are listed first, followed by activities specific to subsets of sites categories. Activities that apply only to water systems are listed last.

4.4.1 Generic Characterization Activities for All Site Categories

- Develop a detailed description and determine the dimensions of physical areas affected. Areas might include (Box 310) urban or rural environments,

outdoor environments, enclosed or semi-enclosed structures, and water systems (natural or man-made).

- Estimate the surface area and volume of materials and surfaces (both contents and structure) that may be potentially contaminated. Detailed maps of the facility, area, or water system will be required to categorize completely the various contents and attributes of a contaminated site (LBL, 2004; NRC, 2005, p. 161).

4.4.2 Enclosed and Semi-Enclosed Facilities

- Identify the types of materials and surfaces comprising the structure and its contents. Surfaces generally fall into one of two categories—hard, nonporous (e.g., walls, hard flooring, and metal surfaces) and porous (e.g., ceiling tile, upholstery, and carpet). The presence of soil or other organic material on the surface should be noted because it could decrease the effectiveness of the decontamination method. Furthermore, the composition of treated material needs to be evaluated (i.e., material compatibility) because of the potential for interference with the decontaminant, the possible production of hazardous by-products that remain after treatment, and the potential effects of the decontaminant or its by-products on sensitive equipment.

- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release, collecting information about a facility's HVAC system (Box 310; DHHS, 2002), and identifying transport systems (e.g., buses or trains between terminals in airports) or other transport mechanisms (e.g., wind, water, humans, fomites) that might facilitate the spread of an airborne biological agent (Box 309). Potential reservoirs of contamination that could contribute to exposure route determinations should also be considered. Desktop computers and other objects with internal fans that draw in air might serve as reservoirs in enclosed facilities.

4.4.3 Outdoor Areas

- Document environmental conditions at the site during and after the contamination incident (Box 303). Conditions such as ambient temperature, humidity, exposure to sunlight, cloud cover, wind speed and direction, rate and directional flow of water, and rainfall may all be important information.

- Determine potential routes of exposure to the biological agent (e.g., inhalation, or skin contact) that would be unique to the affected site. Part of this evaluation includes assessing the potential spread of contaminant from point of release. Transport mechanisms to consider are wind, water, vegetation, and animals. Adhesion to people and clothing, transmission from one person to another, and movement associated with transportation and transit vehicles are also potential means of pathogen movement. Environmental reservoirs could include water, soil, damp organic materials, fountains, pools, atriums, crawl spaces, plantings, animals and insects.

- Use mathematical models (e.g., air movement or plume models), if appropriate, to characterize the fate,

spread, and transmission of the agent. Models have inherent limitations and require accurate input and parameters to be useful in the remediation process (Allwine et al., 2002; Lee et al., 2002).

4.4.4 Drinking Water Facilities and Water Sources

- Obtain a complete and accurate map of all connections and components of the water distribution system.

- Use modeling to identify the potential locations and level of contamination. A variety of models are in use at many water utilities and are available to assist in predicting flow within distribution systems given a variety of conditions. Ultimately, however it may be necessary to test the accuracy of predictions with tracer studies, following the distribution of nontoxic tracers as they move through a distribution system.

- Measure residual disinfection levels at or near the point of entry, estimate the transit time to the most distant downstream customer (to determine if the agent has already cleared the system), and look for storage vessels that may have greater water age/residence time than the rest of the system.

- Document the physical–chemical characteristics of the water system. Water may have a wide range of physical and chemical characteristics, some of which can impact the persistence or detectability of pathogens or toxins. Factors such as metal ion content, presence or absence of disinfectant residuals, and temperature should be collected if possible.

4.5 Site Containment

(Boxes 204, 205, 304)

Containment (Boxes, 204, 205, and 304) is the set of actions taken to prevent the further spread of a contaminant from a particular area or to prevent its movement within that area. Such actions include:

- Cordoning off any area known or suspected of being contaminated.

- Turning off a facility's HVAC system, if appropriate and after considering the specific characteristics of that system (i.e., would shutting down the system decrease exposure to a contaminant that is present in the building?).

- Sealing off all air ducts, windows, doors, conduits and other vents that might allow contaminants to escape outside a facility.

- Closing valves or segregating stand-alone portions of a water distribution system known to be contaminated (e.g., isolating pressure zones, storage tanks, pump houses, and the like).

- Ensuring site security by establishing procedures to restrict entry of unauthorized personnel (e.g., installing perimeter fencing, posting signs, installing physical barriers, or using guards at all times).

- Establishing standard work zones.

Site containment should be initiated during first response (Box 204 and 205) and then maintained or expanded during remediation/cleanup (Box 304). For example, in the case of a covert release in an enclosed or semi-enclosed facility, air samplers previously placed throughout the facility should detect

biological agents. Once an environmental screening sample is positive for a biological agent (or in the case of an overt release, once a surface sample detects an agent) the immediately affected area may be evacuated and contained (Box 205).

For outdoor areas, it may be difficult to determine the area contaminated with a biological agent and the boundaries of that contaminated area. For example, a containment decision regarding an incident in which a biological agent is suspected of having been dispersed from an airplane over a wide area would likely require consideration of many factors in addition to environmental sampling. Meteorological data (e.g., wind speed and direction), predictive modeling, data from pre-positioned outdoor samplers (e.g., Bio Watch, see Shea and Lister, 2003), and possibly information on the flight pattern of a suspicious aircraft could be useful in informing such a decision.

For drinking water facilities and water sources, water sampling combined with computer modeling of how and where a contaminant may spread through the system would be a practical approach to determine locations that need to be segregated and decontaminated.

Establishing standard work zones at a contaminated site is critical to ensuring that any containment activities and subsequent decontamination activities are safely and effectively conducted. The purpose of work zones is to:

- Reduce the accidental spread of biological agents from contaminated areas to clean areas by natural processes, workers, or equipment.
- Confine work activities to the appropriate areas, thereby minimizing the likelihood of accidental exposures.
- Facilitate the location and evacuation of personnel in case of an emergency.
- Prevent unauthorized personnel from entering controlled areas.

When establishing work zones at a site, the site map may provide a useful format for compiling relevant data. In the absence of sampling results, up-to-date site maps can provide essential information on potential and suspected hazards and potential exposure pathways.

Although a site can be divided into as many zones as necessary to ensure minimal employee exposure to hazardous substances, the three most frequently identified zones are the Exclusion Zone ("Hot Zone"), the Contamination Reduction Zone ("Warm Zone"), and the Support Zone ("Cold Zone") (See Appendix 4 for a detailed description of each zone). In effect, those areas recognized as "cold" have been "cleared" as free from contamination. Movement of personnel and equipment among these zones should be minimized and restricted to specific access-control points to prevent cross-contamination. The initial work zones should be monitored through ongoing quality-assurance environmental sampling to determine if the zones are adequate for continued containment of the agent in affected areas and for the safety of workers and other personnel in the immediate vicinity of the release.

4.6 Risk Communication

(Boxes 200, 211)

A Joint Information Center (JIC) should be established immediately (Box 103 and Section 3.3.2) to coordinate all public affairs activities and media releases regarding a biological incident. A Public Information Officer (PIO) who reports to the IC/UC should be appointed to develop and release information (Boxes 200

and 211) about the incident to news media and all agencies and organizations involved.

The PIO establishes information-collection requirements, assists in approving the release of all information, and provides information updates. Multiple phone lines should be provided and staffed by knowledgeable individuals. Other equipment needs for the JIC depend on the size and impact of an incident. Additional guidance can be obtained from the JIC Manual developed by the National Response Team (NRT JIC Manual, 2000, available at *http://www.uscg.mil/hq/nsfweb/nsf/onlinedoc.html*).

4.6.1 Developing a Public Communication Strategy

Every crisis evolves in phases, as shown in Figure 3. Targeted communication relying on good risk communication principles, must evolve in synchrony with the phases and must be directed toward phase-specific activities. The JIC staff should be familiar with the basic tenets of risk communication and with the unique informational requirements of each phase. The operational requirements of each phase will vary according to the intensity and longevity of a crisis.

The designated PIO must communicate information the public wants and needs to reduce the incidence of illness and death. It is vital that the spokesperson's communications reduce the likelihood that:

- Scarce public health and safety resources might be misallocated (e.g., through pressures arising from incomplete or misinformation).
- Public health and safety recommendations are ignored or circumvented.

Early during an emergency, the PIO should follow good risk communication principles to describe:

- The incident and its magnitude (who, what, where, when, why, and how).
- What we don't know about the incident.
- Health and safety risks for individuals and communities.
- What is being done to respond to the incident (see Appendix 6).
- What actions the public can take.

4.6.2 Pre-Crisis Communication Planning

A risk communication plan should be developed by the JIC and put in place before a biological incident occurs. Pre-planned messages should anticipate necessary guidance for target audiences and should relay accurate information to address the public's concerns. Additional steps that can be taken in advance of a potential crisis or emergency include:

- Identifying regulatory organizations, authorities, and guidance documents.
- Identifying stakeholders and interested parties.
- Developing a public communication strategy.
- Establishing points of communication with local, State, and Federal agencies.
- Deciding how to deliver appropriate risk communication messages.
- Assessing demographic data

(e.g., communicating with a non-English-speaking population).

4.6.3 Crisis Communication During the First 48 Hours

During the first few days of an incident, it is necessary to quickly assess the potential response level required in terms of crisis communication, to assemble the facts as they become available, and to secure necessary resources to meet the expected buildup of media interest and demand for public information. Tasks during the initial phase of the crisis include:

- Verifying the incident and its magnitude.
- Notifying the chain of command.
- Coordinating with partner organizations.
- Establishing an initial media response.
- Assessing the level of public information and media response required.
- Assigning individuals to liaison with the media, gather information, translate messages into lay language, and execute support tasks.
- Allocating resources.

Additional information on the topic of risk communication is available at *http://www.hhs.gov/emergency* as well as from the CDC's *Crisis and Emergency Risk Communication* (Reynolds, 2002) and in the NRT's document, *Technical Assistance for Anthrax Response* (NRT, 2005). HHS has developed a series of risk communications based messages for use in the first hours of a chemical, biological, radiological or nuclear (CBRN) incident. These messages address major CBRN events along with suicide bombs and have been focus-group tested with the public. These messages are available at *http://www.bt.cdc.gov/firsthours/*

4.7 Characterization Environmental Sampling and Analysis (Box 305)

As explained in Section 4.2, the results of initial screening sampling (Box 205) provide evidence to confirm or reject a preliminary hypothesis concerning the distribution and nature of a contaminant, and to inform preliminary public health decisions and actions. More in-depth characterization environmental sampling and analysis (Box 305) is conducted to determine the appropriate public health response and provide input concerning further remediation actions. Thus, during the characterization phase, further hypotheses about the location of contamination are tested by data collection, including environmental characterization sampling. Analysis of the results of such sampling facilitates evaluation of each hypothesis and allows for the development of more advanced hypotheses for improved characterization. It is important to note that most current sampling and analytical methods for biological agents is non- or semi-quantitative.

If desired, the IC/UC may appoint an advisory panel of multidisciplinary experts, called a TWG, to help develop a SAP, Remediation Action Plan (RAP), and other planning documents. As described in Section 4.19, the IC/UC may also form an Environmental Clearance Committee (ECC) of independent experts to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. State and local planners should ideally identify ECC members as part of their advance planning process for biological incidents and select members who

are knowledgeable about regional issues. The ECC will interact early on with the TWG group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG.

A characterization environmental sampling plan should be designed to minimize health risks to the sampling team by minimizing the time spent in the contaminated area. The sampling plan should specify the minimum number of samples needed to provide adequate characterization given the resources available at that time. An additional constraint on sample number is the capacity of laboratory support for sample processing and analysis. Activities such as maintaining chain of custody, archiving, and complicated processing and manipulation of samples may limit the rate and maximum number of samples that can be processed and analyzed to far fewer than what might be predicted from the analytical capacity of a laboratory. Sampling strategies will be site-specific and are determined by the contaminant, presumed level of contamination, location of contamination, and other factors.

Standardized formats for characterization sampling methods and hypothesis testing are not currently available for every condition (e.g., sampling for a particular biological agent on a particular type of surface or environmental matrix). However, a wealth of general information on sampling (Buttner et al., 2004; CDC, 2002; EPA, 2002b) and analysis is available to guide implementation. Most hypotheses will center on one or two possible notions. For example: (1) contamination is not widespread, and (2) the contamination will have one or more areas of maximum concentration and some distribution, with a gradient of decreasing contamination away from the contaminated zones. Once the hypotheses are formulated and tested, and after the spatial distribution, environmental persistence, and concentration of contamination are better understood, a plan for decontamination can be formulated.

All of the above elements are incorporated into a Characterization Environmental SAP. The Characterization SAP articulates an overall strategy specific to the contaminated site, lists the methods and tools to be employed (e.g., environmental sampling, sampling of animals, and use of tracer studies), and describes how the tools will be applied to implement the strategy. For example, the overall strategy might be to use wipe samples in a targeted area at the suspected point of release of biological agent, along pathways where the agent may have been tracked, and at air-intake vents nearby. From these samples, the locations and amounts of the contaminant can generally be determined. In an interior space, the strategy might include modeling and tracer studies of airflow through the HVAC system and the affected area to determine other possible locations that need to be sampled. In an outdoor space, the strategy might include sampling animals in the area or sampling on unweathered surfaces of vegetation. In a water distribution system, the strategy might include modeling and tracer studies of flow in the distribution system. In describing how the tools will be applied, the SAP defines the sampling zones and sampling units; specifies the number and type of samples to be taken in each sampling unit; specifies locations for each type of sample; and describes how samples will be collected, packaged, and transported to the laboratory for analysis. The Characterization SAP also lists the laboratory or laboratories that will analyze samples; the laboratory procedures and protocols that will be followed in handling, processing, and analyzing samples; the laboratory's quality-assurance procedures; and how it will document and report the results.

Many pieces of information concerning environmental sampling are critical when determining the associated risk. However, some of the information can be difficult to obtain during an incident. In such cases, first approximations or conservative estimates are used. For example, the absolute limit of detection of a sampling and analysis method on a given surface for a particular biological agent may never be known because methods are best tested under controlled conditions. In addition, many factors— including humidity, light, temperature, roughness of a surface, pH, and other variables—may affect the resulting analysis (sampling efficiency, extraction of biological agents from a sample collection matrix, or detection in a given assay format). In some cases, internal controls can be used during sampling, processing, and analysis to gauge the performance of detection methods; however, they do not absolutely guarantee an accurate understanding of biological agent levels.

One important aspect of environmental sampling is to collect samples at locations where the biological agent is not detected. The lack of detection is not a guarantee that the agent is not present; rather, it means that the biological agent may be present at or below the limit of detection. Individuals who are unfamiliar with environmental sampling sometimes misinterpret the meaning of the inability to detect a contaminant or negative (nonreactive) assay results. A classic definition of a detection limit is that the method will detect a biological agent at a particular concentration in a defined test protocol some proportion (generally 95%) of the time. This means that at least some times (5% of the time in this example), the presence of the biological agent at the detection limit will result in failure to detect that agent. Many other factors can explain the inability to detect a biological agent. For example, failure to detect can arise from:

- A fault or inconsistency in the application of a protocol.
- Failure of decontamination agent.
- Natural variation in sampling technique.
- A matrix component that interferes with the assay.
- A change in state of contaminant (e.g., loss of a plasmid necessary for detection).
- Assay limitations.
- Actual absence of the biological agent.

A negative assay result for an environmental sample is simply the lack of ability to detect a biological agent, and such a result may not necessarily indicate the absence of target organisms.

The ultimate mass of material or number of organisms released may not be discernable through environmental analysis, or may only become known after the individuals releasing the material are captured and interrogated. It may be possible to estimate the amount of material in a particular release, or to place an upper bound on this number based on the delivery mechanism. However, such information will likely be unavailable during remediation of the affected site.

The physical and chemical properties of the agent and its subsequent interaction with the environment (e.g., settling, attraction to surfaces, and agglomeration to other materials) also may not be known. Furthermore, most of the bulk material in a recognized, intentional incident will likely have been removed from the scene by law enforcement personnel, and some information about the material (e.g., additives, milling, and delivery systems) may be prosecution-sensitive.

This means that the information may be missing from the data sets used to construct remediation plans.

In spite of these possible unknowns, with a good environmental SAP, Hot Zones and contamination gradients (including areas where the contaminant was not detected) can be determined and used to help guide the remediation effort. Even though underlying uncertainties in sampling methodologies are likely, scientifically-based decisions can be made.

4.8 Risk Assessment (Box 306)

As part of the risk management paradigm described in Section 3.1, potential risks posed by a biological agent at a specific site need to be assessed to assist decision-making about setting clearance goals (Section 4.9), formulating a decontamination strategy (Section 4.10), and developing a RAP (Section 4.11). As previously described, the four basic components of risk assessment are hazard identification, dose–response assessment, exposure assessment, and risk characterization. The overall goal for site-specific environmental risk assessment (Box 306) is to collect and evaluate all relevant information about the biological agent, its characteristics, and potential or measured exposure, and then provide to the decision-maker a scientifically reliable, quantitative or qualitative estimate of the potential level of risk to humans, animals, or the environment.

As discussed in Section 4.3, the identity and characteristics of a biological agent that has been confirmed to be present at a particular site are essential for hazard assessment. Among the most important characteristics to ascertain are the length of time the agent can survive in the contaminated setting (persistence), whether the agent is present in a form that easily disperses, likely routes of exposure, and the degree of resistance to inactivation.

A dose–response assessment is usually based on a review of available animal toxicology and/or human epidemiological data and medical incidence data. Any available data on the specific biological agent of concern needs to be collected and evaluated to ascertain whether a dose–response relation (i.e., an infectious dose) can be established. It is important to remember that infectious dose estimates rely on a "denominator" population. Frequently cited infectious doses are ID50 or the number of organisms that would cause illness in 50% of the population that was exposed. A minimum infectious dose is the smallest number of organisms administered to an individual (animal), or calculated to have been present in an exposure in a epidemiological study, that resulted in illness in at least one individual; animals or individuals exposed to less than this dose did not become ill in that population. Any given individual exposed to a number of organisms less than the established minimum infectious dose still may become infected if that individual is more susceptible than those in the study population, the exposure mechanism is different (i.e., inhaled in an aerosol versus by nasal lavage), or the organisms are more virulent (either a different strain or prepared with virulence-enhancing materials). The statistical power of many calculated minimum infectious dose studies may also be very small. For example, a study of 1,000 primates exposed to an anthrax aerosol may demonstrate a minimum infectious dose, whereas that dose is still infectious to one individual per every 10,000 living in an urban area.

Although infectious dose can be useful in qualitatively estimating human health effects, and such information is useful to set preliminary clearance goals, these data depend on the precise conditions present in the study from which the data were generated, and the information may not be directly applicable to the situation at hand. Furthermore, a recent review by the National Research Council of the National Academies of Science concluded that infectious doses for pathogenic biological agents cannot

be determined with confidence because the infectivity and virulence of pathogens can vary by strain, within species, and by the type of preparation used (NRC, 2005). Therefore, available information on infectious dose should not be over-interpreted. Nevertheless, infectious dose and related data are available for biological agents from various sources (USAMRIID, 2005; EPA, 2006; CDC, 1999).

A site-specific exposure assessment is performed by integrating the results of screening environmental sampling (Section 4.2 and Box 205), characterization of the site (Section 4.4 and Boxes 302–303), and characterization environmental sampling (Section 4.7 and Box 305). Sampling data may also be used to document the locations and levels (if quantitative analyses were performed) of biological agent, and site characterization, gives an indication of site structure, the presence of conditions that can spread an agent, and the types of items and environmental matrices at the site. Modeling can also be performed to assess the potential movement of biological agent from one location to another.

For chemical agents and biological toxins, site-specific risk characterization is usually performed by combining the dose–response assessment with the exposure assessment to generate quantitative estimates of the degree of risk that a contaminant may pose to humans or other susceptible species. However, in the case of most biological pathogens, because of the difficulties surrounding infectious doses, it is unlikely that a quantitative risk characterization can be developed. Nonetheless, a qualitative risk characterization still has significant value and needs to be provided to decision-makers. Such a characterization is instrumental in helping decision-makers determine clearance goals and a decontamination strategy. For example, a risk characterization that concludes that the biological agent at a particular site is persistent, easily aerosolizes, and presents a significant risk of disease to humans via inhalation would likely drive the selection of stringent clearance goals and an aggressive decontamination strategy.

4.9 Clearance Goals

(Boxes 307, 308, 312, 315, 316)

There is no simple formula for setting clearance goals (Box 307) as part of the risk assessment process (Box 306). The collective, professional judgment of technical experts described in Section 3.2, applied within the context of the concerns of stakeholders, should be used to set clearance goals (Raber et al., 2001) appropriate to the site-specific circumstances (Box 307). A practical clearance goal is to reduce residual risk to levels acceptable to the site-specific IC/UC by employing an optimization process. The goals may also be influenced by national security, economic, sociological and psychological considerations, available resources, and potentially competing remediation priorities (e.g., in the event of multiple attacks). In cases where contamination is extensive, intermediate goals may be set, complemented by other interventions (Boxes 315, 316), such as prophylaxis, shelter-in-place advisories, medical monitoring, PPE, and other ESF #6 mass-care considerations (see ESF #6 at *http://www.nmfi.org/natlresp/files/ESF6.pdf*). There may also be separate clearance goals for different locations within a single site. This may happen if the area is sufficiently large and complex to contain variation in terms of parameters such as natural occurring background or factors which influence sampling or analysis.

Fortunately, for most pathogens, the passage of a short time may be sufficient to reduce or dispense with the need for decontamination because many agents do not survive for long in the environment (Box 308). However, certain toxins such as T-2 mycotoxin, and persistent pathogens such as *B. anthracis* spores, pose long-term remediation challenges, as

do organisms that have been genetically modified or formulated to be more persistent. Moreover, although certain contaminants are not considered particularly persistent, under appropriate conditions they may persist for days, months, or even years. The risk assessment activities previously described provide the information on which clearance goals will be based.

Risk management considerations, such as potential use of public health interventions, cost and feasibility of available decontamination options, past experience in similar situations, the public's perception of an acceptable level of risk, and regulatory and stakeholder needs (Box 312) also factor into determining the clearance goal. For example, if an epidemiological investigation suggests that an agent was present in a specific area, but no agent can be detected using currently available sampling methods, then a risk management decision may be made to use an effective decontaminant, thus providing some assurance to the public that health risk has been reduced as much as possible.

Setting realistic, site-specific clearance goals should be based on the results of the best possible risk assessments, careful consideration of scientific uncertainties, use of proven technologies wherever possible, verification of decontamination effectiveness, and strong stakeholder involvement throughout the decision-making process. A practical clearance goal is to reduce residual risk (Canter, 2005) to levels that the IC/UC, in coordination with the appropriate authorities, deems consistent with the terms of the risk management principles and the optimization process described in Chapter 3. The aim of such a process is to reduce exposure levels as low as is reasonable while considering potential future land uses, technical feasibility, costs and cost effectiveness, and public acceptability.

4.10 Decontamination Strategy (Boxes 400–404)

The IC/UC develops an overall decontamination strategy (Boxes 400–404) that will guide the development and execution of all remediation activities. The strategy is based on agent-and incident-specific information, such as the following:

- Identity, formulation, and key characteristics of the biological agent (e.g., agent species and subspecies, environmental persistence, and ability to aerosolize).
- Mode of delivery of the biological agent and nature and extent of its spread.
- Results of environmental sampling, including agent location and quantities.
- Epidemiological evidence (human disease cases) and what it shows (e.g., inhalational versus dermal route of exposure).
- Health risks posed by the biological agent.
- Nature of site or items to be decontaminated (Box 310, i.e., an entire facility or just one area within a facility; outdoor environment—rural or urban; an individual water tank, or entire multi-jurisdiction metropolitan water distribution system).
- Acute and chronic toxicities of chemical(s) to be used in the decontamination process.
- Public perception, such as acceptance of the process by the public.
- Environmental concerns, such as potential by-products, air emissions, residues, and disinfection by-products.

- Valid test data demonstrating the efficacy of selected decontamination process.

- Conditions required for effective application of a decontamination process (e.g., specified ranges of relative humidity, temperature, fumigant concentration, and contact time for fumigations, or pH for certain surface treatments).

- Timeframe of the process and associated costs.

- Potential collateral damage caused by the decontamination process (i.e., effects of the process on building infrastructure or equipment).

Considering all relevant information, an overall decontamination strategy is developed and articulated in the RAP. For example, if anthrax spores were delivered to or passed through a mailroom in a letter, and if environmental samples are collected that test positive, and if medical evidence of inhalation exposure is available (e.g., data indicate aerosolizability of spores, positive nasal swabs in recently exposed persons, or persons exhibit symptoms of inhalational anthrax), then a strategy of decontamination with a gas or vapor fumigant preceded by pre-cleaning of surfaces with a liquid antimicrobial pesticide in heavily contaminated areas would be indicated. As another example, in the case of a contaminated drinking water system, different strategies such as the following could be considered: (a) continue to treat the water by conventional disinfection, (b) increase the level of disinfection for all or part of the system, or (c) issue end-of-pipe treatment devices.

The overall goal of the decontamination strategy should be to achieve the clearance goals while minimizing resources, cost, and time. Such a strategy requires optimizing the balance among source reduction (Section 4.14), waste disposal (Section 4.15), decontamination (Section 4.16), and decontamination verification (Section 4.17) activities.

4.11 Remediation Action Plan

(Box 406)

Once a decontamination strategy is developed, a RAP is assembled that spells out an overall plan for decontaminating the contaminated site and its contents (Box 406). The RAP and Clearance SAP (Section 4.18) are generally created at about the same time because the remediation strategy can directly affect characterization and clearance sampling strategies. For example, if contamination is limited to a specific room, and the overall remediation strategy is to treat only the surfaces with a liquid decontamination agent then the sampling strategy may be to conduct clearance environmental sampling focused on that room and to conduct random/grid samples in rooms that are adjacent or connected by a common HVAC system. The RAP generally includes the following sections, each of which is described elsewhere in this chapter:

- Containment (Box 304).

- Characterization of the biological agent and site, including characterization environmental sampling strategy and results (Box 305).

- Worker safety and health and decontamination (Box 316, 403).

- Clearance goals (Box 307).

- Site preparation (Box 401).

- Source reduction (Box 402).

- Waste disposal (Box 405).

- Decontamination of affected sites (Box 407).

- Offsite decontamination of essential items (Box 404).

- Decontamination verification (Box 408).
- Clearance environmental sampling and analysis plan summary (Box 406).
- Clearance decision-making criteria (Box 406).

The RAP contains appropriate tables, figures, drawings, references, and appendices of key information from other documents, such as procedures and methods used in the remediation process and the characterization environmental sampling report.

Because the RAP specifies how the remediation activities will be carried out, the IC/UC in coordination with the appropriate State/local authorities, needs to approve the plan before it is implemented. The IC/UC in coordination with the appropriate State/local authorities must also approve any changes to the RAP as the remediation process progresses. Finally, if any Federal or State agencies have jurisdiction over some or all activities described in the RAP, they should review and approve the RAP as well. For example, the EPA has statutory responsibility under the *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) for registering (licensing) or exempting from registration the sale and use of antimicrobial and other pesticide products in the US (7 U.S.C. 136-136y). Because no antimicrobial pesticide is currently registered by the EPA specifically for the inactivation of *B. anthracis* spores, a Federal or State agency will need to check with EPA about obtaining an emergency exemption from EPA for each specific use of a selected antimicrobial pesticide to decontaminate a facility. EPA has the authority to issue such exemptions (FIFRA section 18) when emergency conditions exist. Most exemptions require an application and quick review from EPA before they can be issued. However, where the discovery of an emergency condition and the need to use a pesticide require quicker action than this would allow, EPA would expect to issue a crisis exemption. After the 2001 bioterrorist attacks, crisis exemptions were issued to permit the sale and use of several antimicrobial pesticides to decontaminate sites, and essential items removed from the sites and treated in offsite locations, following review and approval of site-specific RAPs.

4.12 Worker Health and Safety (Box 403)

Health and safety requirements must be addressed (Box 403) for all workers involved in the response and recovery following a biological attack. Workers include emergency responders, such as emergency medical personnel, police, firefighters, responders from government agencies, public health officials and volunteers, and those critical workers that may need to report to maintain critical infrastructure and key resources (power, healthcare, etc.). Short- and long-term remediation and restoration workers are also included (e.g., workers from government agencies, decontamination contractors, and employees at the contaminated facility).

The OSHA HAZWOPER standard (29 CFR 1910.120 and 29 CFR 1926.65) applies to each employer of the involved workers. For first/emergency response and remediation operations, this standard requires a written Health and Safety Plan (HASP) that identifies site hazards and appropriate controls to protect employee health and safety. All site hazards should be incorporated into the HASP, including physical, biological, and chemical hazards, as well as any hazards associated with decontamination agents used during remediation. Required elements of the HASP are described in the HAZWOPER standard and include the following:

- Organizational structure.
- Comprehensive workplan.

- Site characterization and job-hazard analysis.
- Engineering and work practice controls.
- Site control.
- Training.
- Medical surveillance.
- PPE.
- Exposure monitoring.
- Spill containment.
- Decontamination.
- Emergency response.
- Standard operating procedures for safety and health.

A site-specific HASP promotes efficiency and enhances completeness, clarity, and coordination among all affected parties. The HASP is a living document that is revised as necessary to reflect changes in site conditions or operations. Because some elements overlap, it may be useful to expand the HASP to include those elements necessary to protect the local community and environment (e.g., disposal of waste from decontamination or monitoring community exposures to fumigants). Additional written programs, plans, or procedures may also be necessary to meet the requirements of other applicable OSHA standards. For example, employees will likely need to use PPE during emergency response and remediation. Pursuant to 29 CFR 1910.132, employers will need to assess the workplace to determine whether and what PPE is necessary to protect workers. In addition, employers will need select appropriate equipment, ensure that it properly fits the workers and train each worker in its use. Moreover, employees will likely need to use respiratory protection during facility decontamination, so a written Respiratory Protection Program also is required in accordance with 29 CFR 1910.134.

Additional OSHA general industry and construction standards may also apply (29 CFR 1910 and 1926). For more information regarding health and safety considerations and OSHA requirements, refer to *www.osha.gov*. Additional helpful resources include the following:

- Anthrax eTool (OSHA): *http://www.osha.gov/SLTC/etools/anthrax/index.html*
- Model Health and Safety Plan (HASP) for Cleanup of Facilities Contaminated with Anthrax Spores (OSHA): *http://www.osha.gov/dep/anthrax/hasp/index.html*
- Safety and Health Topics: Bioterrorism (OSHA): *http://www.osha.gov/SLTC/bioterrorism/index.html*
- Technical Assistance for Anthrax Response (November 2003), Chapter 5: Health and Safety Considerations (NRT): *www.nrt.org*
- Safety and Health Topics web page on Biological Agents: *http://www.osha.gov/SLTC/biologicalagents/index.html*
- Recommendation for the Protection of Postal Mail Carrier Workers Delivering Antibiotics Door-to-Door Following an Anthrax Attack (CDC)
- Interim Recommendations for Firefighters & Other First Responders for the Selection & Use of Protective Clothing & Respirators Against Biological Agents (CDC, October 25, 2001): *www.emergency.cdc.gov/documentsapp/Anthrax/Protective/10242001Protect.asp*

- Interim Recommendations for the Selection and Use of Protective Clothing and Respirators Against Biological Agents (CDC, October 2001): *www.bt.cdc.gov/DocumentsApp/Anthrax/Protective/10242001Protect.asp*

- Guide for the Selection of Personal Protection Equipment for Emergency First Responders National Institute of Justice (NIJ) Guide 102-00 (November 2002): *www.ojp.usdoj.gov/nij/pubs-sum/191518.htm*

- *Technical Assistance for Anthrax Response - Interim-Final Draft* (National Response Team (NRT), July 2005): *http://www.nrt.org/production/NRT/NRTWeb.nsf/PagesByLevelCat/Level2TA?Opendocument*

- Anthrax in the Workplace Risk Reduction Matrix (OSHA): *www.osha.gov/dep/anthrax/matrix/index.html*

- Anthrax eTool "Protecting the Worksite against terrorism" (OSHA): *www.osha.gov/SLTC/etools/anthrax/index.html*

Some workers will also be involved in the delivery of medical countermeasures. Mail carriers, their security escorts, traditional first responders, and certain personnel working in critical capacities are expected to be working during the first 24 to 48 hours of the response. Separate guidance is currently being developed to address the protection of these responders.

As described in Section 4.5, workers who enter the Hot Zone must wear appropriate PPE and will need antibiotics, antivirals, or other form of preventive care. When they exit the Hot Zone, they and their equipment must be decontaminated. Decontamination of workers in the Warm Zone ensures that they are not contaminated while removing their PPE, by materials that they may have contacted in a contaminated work area (Hot Zone), and that they do not track contamination into clean areas of the site (Cold Zone). Such procedures can include the following:

- Mechanical decontamination (washing with soap and water to physically remove a potential contaminant) is typically used on workers.

- Chemical decontamination (applying disinfectants or sterilants to inactivate the biological agent) is typically used on PPE or nonsensitive equipment. As described in Section 4.16, only antimicrobial pesticides authorized specifically for the specific biological agent involved should be used.

Procedures for decontaminating equipment are provided in Appendix 5.

4.13 Site Preparation

(Boxes 403–404)

Before decontamination methods specified in the RAP can be applied, the site and its contents need to be prepared for the remediation or cleanup process. Such preparation can cover a multitude of tasks (Boxes 403–404), such as:

- Assembling a worker decontamination unit.

- Testing a facility for leaks.

- Constructing internal waste-processing and load-out units.

- Installing and testing chemical generation systems.

- Installing and testing chemical, temperature, and humidity monitoring systems.

- Installing and testing negative air units and air scrubbing systems.

- Subdividing existing space with temporary walls.

Where fumigations are performed, site-preparation tasks can be time-consuming, costly, resource-intensive, and complex, and they need to be carefully planned and documented. Once all components of the decontamination and monitoring system are shown to work independently, some testing may be necessary to demonstrate that they all work together as a system. For example, a low-level performance test may be conducted prior to a large fumigation, which includes the scrubbing system, to show that the system as a whole will likely work when run at full capacity.

Site preparation for a water-distribution system may include isolation of various segments and infrastructure devices. It may also include such activities as installing backflow-prevention devices to prevent recontamination of disinfected distribution system segments. Certain distribution system components, such as pressurization and storage tanks, may be drained. Provisions may need to be made for installing additional equipment and to maintain system operations and pressure as various critical system segments are taken off-line. Replacement water may need to be provided to critical operations. If protocols such as relining pipes or aggressive flushing are to be used, supplies must be obtained, and the protocols must be tested to ensure safety and efficacy.

4.14 Source Reduction

(Boxes 401–402)

Source reduction (Boxes 401–402) is the process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, of cleaning items remaining on site prior to the main decontamination activity, and of cleaning surfaces. The decision about whether source reduction is needed is made on a case-by-case basis (i.e., considering whether decontamination can be done leaving articles in place). In some cases, source reduction could take place early in the response and recovery process and long before the decontamination phase is underway. If source reduction is performed, the goals are to:

- Reduce the number of potentially contaminated items and/or materials present.

- Ensure that any material that might inhibit decontamination is removed.

- Reduce high levels of contamination before full decontamination.

As part of the source reduction process, items to be removed from the site are pre-treated, as appropriate (e.g., essential items to be sent for treatment in ethylene oxide sterilization chambers are not pretreated with diluted bleach), and placed in packaging specified by the Department of Transportation and State and local governments. The packaging is also treated, usually with a 1:10 dilution of pH-adjusted bleach. The packages are then removed from the facility and transported (Box 404) to the appropriate offsite facility for disposal or treatment and disposal (Box 405), recycling, or reuse, depending on the nature of the items.

Exposed surfaces and items remaining in the site may be cleaned by HEPA vacuuming, scrubbing, and/or washing to physically remove dirt, grease, or other inorganic or organic matter, including the biological agent itself.

Decisions about which items or materials to remove from a contaminated area prior to decontamination depend on many factors, including:

- Sensitivity of essential items to damage by the decontamination chemical.
- Difficulty of decontaminating items onsite (e.g., paper and other porous items).
- Potential for items to absorb or deactivate the decontamination chemical.
- Potential for toxic residues to remain on or in items after treatment.
- Value of items compared to the cost of treatment.

Items or materials that are to be removed can be grouped into the following categories:

- Essential or sensitive items that must be removed, decontaminated elsewhere, and saved or restored for reuse (e.g., art works and valuable papers).
- Items or materials that can be removed, treated elsewhere, and destroyed (e.g., site debris).
- Items or materials that can be removed, treated elsewhere, and recycled (e.g., metals).
- Items or materials that can be treated and cleared onsite, then sent offsite for recycling (e.g., batteries and fluorescent lights).

Once decisions about the fate of items or materials are made, the source reduction activities are incorporated into the RAP and carried out as specified.

The parallel concept of source reduction in water distribution systems is flushing of water to waste. Such action should reduce the amount of contaminated water, and the flushing action should help to remove contaminants within pipes. The fate of potentially contaminated water must be predetermined before flushing decisions are made.

4.15 Waste Disposal (Box 405)

As part of source reduction, decisions are made about what to do with materials or items to be removed permanently from the site. In addition to such wastes, other wastes are created by decontamination processes, such as water used to rinse PPE, employee shower water, and scrubber wastewater.

A major issue for all types of waste is finding waste disposal sites and/or treatment facilities that will accept either treated or untreated wastes (Box 405). A few facilities have medical-waste incinerators capable of handling sizable quantities of untreated medical waste. Because of uncertainties and negative public perceptions about health risks associated with biological agents, nonmedical waste disposal sites may refuse to accept treated wastes, even if the waste has been shown by sampling not to be contaminated. Nonetheless, to the extent feasible, wastes should be decontaminated on-site in order to minimize the need to transport, treat and dispose of contaminated wastes off-site.

Although source reduction is generally completed before the main decontamination activity, waste disposal continues until the end of decontamination because of the continuing production of wastewater and other consumables

used by onsite workers. Waste is removed from the facility throughout the entire remediation process and transported to an appropriate offsite facility, depending on the nature of the waste. Information on methods of disposal of biologically contaminated waste can be found at *http://www2.ergweb.com/bdrtool/login.asp* (Thorneloe, 2007).

Wastewater collection and treatment facilities are typically designed to accommodate pathogenic microorganisms. There are, however, circumstances under which a specific wastewater treatment system may not be able to handle wastewater from a particular contamination incident. For example, a rapid influx of a large volume of water, particularly if contaminated with a large quantity of a persistent agent, may challenge a wastewater system beyond its capacity. Many communities have combined waste and storm water collection and treatment systems. Some of these systems maintain combined storm sewer overflow. In the case of a storm water runoff event, or perhaps a large-scale flushing, the system will allow the overflow that exceeds the capacity of the wastewater treatment plant to run directly into receiving rivers or streams. In a biological incident, the potential for environmental contamination, through this and other routes, must be evaluated. The safety of wastewater treatment system workers must also be considered in these decisions. In addition, the wastewater treatment authority must grant permission for the discharge of wastewater into its system.

4.16 Decontamination of Sites or Items (Box 407)

Once a determination is made that decontamination of any kind is necessary to mitigate a biological agent, the most appropriate decontamination method(s) for the biological agent and affected site and its contents need to be evaluated and selected (Box 403). A wide array of physical and chemical (antimicrobial) decontamination methods for mitigating biological agents is available for consideration. Physical decontamination either inactivates the agent through physical means, such as heat or radiation, or removes the agent such as by washing with soap and water or vacuuming with a HEPA filter.

Chemical decontamination inactivates the agent through the use of antimicrobial disinfectants or sterilants. Current technologies for chemical (antimicrobial) decontamination fall into three categories: liquids, foams and gels, and gases and vapors (Fitch et al., 2003 and references therein). Because no single technology is applicable in all situations, the determination to use a particular method is made on a site-specific basis. Liquids are effective against many biological agents when applied to hard, nonporous surfaces, but they can cause corrosion to sensitive equipment. Foams and gels are effective against certain biological contaminants, but some can pose a post-decontamination cleanup issue. Gases and vapor fumigants are effective for inactivation of biological agents under controlled environments and conditions, but they involve complex operations. Gases offer advantages in decontamination, but the quantities of certain gases required for large-scale decontamination can create inherent safety hazards. Certain gas-phase water disinfection systems involve the generation of gas onsite, using chemical or electrochemical processes that offer some advantages in terms of removing the requirement for storage of compressed gases. Difficulties with some such systems include measuring the efficiency of the gas-producing reaction, and establishing that the required contact time and concentration gradients are achieved. Appendix 7 lists some key characteristics of liquid, gas, and vapor chemicals that have been used under FIFRA crisis exemptions to inactivate *B. anthracis* spores in contaminated facilities.

Although many different technologies are available for decontaminating surfaces, enclosed spaces, and water, each has advantages, disadvantages, and limitations when considering the agent and material(s) being decontaminated. No single technology, process, or strategy is effective in every case because decontaminating an area or item contaminated by a biological agent involves numerous and variable issues that are specific to individual locations (Hawley and Kozlovac, 2004; OSHA Anthrax E-tool, 2002; Canter et al., 2005). (also see *http://www.epa.gov/nhsrc/decon.html*)

Deciding which decontamination methods to use requires a rigorous evaluation of available methods and consideration of safety, efficacy, cost, and other factors. This decision is tied to the site-specific optimization process. Following a detailed analysis, and taking into account site-specific details, the IC/UC selects the decontamination method or combination of methods most appropriate to remediate the contaminated site and its contents.

Key considerations for selecting one or more decontamination methods include the following:

Safety

- Adequacy of site containment.
- Physical–chemical properties (e.g., explosivity or sensitivity to ultraviolet light) of the antimicrobial pesticide and potential formation of hazardous degradates.
- Toxicological characteristics and potential risks to humans of the antimicrobial pesticide and its potential chemical degradates.
- Persistence of the antimicrobial pesticide and degradates.
- Penetration capability of the antimicrobial pesticide.
- Exposure limits applicable to workers in the general population [e.g., Permissible Exposure Limit (PEL), Threshold Limit Value (TLV), and Short Term Exposure Limit (STEL)] of the antimicrobial pesticide.

Efficiency

- History of use in similar decontamination processes.
- Penetration capability of decontaminating agent.
- Availability of acceptable efficacy data.
- Registration and exemption history under FIFRA.
- Capacity of the gas or vapor generation system.
- Methods for evaluating the efficacy of the antimicrobial pesticide (e.g., spore strips and environmental samples).

Generation, Distribution, Monitoring, and Removal

- Mode and capacity of generation of antimicrobial pesticide (i.e., available and ready-to-use versus generation onsite).
- Equipment and chemicals needed to generate and distribute gases, liquids, foams, gels, or vapors.
- Methods for preventing accidental release of decontaminant beyond the area to be decontaminated (e.g., HEPA filters on negative air vents or scrubbers) and to detect or monitor such releases.

- Equipment and methods needed to sample and monitor gas or vapor decontaminant concentrations, temperature, relative humidity, and other parameters required to ensure effective decontamination and that exposure limits are not exceeded for workers or the general public.
- Waste materials created (e.g., wastewater).
- Capacity of the decontamination generation and distribution system.
- Removal or deactivation of residual decontaminant and decontaminant by-products after decontamination.
- Structure and operation of a facility's HVAC system

Cost and Timeframe

- Materials (e.g., unit cost and quantity of chemicals needed).
- Equipment for generation, distribution, monitoring, and removal activities; PPE; packaging and containers for removed items and trash; wastewater disposal and treatment costs.
- Labor for planning, constructing, testing, operating, and dismantling equipment and materials.
- Indemnification agreements, if needed.
- Timeframe to set up, perform decontamination, and remove equipment.

Various safety measures may be employed during decontamination. These include, but are not limited to, ambient air monitoring near the building and in nearby neighborhoods to detect any escape of decontaminant; having police, rescue workers, and other staff on standby in the event of a catastrophic release of decontaminant or other emergency condition; and precautionary evacuation of nearby businesses or residences, where appropriate.

After the decontamination strategy and methods are selected, the IC/UC must ensure that the products are approved for the target biological agent, which could be either a biotoxin or a pathogenic microorganism. Products used against biotoxins are not federally regulated, but any substance intended to prevent, destroy, or mitigate any virus, bacteria, fungi, or other microorganisms that are not in or on living persons or animals are required by FIFRA, as amended, to be either registered or exempted prior to sale, distribution, and use. If the products selected are not registered for inactivating the specific target microorganism, the IC/UC must consult with the EPA to determine the requirements. Once approval is obtained to use the requested antimicrobial pesticide(s), the site is prepared, source reduction occurs, and decontamination methods are applied (Box 407) according to specific use directions to ensure that the methods are effective against the target pathogen and do not cause adverse effects to human health or the environment. Depending on the specific situation, State and local regulations may also affect the selection and use of particular decontamination strategies (See section 4.11 above).

4.17 Decontamination Verification (Box 408)

Decontamination processes are monitored as they are being carried out and then evaluated as to whether they have been conducted according to the specified parameters (Box 408). To be effective, liquid antimicrobial pesticides applied to hard, nonporous surfaces must be applied at a

specific concentration, temperature and contact time. Accordingly, the product must be mixed to the specified use-dilution concentration, the appropriate temperature (normally 20° C) maintained, and the minimum contact time achieved. When these parameters have been met, the decontamination with the liquid antimicrobial pesticide can be judged as likely to have been successful.

For gaseous or vaporized antimicrobial pesticides, four parameters are key to their efficacy—temperature, relative—humidity, chemical concentration and contact time. These parameters are monitored and recorded for each of the four phases of the fumigation process—(de)humidification, conditioning, decontamination, and aeration. Maintaining these variables in the prescribed ranges throughout fumigation is one indicator of the efficacy of the process.

Biological indicators (BI) contain nonpathogenic (surrogate) spores that are selected to be generally more difficult to inactivate than virulent species of spores. A variety of spore preparations can be used such as *Bacillus atrophaeus* and *Geobacillus stearothermophilus*. Usually, a specific number of viable spores (e.g., one million) is dried on filter paper ("spore strips") or stainless-steel discs ("coupons") contained in a glassine or Tyvek pouch. BIs are used during fumigation to provide a general (but not definitive) indication of whether the fumigation was effective. Because the spores on BIs have in some cases been observed to be easier to inactivate than spores on coupons in sporicidal efficacy tests, the BIs may be more indicative of when fumigation is not effective rather than when it is effective. Thus, in a particular fumigation zone, if one or more BIs are positive by culture after treatment, then that zone would need to be re-treated. In addition, the fact that all BIs are negative would not guarantee that all spores have been inactivated.

BIs are usually placed in various locations and at a frequency of one per 100 square feet of floor space or as otherwise specified in the Clearance SAP. Placing BIs in locations of known or suspected contamination and in spaces hard to reach by the fumigant is the standard practice. Positive and negative control BIs are also employed. After fumigation is complete, treated and control BIs are sent to an analytical laboratory with demonstrated experience in analyzing BIs from biomedical sterilization and other relevant fumigation processes. They are then incubated by culture to determine spore viability.

When the process parameters are met, and all spores on the BIs have been killed, the fumigation can be judged as likely to have been effective. If some BIs are positive, then environmental sampling is performed at locations of the positive BIs; and if this sampling is positive, additional treatment of the area is required. However, the overall criterion of the success of the remediation is currently based on an indoor environmental clearance sampling which indicates no growth by culture in any sample, as described in the Section 4.18.

For decontamination of water, the antimicrobial pesticide concentration, contact time, and temperature parameters must be met. The parameters may vary as a function of different pH or other water-quality parameters. Water treatment residuals may impact the distribution system's ability to establish or maintain appropriate conditions. Treatment chemicals added to enhance flocculation or used for system-wide softening may interact with disinfectants; thus, decontaminant concentration must be carefully monitored during the decontamination process. Rust, pipe tubercles, rough pipe joints, pumps, biofilm, and other pipe features may provide "sinks" or hiding places for pathogenic microorganisms to escape the effects of decontaminant flowing through a distribution system.

4.18 Clearance Environmental Sampling and Analysis

(Box 500)

When all decontamination activities have been conducted (Section 4.16) and verified (Section 4.17), clearance environmental sampling is performed (Box 500). Clearance sampling activities may include aggressive air sampling using blowers to potentially aerosolize any remaining agent, and sampling in any area where residual, viable agent could remain after decontamination (Ferro et al., 2004; Rodes et al., 2001; Thatcher and Layton, 1995). Clearance sampling should also be designed to continue testing the hypotheses described for screening environmental sampling in Section 4.2.

The strategy for post-remediation environmental sampling (Box 406) depends on the nature and extent of the contamination, as determined by characterization sampling that was conducted prior to remediation. For example, if characterization sampling indicates heavy contamination in one area, some contamination in the surrounding area, and none in remaining areas, the strategy can implement targeted surface sampling for the first area (i.e., taking clearance samples at exactly the same locations where positive samples occurred), biased surface sampling in the second area, and random surface sampling in the remaining areas. If the contaminant is easily aerosolized, the strategy may also include aggressive air sampling to ensure that some of the contaminant is not still suspended in the air or easily re-suspended. The sampling plan must specify what kinds of samples will be taken and in which exact locations.

For water distribution systems, collection of water samples throughout the system may be supplemented by collecting water in areas where the flow of water is slowed due to hydrological conditions. Locations such as point-of-use filters and water softeners may act as concentration devices for sampling small amounts of water over time. During remediation activities, it may be possible to physically sample the insides of pipe walls, using swabbing techniques similar to those used for sampling moist, hard surfaces. It should be possible to develop a sampling plan that would contain elements of targeted and biased sampling by coupling an understanding of the epidemiology of a disease outbreak with knowledge of the hydrologic functioning of a water distribution system. This approach should enhance the probability of detecting any residual contaminant beyond a simple, randomized sampling strategy.

Clearance sampling determines whether the remediation was successful and persons can be allowed to return to the area without PPE. The objective of clearance sampling is to provide the best available scientific evidence that a biological agent is no longer present at a level that poses a significant risk to human health (Box 501). Generally, the clearance goal (Section 4.9 and Boxes 307 and 406) is developed as part of the SAP, before remediation steps are taken, so that the overall criterion for judging the success of remediation is clear from the beginning of the project. The criterion for success is developed specifically for each site and the specific biological agent involved. The criterion must take into account potential risks associated with the agent (estimated using risk assessment methods described in Section 4.8) and the amount and type of sampling needed to provide a high level of confidence in a decision to declare the remediation successful.

Experience to date in decontaminating various agents at different sites indicates that post-remediation clearance sampling is the primary means of demonstrating the absence of biological agent and, therefore, the success of remediation for enclosed or semi-enclosed facilities. The overall criterion for success of a decontamination process that has been used to date in responding to the 2001 attacks with *B. anthracis* spores is

"no growth" on any clearance environmental sample processed by culture. However, there is research underway that may help establish a scientific basis for setting a decontamination goal other than "no growth". Future decisions on decontamination effectiveness also factor in better data on agent characteristics/behavior (both indoors and outdoors), improved sampling strategies, and new methods of exposure and risk assessment.

4.19 Clearance Decision

(Boxes 501–508)

The IC/UC in coordination with the appropriate State/local authorities ultimately makes a clearance decision based on a judgment as to whether the criteria for decontamination verification and clearance have been met (Boxes 501 and 503). The judgment is based on a thorough analysis of all sampling, process, and other data that are pertinent to the criteria for success, as outlined in the SAP and in the RAP. If desired, the IC/UC may appoint an ECC, to review and evaluate relevant clearance data and recommend whether the remediation should be judged successful. The ECC is usually formed early so that it can be informed of and have input into the environmental sampling concepts to be used in developing the SAP. If the IC/UC forms a TWG, the ECC will likely interact with that group to a limited extent to be informed of the characterization environmental sampling and the decontamination approaches recommended by the TWG. To maintain its independence, the ECC does not participate in the decision-making process for decontamination. After decontamination activities and clearance environmental sampling are completed, the ECC reviews all pertinent data (e.g., fumigation results and characterization and clearance environmental sampling data) and, as an advisory group, provides a recommendation (Box 506) to the IC/UC as to whether remediation has been successful (Boxes 503 and 504) and people may re-enter the site (Box 505) without using PPE. The IC/UC then makes a clearance decision in coordination with the responsible local or State or Federal authority. Public health agencies typically makes the final clearance decision, but with input from the IC/UC.

If after review, the clearance goal(s) that were originally established (Box 307) are judged as unmet (Box 501), or decontamination is deemed unsuccessful, or both, then one or more subsequent decisions must be made. If additional decontamination is deemed necessary (Box 507), other decontamination options could be evaluated (Box 400) and possibly implemented (Box 407), or the same decontamination technology could be repeated, and the clearance decision process repeated. Alternatively, decision-makers may opt to modify the originally specified clearance goal(s) (Box 508), in which case the decision process (commencing with Box 307) would be repeated. Clearly, modified clearance goals would require buy-in by stakeholders and regulators (Box 503), and assurance that long-term environmental and health issues have been addressed (Box 504). The incident command system should also communicate these clearance decisions in the context of the risks involved to all stakeholders.

4.20 Restoration/ Reoccupancy

(Boxes 600–605)

Site-specific restoration (reoccupancy or transitional) plans, developed in the optimization context (Box 600), will vary dramatically, depending on the extent of potential residual contamination, the amount of renovation necessary to meet local safety codes, or any enhancements deemed appropriate (Box 601). An example of an "enhancement" that has been implemented by the U.S. Postal Service is their Bio-Detection System. Before opening a site to the general public (Box 605), decontamination

must be judged successful such that no significant risk exists, even with no "control" action on the part of individuals (e.g., PPE, training, standard operating procedures, or medical surveillance). Risk communication (Box 600) continues as part of the restoration/reoccupancy process. It is also possible that a phased restart of business operations (Box 603) might have been planned in parallel with other response and recovery activities. Such a phased approach may be specified in a COOP (Box 216). This phased approach should also be coupled with appropriate risk communication.

Reoccupancy and reuse criteria (Box 602) described in the recovery plans may require the use of longer-term environmental and public health monitoring (such as air monitoring and health monitoring of workers; (see Box 604) if needed to provide evidence that established criteria are met. Occupational (worker) sites have flexibility to use engineering or administrative controls to provide protection as implemented in a site-specific HASP (Section 4.12). With such alternative controls, the HASP can provide adequate protection while providing more flexibility in setting decontamination criteria (i.e., workers can occupy a site that was once and may potentially still be contaminated). Components of a reoccupancy program can include some or all of the elements described in Appendix 8.

The reuse of water in a distribution system might involve a phased approach as well. For example, water service might first be re-established for certain life-essential services, such as fire fighting, then the appropriate authorities might approve certain non-consumption uses, such as washing and sanitation. Finally, the water distribution system would be certified as sanitary for drinking water. Authority to make decisions on the reuse of previously contaminated water systems varies from state to state.

The IC/UC in coordination with the appropriate authority makes the decision to allow re-occupancy of facilities/residences or reuse of distribution system water, given the particular terms for decontamination of individual dwellings, to ensure no new contamination to the distribution system. Reoccupation decisions are also generally overseen by local authorities.

4.21 References

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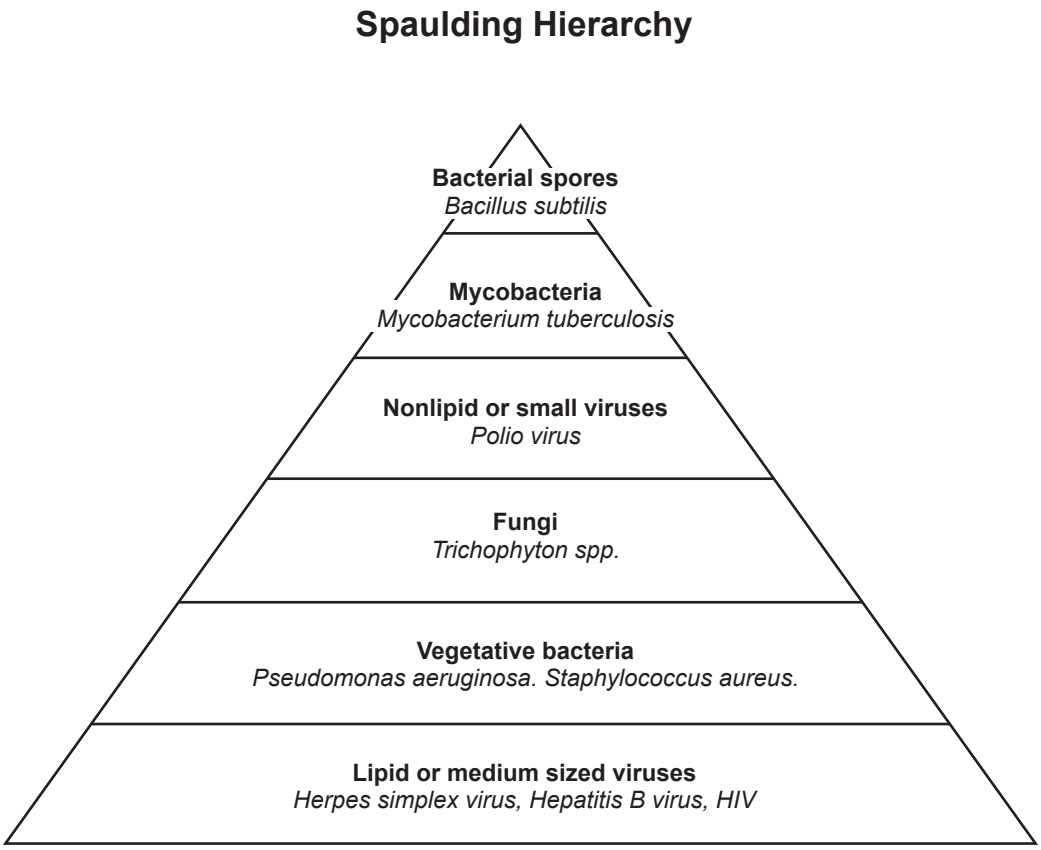
Appendix 1 Microbial Resistance to Disinfectants



Descending order of resistance to germicidal chemicals. This hierarchy considers broad classifications of microbial categories. It is considered a rough guide to general susceptibility of microbial organisms to disinfectants.

Figure A1-1. Spaulding hierarchy; Reprinted from American Journal of Infection Control, Vol. 24; Rutala, W. A. "APIC Guidelines for Selection and Use of Disinfectants" p. 314, Copyright 1996, with permission from Elsevier.

Appendix 2 National Response Framework Structure and Annexes

The figures in this appendix provide additional information about the structure and content of the National Response Framework and its Annexes and Appendices.

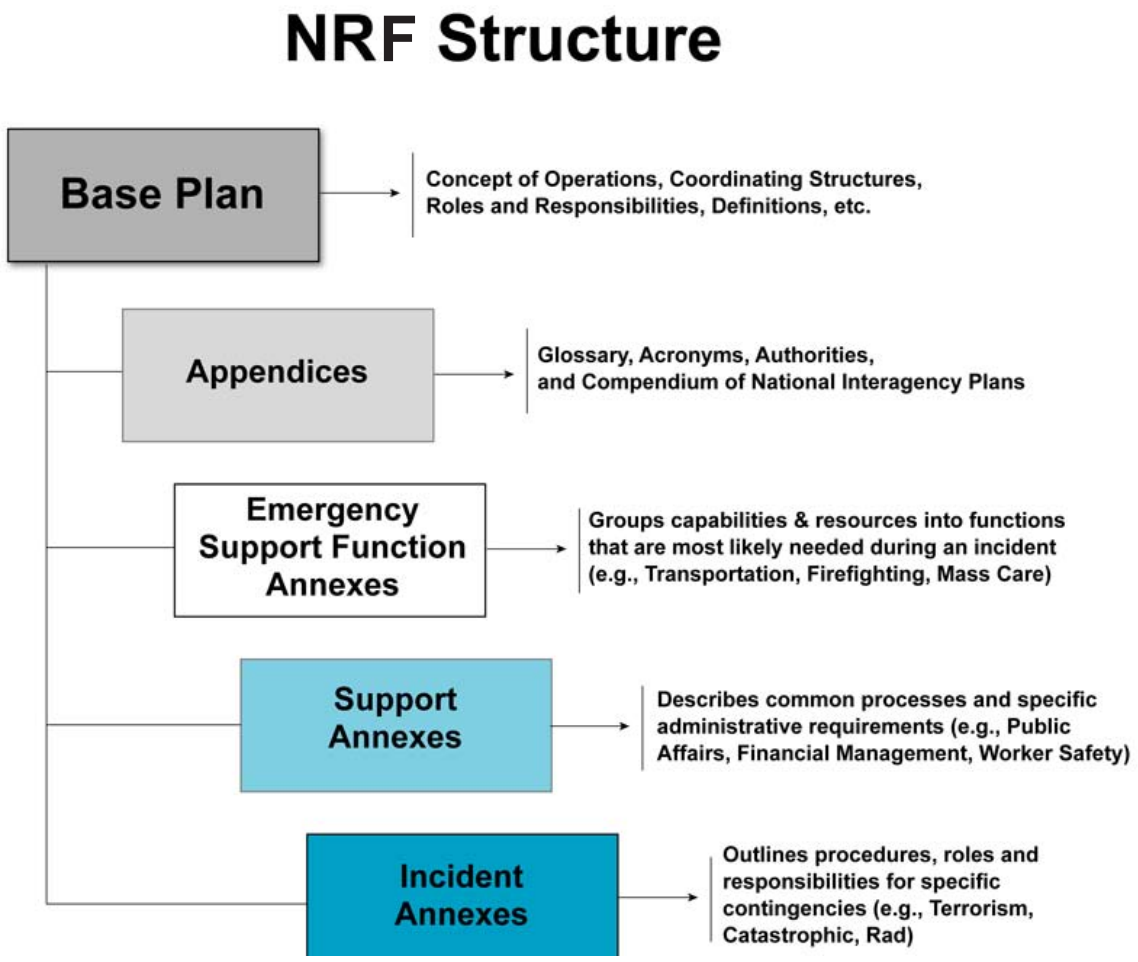


Figure A2-1. Structure of the National Response Framework.

Appendix 2 National Response Framework Structure and Annexes *(cont'd)*

Emergency Support Functions / Annexes

ESF #1 - Transportation
ESF #2 - Communications
ESF #3 - Public Works and Engineering
ESF #4 - Firefighting
ESF #5 - Emergency Management
ESF #6 - Mass Care, Emergency Assistance, Housing and Human Services
ESF #7 - Logistics Management and Resource Support
ESF #8 - Public Health and Medical Services
ESF #9 - Search and Rescue
ESF #10 - Oil and Hazardous Materials Response
ESF #11 - Agriculture and Natural Resources
ESF #12 - Energy
ESF #13 - Public Safety and Security
ESF #14 - Long-Term Community Recovery
ESF #15 - External Affairs

Support Annexes

Critical Infrastructure and Key Resources*
Financial Management
International Coordination
Public Affairs
Tribal Relations
Volunteer and Donations Management
Worker Safety and Health

Incident Annexes

Biological Incident
Catastrophic Incident
Cyber Incident
Food and Agriculture Incident
Mass Evacuation Incident*
Nuclear / Radiological Incident
Terrorism Incident Law Enforcement and Investigation

* New annexes

Figure A2-2. National Response Framework annexes.

Appendix 3 Federal Agency Roles and Responsibilities for Biological Decontamination

The table below identifies the specific roles and responsibilities of key Federal agencies for various aspects of biological decontamination. Source documents related to the responsibilities are identified in the table.

Table A3-1. Roles and responsibilities of Federal agencies in biological decontamination activities.

BIOLOGICAL INCIDENTS (Page 1 of 3)			
Activity	Activity Description	Key Federal Agencies	Source
Public (victim) decontamination	Public decontamination may include providing technical advice or direct assistance for: – Procedures to protect and decontaminate public – Medical monitoring and decontamination of possibly affected victims – Establishing a registry of potentially exposed individuals	**HHS** – Primary agency responsible for coordinating federal support* *It is important to note that the NRF provides that victim decontamination is primarily the responsibility of state, local, and tribal governments. Federal assistance is limited.	NRF ESF #8 NRF Biological Incident Annex NRF Catastrophic Incident Annex

Appendix 3 Federal Agency Roles and Responsibilities for Biological Decontamination *(cont'd)*

BIOLOGICAL INCIDENTS Continued (Page 2 of 3)			
Activity	Activity Description	Key Federal Agencies	Source
Environmental Decontamination /Cleanup	Environmental decontamination/cleanup generally includes the following types of activities: - Environmental sampling/analysis/monitoring (e.g. for site characterization as well as to verify adequacy of cleanup) - Removal and/or remediation activities (which include decontamination/cleanup) of buildings, residences, open land, etc. - Waste/debris management The agency(ies) conducting these activities will also provide for decontamination of the response worker personnel.	While HHS is the designated overall Federal coordinating agency for biological incidents, the environmental decontamination/cleanup is led by other agencies. Certain agencies have specific roles related to this area as described: **EPA** or **USCG**: -EPA for the Inland Zone -USCG for the Costal Zone Except for the Federal facilities below. The designation of the lead agencies listed below is not addressed by the NRF but is described in the NCP. DOD/DOE – for incidents involving <u>their facilities, vessels, materials</u> Under the NCP, Federal agencies other than EPA/USCG, DOD and DOE are the lead for non-emergency cleanups associated with their facilities, vessels and material. In addition, for decontamination of microorganisms (not toxins), a product must be registered or given a crisis exemption for use by EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). USDA – in the case of zoonotic agents, HHS will coordinate with USDA for control and management of food supplies **OSHA** will provide technical assistance on worker safety and health issues.	NRF Biological Incident Annex in coordination with ESF #10 NRF Catastrophic Incident Annex NCP Section 300.120 FIFRA NRF Worker Safety and Health Support Annex

Appendix 3 Federal Agency Roles and Responsibilities for Biological Decontamination *(cont'd)*

BIOLOGICAL INCIDENTS (Page 3 of 3)			
Activity	Activity Description	Key Federal Agencies	Source
Emergency removal/disposal of contaminated debris	Emergency removal of debris (e.g. clearing public roads and property	[Note: Waste/debris generated from decontamination and remediation is managed under the ESF #10 environmental cleanup/decontamination activities when activated (EPA/USCG)] **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #3 (in consultation with ESF #10) NRF Catastrophic Incident Annex
Food/Agricultural/Animal decontamination and waste disposal	Coordination of veterinary and wildlife services in affected area – Inspection, sampling, monitoring, and analysis of food products, livestock, poultry, crops, and associated facilities – Control, decontamination, and waste management of contaminated food products, livestock, poultry, crops, or related facilities – Control of contaminated material affecting natural and cultural resources including wildlife	If a biological incident primarily involves an attack on the agricultural sector (i.e., agro-terrorism involving livestock, poultry, or crops), the **USDA/APHIS** is the primary agency supporting the DHS under ESF #11. If a biological incident involves natural, cultural or historic resources, the U.S. Department of Interior (**DOI**) is the Primary Agency. For attacks on food already processed and in the food-distribution system (e.g., adulterated packaged foods), **HHS/FDA** or **USDA/FSIS** takes the lead role, depending on which has regulatory authority for the given food. **OSHA** will provide technical assistance on worker safety and health issues.	NRF ESF #11 Public Health Security and Bioterrorism Preparedness and Response Act, 2002 NRF Food and Agricultural Incident Annex is under development and will further clarify roles and responsibilities. In support of HSPD-9 (Food and Agriculture), five federal agencies developed and issued guidance entitled, "Federal Food and Agriculture Decontamination and Disposal Roles and Responsibilities, November 2005," which provides guidance on how federal, state and local agencies should coordinate in response to various kinds of biological incidents that may occur in U.S. food and agriculture

Appendix 4 Standard Work Zones for a Contaminated Site

(See Section 4.5)

Exclusion Zone (Hot Zone)

The Exclusion Zone is the area where contamination is either known or expected to occur and where the greatest potential for exposure exists. The outer boundary of the Exclusion Zone, called the Hotline, separates the area of contamination from the Contamination Reduction Zone. The Hotline should initially be established by visually surveying the site and determining the extent of biological agents or related material present with preliminary environmental sampling. Other factors to consider in establishing the Hotline include:

- Providing sufficient space to protect personnel outside the Exclusion Zone from potential fire or explosion.
- Allowing an adequate area within which to conduct site operations.
- Reducing the potential for contaminant migration.

The Hotline should be physically secured (e.g., using chains, fences, or ropes) and/or clearly marked (e.g., using lines, placards, hazard tape, or signs). During subsequent site operations, the boundary may be modified and adjusted as more information becomes available. The Exclusion Zone may also be subdivided into different areas of contamination based on known or expected types and degrees of hazards. If the Exclusion Zone is subdivided in this manner, additional demarcations (e.g., "Hazards Present" or "Protection Required") may be necessary.

Access to and from the Exclusion Zone should be restricted to Access Control Points at the Hotline. Access Control Points are used to regulate the flow of personnel and equipment into and out of the contaminated area and to verify that site control procedures are followed. Separate entrances and exits should be established to separate personnel and equipment movement into and out of the Exclusion Zone.

All persons who enter the Exclusion Zone must wear the appropriate level of Personal Protective Equipment (PPE) for the degrees and types of hazards present. PPE should be chosen following a careful risk assessment, and it should be appropriate to the biological agent, as well as any other hazardous material used in the work area. In addition, employers need to ensure that workers entering the Exclusion Zone have received training in the proper use of the PPE they are using (29 CFR 1910.132, 29 CFR 1910.134). If the Exclusion Zone is subdivided, different levels of PPE may be appropriate. Each subdivision of the Exclusion Zone should be clearly marked to identify hazards and the required level of PPE.

Sampling equipment needs to be properly calibrated and clean prior to entering the contaminated area. If electronic communications devices (such as radios) are used, the equipment should be easily decontaminated. Upon exiting the contaminated area, all equipment and gear must be either decontaminated or discarded properly. No contaminated equipment or gear should be allowed to enter the clean area. A change in situation may require a change in containment strategy, including the perimeters. As the situation matures or comes under control, expanding or shrinking the security perimeter and containment zones may be necessary.

Contamination Reduction Zone (Warm Zone)

The Contamination Reduction Zone is the area in which decontamination of personnel, equipment, and items coming out of the Hot Zone takes place. It is the transition area between the Exclusion Zone and Support Zone. The purpose of the Contamination Reduction Zone is to reduce the possibility that the Support Zone will become contaminated or affected by site hazards.

The Contamination Control Line marks the boundary between the Contamination Reduction Zone and Support Zone and separates clean areas of the site from those areas used to decontaminate workers and equipment. Access Control Points between the Contamination Reduction Zone and Support Zone should be established to ensure workers entering the Contamination Reduction Zone are wearing the proper PPE and that workers exiting the Contamination Reduction Zone to the Support Zone remove or decontaminate all potentially contaminated PPE.

Support Zone (Cold Zone)

The Support Zone is the uncontaminated area where workers are unlikely to be exposed to biological agents or dangerous conditions. Because the Support Zone is free from contamination, personnel working within it may wear normal work clothes. Any potentially contaminated clothing, equipment, and samples (that is, contaminated outer containers for samples) should remain inside the Contamination Reduction Zone or the Exclusion Zone.

Designation of the Support Zone should be based on all available site characterization data and should be located upwind from the Exclusion Zone. The Support Zone should be in an area that is known to be free of elevated (i.e., higher than background) concentrations of hazardous substances.

It is important to evaluate the initial activities to determine if they are adequate for continued containment of the agent in affected areas, and to monitor the safety of remediation workers and other personnel in the immediate vicinity of the release.

Appendix 5 Decontamination for Workers in Level-C PPE *(See Section 4.12)*

The following is a typical decontamination procedure appropriate for workers using Level- A, B or C PPE:

1. Worker proceeds to Exclusion Zone exit.

2. Worker washes the bottom of rubber boots in tub with a soapy water solution.

3. Worker enters the Contamination Reduction Zone.

4. A decontamination assistant or the worker's designated "buddy" inspects the suit for gross contamination in the form of dust and dirt. If dust or dirt is observed, the outer suit is sprayed with a fine mist of soapy water from a pump sprayer. Alternatively, a HEPA vacuum may be used.

5. Worker removes outer suit and discards it into bag/drum, leaving respiratory protection on.

6. Worker removes items such as boots, outer gloves, inner gloves/suit/scrubs, respirator cartridge(s), and discards them in biohazard bag within the Contamination Reduction Zone.

7. Worker proceeds to a separate, delineated equipment-cleaning area to completely submerge and clean all reusable PPE (i.e., respirator, hard hat, rubber boots, etc.) in soapy water or other antimicrobial solution as appropriate for the biological agent and PPE.

8. Worker proceeds to a separate delineated PPE storage area where reusable equipment is dried and stored.

9. Worker proceeds to personnel shower (if appropriate) and/or hand washing facility.

10. If showering, worker thoroughly washes hands, hair, face, and neck.

11. Worker dries and dons street clothes, then exits Contamination Reduction Zone.

12. Worker enters the Support Zone.

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Appendix 6 Basic Tenets of Crisis and Emergency Risk Communication

(http://www.bt.cdc.gov/erc/leaders.pdf) ***(See Section 4.6)***

- Don't over-reassure. The objective is not to placate but to elicit accurate, calm concern.

- Acknowledge uncertainty. Offer only what you know. Show your distress and acknowledge your audience's distress. "It must be awful to hear …."

- Emphasize that a process is in place to learn more. Describe that process in simple terms.

- Give anticipatory guidance. If you are aware of future negative outcomes, let people know what to expect. (e.g., side effects of antibiotics).

- Be regretful, not defensive. Say, "We are sorry…" or "We feel terrible that…" when acknowledging misdeeds or failures from the organization. Don't use "regret," which sounds like you're preparing for a lawsuit.

- Acknowledge people's fears. Don't tell people they shouldn't be afraid. They are afraid and they have a right to their fears. Don't disparage fear.

- Acknowledge the shared misery. Some people will be less frightened than they are miserable, feeling hopeless and defeated. Acknowledge the misery of a catastrophic incident, then help move people toward the future through positive actions.

- Express wishes. Say, "I wish we knew more," or "I wish our answers were more definitive."

- Panic is less common than imagined. Panic doesn't come from bad news, but from mixed messages. If people are faced with conflicting recommendations and expert advice, they are left with no credible source to turn to for help. Candor protects your credibility and reduces the possibility of panic.

- Be willing to address "what if" questions. These are the questions that everyone is thinking about, and they want expert answers. Although it is often impractical to fuel "what ifs" when the crisis is contained and not likely to affect large numbers of people, it is reasonable to answer "what ifs" when people need to be emotionally prepared for them. You may lose credibility by not addressing "what ifs."

- Give people things to do. In an emergency, some actions are directed at victims, and those exposed or have the potential to be exposed. However, those who do not need to take immediate action will be engaging in "vicarious rehearsal" regarding those recommendations and may need substitute actions to ensure that they do not prematurely act on recommendations not meant for them. Simple actions in an emergency will give people a sense of control.

- Ask more of people. Perhaps the most important role of the spokesperson is to ask people to bear the risk and work toward solutions with you. People can tolerate considerable risk, especially voluntary risk. A spokesperson, especially one who is on the ground and at personal risk, can model the appropriate behavior.

Appendix 7 Antimicrobial Decontaminants *(See Section 4.16)*

Table A7-1. Liquid antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. None of these antimicrobial pesticides is currently registered for use to inactivate *B. anthracis* spores.

Chemical	Generation method	Toxicity	Efficacy	Materials compatibility	Approved uses
Aqueous chlorine dioxide	Must be generated onsite	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces at 500 ppm and 30 min. contact time	No known problems	EPA registered sanitizer and disinfectant for many uses
Hydrogen peroxide and quaternary ammonium	Requires mixing of three separate components	Acutely toxic; skin and eye irritant.	Mixture is sporicidal on nonporous surfaces after several hours of contact time	No known problems	EPA registered as a disinfectant for many uses
Hydrogen peroxide and peracetic acid	Ready-To-Use Liquid	Acutely toxic; irreversible eye damage.	Several products are sporicidal on nonporous surfaces with contact times ranging from 15 to 30 minutes.	No known problems	EPA registered sanitizer, disinfectant and sterilant for many uses
Sodium hypochlorite	Dilute 5.25-6% solution to 5,250 to 6,000 ppm; adjust pH to 7.	Acutely toxic; skin and eye irritant.	Sporicidal on nonporous surfaces after 60 minutes contact time.	Corrosive to stainless steel and other metals	EPA registered sanitizer and disinfectant for many uses

Appendix 7 Antimicrobial Decontaminants *(Cont'd)*

(See Section 4.16)

Table A7-2. Gas and vapor antimicrobial pesticides used under FIFRA crisis exemptions to inactivate *Bacillus anthracis* spores. None of these antimicrobial pesticides is currently registered for use to inactivate *B. anthracis* spores.

Chemical	Generation method	Toxicity	Exposure limits	Materials compatibility	Penetration	Sporicidal uses
Formaldehyde gas	Onsite heating of paraformaldehyde prills (flakes)	Acutely toxic, animal carcinogen, genotoxin	0.75 ppm PEL 2.0 ppm STEL 20 ppm IDLH	Relatively unreactive	High	Biosafety cabinets, clean rooms, mail bags, mail equipment, buildings
Chlorine dioxide gas	Onsite reaction of precursor materials (sodium chlorite & others)	Acutely toxic, respiratory and eye irritant, no cancer data	0.1 ppm PEL 0.3 ppm STEL 5.0 ppm IDLH	May affect metals (Al, Cu, brass), computer parts, carpets and low grade paper at high CT values	High	Buildings
Hydrogen peroxide vapor	Onsite vaporization of liquid hydrogen peroxide	Acutely toxic, respiratory irritant, no cancer data	0.1 ppm PEL 0.3 ppm STEL 5.0 ppm IDLH	Relatively unreactive	Medium, does not penetrate paper	Medical equipment, buildings
Methyl bromide (MB) gas	Onsite heating & vaporization of liquid MB from cylinder	Acutely toxic, no cancer data	4.0 ppm TLV 20 ppm PEL 250 ppm IDLH	May affect animal fur, leather, natural latex, and sulfur-containing articles	Very high	Experimental (efficacy studies on *Bacillus anthracis* and spore strips)
Ethylene oxide gas	Onsite release of gas from cylinder	Acutely toxic, reproductive toxin, genotoxin, possible human carcinogen	1.0 ppm PEL 5 ppm STEL 800 ppm IDLH	Relatively unreactive	Extremely high	Medical equipment, critical items

Appendix 8 OSHA Reoccupancy (Transitional) Plans *(See Section 4.20)*

Hazard Awareness Training

Hazard awareness training is intended to communicate information concerning hazards of biological agents and appropriate protective measures to employees. The training may include, but is not limited to:

- Elements of the re-occupancy program.
- The health hazards of the biological agent, including routes of entry, signs and symptoms of exposure, synergistic effects, and any medical conditions that would place employees at increased risk.
- Operations in the work area where the biological agent has been identified.
- Dissemination of sampling results, including information on accessing results.
- Any applicable control measures, such as appropriate engineering controls, work practices, housekeeping, or PPE.
- Implementation of interim standard operating procedures to prevent potential exposure during operations, maintenance, cleaning, or the like.
- Frequent updates regarding any ongoing sampling, decontamination, control, medical surveillance, and related activities being performed at the facility, as applicable.

Medical Surveillance

A medical surveillance program may be implemented to ensure that employees receive appropriate preventive care. Medical surveillance includes, but is not limited to:

- Identification of employee populations at risk and establishment of controls for such employees (such as work reassignment, PPE, and prophylactic medication).
- Administrative follow-up on absentees (such as those on sick leave).
- Selection of prophylactic medication, as appropriate.
- Response to symptoms reported by employees.

Reoccupancy (Transitional) Sampling

Additional sampling may be conducted to confirm that occupied areas remain safe for occupancy. Sampling during this period is continued until repeatable results demonstrate that contamination remains insignificant. Elements of reoccupancy sampling include, but are not limited to:

- Determining appropriate sampling techniques. Recommended techniques may include nonaggressive, high-volume, air sampling, HEPA vacuum surface sampling, and if appropriate, bulk sampling (such as bulk samples from HEPA vacuums used to clean surfaces, or ventilation system filters).

- Use of high-volume air sampling as a tool to characterize levels of biological agent in the air and provide exposure information to employees.

- Identification of specific locations and frequency of sampling.

Personal Protective Equipment

The workplace must be reassessed to select and use appropriate PPE to protect employees from potentially remaining biological agent hazards. The specific types of PPE used depend on the actual operation in question and results from the reassessment. Examples of work operations where modifications to PPE may be necessary are as follows:

- Operating equipment or working on surfaces where the biological agent was previously identified.

- Performing maintenance tasks, such as cleaning equipment or changing HEPA vacuum or ventilation system filters.

Personal Hygiene

A personal hygiene program may be implemented for certain facility areas and operations to reduce the risk of additional exposures and spreading contamination. Procedures that may be required include:

- Assuring that food or beverage is not present or consumed, tobacco products are not present or used, and cosmetics are not applied in specified areas.

- Regular washing of hands and/or face, and before eating, drinking, using tobacco, or applying cosmetics.

- Showering as necessary.

Interim Standard Operating Procedures

Interim standard operating procedures (SOPs) must be developed to address special work activities necessary under the reoccupancy (transitional) program. Affected employees should receive training on the interim SOPs. The SOPs include, but are not limited to, the following topics:

- Maintenance and housekeeping procedures developed or modified to prevent the spread of potential contamination and protect employees. Examples include:
  - Use of HEPA vacuum to clean surfaces instead of sweeping or other methods.
  - Cleaning, maintenance, and filter and bag removal for HEPA vacuums.
  - Maintenance and cleaning of facility equipment.
  - Cleaning floors and other surfaces.
  - Handling and disposal of wastes.

- Changes to regular work operations and equipment, as applicable.

- Modifications to facility-wide mechanical systems, particularly HVAC systems. Examples of HVAC modifications include:
  - Increase in ventilation rates (air changes per hour).
  - Increase in percentage of outside air.
  - Use of HEPA filters to collect dust in circulated air.

- Other applicable major elements implemented as part of the reoccupancy program, as described previously (training, medical surveillance, sampling, PPE, or hygiene).

Appendix 9 Glossary

ANTIMICROBIAL AGENT

Any agent that kills or suppresses the growth of microorganisms. (Block, 2001)

AREA COMMAND (UNIFIED AREA COMMAND)

An organization established (1) to oversee the management of multiple incidents that are each being handled by an ICS organization or (2) to oversee the management of large or multiple incidents to which several Incident Management Teams have been assigned. Area Command becomes Unified Area Command when incidents are multi-jurisdictional. Area Command may be established at an Emergency Operations Center (EOC) facility or at some location other than an Incident Command Post. (DHS, 2008)

ANTHRAX

A non-contagious, infectious, often fatal, naturally occurring disease caused by the bacterium *Bacillus anthracis* that may be contracted by humans or animals via exposure through inhalation, the skin, or the gastrointestinal tract.

BACILLUS ANTHRACIS

A spore-forming bacterium that causes anthrax. The spore form is about 1 by 2 microns in size and can easily be inhaled. In a warm, moist environment (such as the lungs), spores grow into vegetative, rod-shaped cells that multiply and cause hemorrhage, edema, and necrosis in humans and animals.

BIOSAFETY LEVEL (BSL)

Different biosafety levels developed for microbiological and biomedical laboratories provide increasing levels of personnel and environmental protection from pathogenic microorganisms and hazardous subcellular entities (e.g., prions). Accordingly, laboratories may be classified as BSL-1, BSL-2, BSL-3 or BSL-4, ranked from lowest to highest in degree of safety level.

BIOLOGICAL INCIDENT

A natural or human-caused incident involving microbiological organisms (bacteria, fungi, and viruses) or biologically-derived toxins that pose a hazard to humans, animals, or plants.

BIOLOGICAL INDICATOR (BI)

A standardized preparation of bacterial spores on or in a carrier serving to demonstrate whether sterilizing conditions have been met. Spores of different organisms are used for different methods of sterilization. (Block, 2001)

BIOLOGICAL WARFARE AGENT (BWA)

A microorganism (bacteria, fungi, and viruses) or biologically derived toxin that is intentionally introduced to cause disease or harm in humans, animals, or plants.

BIOTOXIN

A toxic substance that is either produced by, or extracted from, living or dead bacteria, fungi, plants, or animals.

CERCLA

The Comprehensive Environmental Response, Compensation, and Liability Act (42 USC 9601 et seq.), as amended by the Superfund Amendments and Reauthorization Act of 1986. CERCLA authorizes the President and EPA (by delegation from the President) to respond to releases or substantial threats of releases of hazardous substances or of pollutants or contaminants that may present an imminent and substantial danger to the public health or welfare.

CHARACTERIZATION

The process of obtaining specific information about a biological agent, such as its identity, genetic composition, formulation, physical properties, toxicological properties, ability to aerosolize, and persistence, and about the nature and extent of contamination of the agent, such as locations or items contaminated and the amount of contamination. Characterization of the agent and of the contamination at an affected site generally occurs after First Response and before Decontamination.

CHARACTERIZATION ENVIRONMENTAL SAMPLING

Environmental sampling intended to assess the nature (identity and properties) and extent (location and quantity) of contamination of an area or items. Generally occurs after First Response and before Decontamination.

CHARACTERIZATION ZONE

A discrete section of a contaminated site that is examined for the purpose of determining the potential for exposure to the contaminant in that area.

CLEANUP

The process of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Cleanup is a synonym for Remediation. Generally occurs after Characterization and before Clearance.

CLEANUP GOAL

An amount of residual contamination for a specific contaminant in or on an area or item that, once achieved following decontamination, provides acceptable protection to human health and the environment. A cleanup goal specifies criteria for determining the success of decontamination that are measurable and for permitting unprotected reentry.

CLEARANCE

The process of determining that a cleanup goal has been met for a specific contaminant in or on a specific site or item. Generally occurs after Decontamination and before Reoccupancy.

CLEARANCE ENVIRONMENTAL SAMPLING

Environmental sampling that is conducted after the decontamination process is completed for a specific contaminant in an area or on items, and is intended to provide a basis for determining whether the cleanup goal has been met.

CLEARANCE ZONE

A section or sub-section of a contaminated site for which a clearance decision is made.

CONCEPT OF OPERATIONS (CONOPS)

A formal plan that describes the roles, responsibilities, and relationships of organizations involved in a response to a contaminated area or items. Typically, a CONOPS addresses Federal, State, local and tribal agencies and how they should interact when responding to a potential or actual terrorist threat or incident.

CONSEQUENCE MANAGEMENT

Predominantly an emergency management function that includes measures to protect public health and safety; restore essential government services; and provide emergency relief to governments, businesses, and individuals affected by the consequences of terrorism (DHS, December 2004). Includes Remediation/Cleanup (i.e., Characterization, Decontamination, and Clearance) and Restoration/Reoccupancy activities (see Figure 3, p. 38).

CONTAINMENT

In the context of this document, includes actions or measures taken to prevent the spread of a contaminant from a particular zone or to prevent the movement of a contaminant within a zone. Compare with Isolation. This term has been used differently by various agencies.

CONTAMINATION REDUCTION ZONE

The transition area between the Exclusion and Support Zones where responders enter and exit the Exclusion Zone and where decontamination activities take place. Also called the Warm Zone. (EPA, 2004)

CRISIS EXEMPTION

Under the authority of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Administrator of EPA may exempt any Federal or State agency from the pesticide registration requirements of FIFRA, if the Administrator determines that emergency conditions exist which require such exemption. As described in EPA's regulations (40 CFR 166.40 – 166.53), a crisis exemption may be issued, subject to specific conditions, when an unpredictable emergency situation exists—that is, an emergency condition exists and there is insufficient time to request and process other types of exemptions or registration. Other types of emergency exemptions require a State or Federal agency to submit an application to EPA for review and approval.

CRISIS MANAGEMENT

Predominantly a law enforcement function that includes measures to identify, acquire, and plan the use of resources needed to anticipate, prevent, and/or resolve a threat or act of terrorism (DHS, December 2004). Includes Notification and First Response activities (see Figure 3, p. 38).

DECISION-MAKER

A person charged with determining and directing appropriate actions in response to a potential or actual biological incident at a particular site.

DECONTAMINATION

The process of inactivating or reducing a contaminant in or on humans, animals, plants, food, water, soil, air, areas, or items through physical, chemical, or other methods to meet a cleanup goal. Decontamination applies to both disinfection and sterilization processes. Generally occurs as part of Remediation. (Note: Decontamination has been defined in different ways by different Federal agencies and other entities.)

DECONTAMINATION AREA OR ZONE

A section of a contaminated site that can be isolated from other areas and is decontaminated as a unit.

DECONTAMINATION AGENT

A substance that is used to inactivate or reduce a contaminant on humans, animals, plants, or inanimate surfaces or in other media. If the contaminant is a microorganism, the chemical is an antimicrobial pesticide.

DISINFECTANT

A chemical or physical agent that destroys pathogenic or other harmful microorganisms, but not bacterial spores on inanimate surfaces.

DISINFECTION

The destruction of pathogenic and other kinds of microorganisms by physical (e.g., heat, desiccation, freezing, radiation) or chemical means. Disinfection is a less-lethal process than sterilization because it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety associated with sterilization processes. (AAMI, 1995)

EMERGENCY OPERATIONS CENTER (EOC)

The physical location at which the coordination of information and resources to support domestic incident management activities normally takes place. An EOC may be a temporary facility or located in a more central or permanently established facility, perhaps at a higher level of organization within a jurisdiction. EOCs may be organized by major functional disciplines (e.g., fire, law enforcement, environment and medical services), by jurisdiction (e.g., Federal, State, regional, county, city, or tribal), or by some combination thereof. (DHS, 2008)

ENVIRONMENTAL CLEARANCE COMMITTEE (ECC)

An independent group of scientific experts from a variety of local, State, and Federal agencies that provides advice, data, process analysis, and recommendations during and after decontamination of a facility. An ECC provides a final recommendation on whether the cleanup was adequate to justify reopening the facility for normal operations and use. (Proceedings from the 2nd Civilian-Military Anthrax Response Technical Workshop, 2004)

ENVIRONMENTAL SAMPLING

Sampling conducted on inanimate surfaces or in air, water, or soil for the purpose of detecting the presence of a specific biological agent.

EXCLUSION ZONE

An area with actual or potential contamination and the highest potential for exposure to the contaminant. Entry to this area is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Isolation Zone, or Restricted Zone.

FIRST RESPONSE

Actions taken immediately following notification of a biological incident or release. In addition to search and rescue, scene control, and law enforcement activities, first response includes initial site containment, environmental sampling and analysis, and public health activities, such as treatment of potentially exposed persons.

FEDERAL ON-SCENE COORDINATOR (FOSC OR OSC)

The Federal official predesignated by the EPA or the U.S. Coast Guard to coordinate responses under subpart D of the National Contingency Plan (NCP); or the government official designated to coordinate and direct removal actions under subpart E of the NCP. (DHS, 2008)

FUMIGATION

Use of a chemical gas or vapor in a contained space to inactivate biological contaminants (primarily pathogenic bacteria, fungi, and viruses).

HEALTH AND SAFETY PLAN (HASP)

A written plan required under the Occupational Health and Safety Administration's (OSHA's) Hazardous Waste Operations and Emergency Response (HAZWOPER) standard (29 CFR 1910.120 and 29 CFR 1926.65). This standard requires a written HASP, which identifies site hazards and appropriate controls to protect employee health and safety. (NRT, 2003)

HOTLINE

The outer boundary of the Exclusion Zone (Hot Zone) that separates the area of contamination from the Contamination Reduction Zone (Warm Zone).

INACTIVATION

Removal of the activity of microorganisms by killing or inhibiting reproductive or enzyme activity. When referring to an antimicrobial agent, inactivation means neutralizing its activity by any means. (Block, 2001)

INCIDENT

An occurrence or incident, natural or human-caused, that requires an emergency response to protect life or property. Incidents can, for example, include major disasters, emergencies, terrorist attacks, terrorist threats, wildland and urban fires, floods, hazardous materials spills, nuclear accidents, aircraft accidents, earthquakes, hurricanes, tornadoes, tropical storms, war-related disasters, public health and medical emergencies, and other occurrences requiring an emergency response. (DHS, 2008)

INCIDENT COMMAND (IC)

The unit responsible for all incident activities, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for managing all incident operations at the incident site. (National Incident Management System, 2004; DHS, 2008)

INFECTIOUS DOSE (ID)

A dose at which an organism can reproduce in the host and produce a measurable effect. (Johnson, 2003)

ISOLATION

For the purposes of this document, action taken to seal a site to permit fumigation and prevent release of fumigant. Compare with containment. This term has been used differently by various agencies.

ISOLATION ZONE

A contaminated area for which entry is permitted only for persons wearing appropriate personal protective equipment (PPE). Equivalent to Hot Zone, Red Zone, Exclusion Zone, and Restricted Zone.

LABORATORY RESPONSE NETWORK (LRN)

An organization of public health laboratories established by the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) in accordance with Presidential Decision Directive 39, which outlines national anti-terrorism policies and assigns specific missions to Federal departments and agencies. The LRN and its partners maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological terrorism, emerging infectious diseases, and other public health threats and emergencies. (CDC, 2005)

LIFE SAFETY ZONES

Zones established at a contaminated site that are intended to reduce the accidental spread of hazardous substances by workers or equipment from contaminated areas to clean areas. Safety zones specify the type of operations that occur in each zone, the degree of hazard at different locations within the release site, and the areas at the site that should be avoided by unauthorized or unprotected employees.

NATURAL ATTENUATION

The destruction or inactivation of a microorganism or products of a microorganism, such as a toxin, via natural, environmental mechanisms such as heat, light, biochemical, or chemical reactions.

NEGATIVE AIR UNIT (NAU)

A system that subjects an area to a slightly negative pressure to ensure that the contaminant (and decontamination chemical) remains in the contamination zone. NAUs consist of a HEPA filter, chemical scrubber, demister, carbon bed, fan, and stack. Air within a building is exhausted through HEPA filters at a rate sufficient to pull a slightly negative pressure in the contaminated zone. (Carlsen et al., 2005)

NOTIFICATION

The process of communicating the occurrence or potential occurrence of a biological incident through and to designated authorities who initiate First Response actions. Generally occurs as the first step in a response to a suspected or actual biological incident.

OPTIMIZATION

A flexible decision process that addresses multiple aspects of the problem and seeks to analyze, consider, and balance these factors in decontamination and recovery activities.

PATHOGEN

Any disease-producing microorganism. (Block, 2001)

PRINCIPAL FEDERAL OFFICIAL (PFO)

The Federal official designated by the Secretary of Homeland Security to act as his/her representative locally to oversee, coordinate, and execute the Secretary's incident management responsibilities under HSPD-5 for major incidents. (DHS, 2008)

PROCESS MONITORING

Measuring and recording the key variables of a decontamination process as they occur. For example, during fumigation, the key variables are gas concentration, temperature, contact time, and relative humidity.

QUALITY ASSURANCE

An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence. (EPA, 2002c)

RECOMMISSIONING

The process of testing and verifying that equipment is fully functional and may be returned to normal use.

RECOVERY

In the short term, recovery is an extension of the response phase in which basic services and functions are restored. In the long term, recovery is a restoration of both the personal lives of individuals and the livelihood of the community. Recovery can include the development, coordination, and execution of service- and site-restoration plans; the reconstitution of government operations and services; programs to provide housing and to promote restoration; long-term care and treatment of affected individuals; and additional measures for social, environmental, and economic restoration. (DHS, 2008) Recovery generally includes actions taken after Notification and First Response activities have been initiated (see Figure 3, p. 38).

REMEDIATION ACTION PLAN (RAP)

A formal plan developed for the Incident Commander that describes actions to remove, reduce, or eliminate contaminants in or on a site and/or items. The RAP is developed during Remediation.

REMEDIATION

The processes of characterizing, decontaminating, and clearing a contaminated site or items, including disposal of wastes. Generally occurs after the First-Response Phase and before the Restoration Phase (see Figure 3, p. 38). A synonym for cleanup. Remediation is not the same as "remedial action," which is defined below.

REMEDIAL ACTION

Long-term response actions that permanently and significantly reduce the dangers associated with releases or threats of releases of hazardous substances that are serious, but not immediately life threatening. If applicable and with available resources, remedial action may be performed in accordance with the *National Oil and Hazardous Substances Pollution Contingency Plan* and under the authority of CERCLA. See 40 CFR 300.430 and .435.

REMOVAL ACTION

Response actions taken to address releases or threatened releases of hazardous substances, pollutants, or contaminants that require a prompt response. If applicable and with available resources, removal action may be performed in accordance with the *National Oil and Hazardous Substances Pollution Contingency Plan* and under the authority of CERCLA. See 40 CFR 300.415.

RENOVATION

The process of reconstructing or refurbishing a facility subsequent to clearance but before allowing occupants to return. (See Figure 3, p. 38)

REOCCUPANCY

The process of renovating a facility, monitoring the workers performing the renovation, and deciding when to permit reoccupation. Generally occurs after a facility has been cleared but before occupants are allowed to return. (See Figure 3, p. 38)

RESIDUAL CONTAMINATION

The detectable amount of contaminant remaining, if any, after an area has been decontaminated.

RESPONSE

Includes immediate actions to save lives, protect property and the environment, and meet basic human needs. Response also includes the execution of emergency plans and actions to support short-term recovery. (DHS, 2008)

RESTORATION

The process of renovating or refurbishing a facility; bringing it to an acceptable condition using the optimization process to determine the appropriate use and associated clearance level at which occupants may return. Generally occurs after the Clearance Phase but before occupants are allowed to return (see Figure 3, p. 38).

RISK

The probability that a substance or situation will produce harm under specified conditions. Risk is a combination of two factors: (1) the probability that an adverse event will occur (such as a specific disease or type of injury), and (2) the consequences of the adverse event. (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997)

RISK ASSESSMENT

Gathering and analyzing information on what potential harm a situation poses and the likelihood that people or the environment will be harmed. [The Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997] A methodological approach to estimate the potential human or environmental risk of a substance that uses hazard identification, dose–response, exposure assessment, and risk characterization.

RISK MANAGEMENT

The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risk while taking into account social, cultural, ethical, and legal considerations. (Presidential and Congressional Commission on Risk Assessment and Risk Management, 1997)

SAMPLING AND ANALYSIS PLAN (SAP)

A plan that describes the methods, strategies, and analyses for characterization sampling, verification sampling (if applicable), and clearance sampling for a contaminated site.

SAMPLING UNIT

A sub-section of a sampling zone, such as walls, floors, and furniture surfaces, that can be sampled and evaluated collectively.

SAMPLING ZONE

A discrete section of a contaminated site in which environmental sampling is conducted.

SCREENING ENVIRONMENTAL SAMPLING

The initial collection of a limited number of environmental samples for the purpose of determining the identity, concentration, viability, and approximate location of contamination by a purported biological agent, and for informing the IC/UC for decision-making on appropriate public health and subsequent remediation actions.

SOURCE REDUCTION

The process of removing certain items and/or materials from a contaminated site for further treatment and reuse or disposal, and of cleaning the remaining site and item surfaces prior to the main decontamination activity. The goals of this process are to (1) reduce the number of items and/or materials present, (2) ensure that any matter that might inhibit decontamination is removed, and (3) generally reduce the levels of contaminant that may be present.

SPORES

The thick-walled resting cells produced by some bacteria and fungi that are capable of survival in unfavorable environments and are more resistant to antimicrobial agents than vegetative cells. (Block, 2001)

STAGING AREA

A safety zone established at a hazardous-substance release site that is designated as the Support Zone (or Cold Zone). It is the area of the site that is free from contamination and that may be safely used as a planning and staging area. (EPA, 2004)

STERILANT

A substance that destroys all microorganisms on inanimate surfaces, including vegetative and spore forms of bacteria and fungi, as well as viruses. Sterilants registered by the EPA must be effective on both porous and nonporous surfaces.

STERILIZATION

A process intended to remove or destroy all viable forms of microbial life, including bacterial spores, to achieve an acceptable sterility assurance level. (AAMI, 1995)

SUPPORT ZONE

Area of a site that is free from contamination and that may be safely used as a planning and staging area. Also called the Cold Zone.

SWAB SAMPLING

Collecting environmental samples from nonporous surfaces by rubbing a small area with a wet, absorptive material attached to the end of a wood or plastic stick.

TECHNICAL WORKING GROUP (TWG)

A group of technical experts assembled by the Unified Command to provide guidance during the planning and implementation of remediation operations. (Carlsen et al., 2005)

UNIFIED COMMAND (UC)

An application of the Incident Command System used when there is more than one agency with incident jurisdiction or when incidents cross jurisdictions. Agencies work together through the designated members of the Unified Command to establish their designated Incident Commander at a single Incident Command Post and to establish a common set of objectives and strategies and a single Incident Action Plan. (DHS, 2008)

VACUUM SAMPLING

Collecting environmental samples by suctioning porous or nonporous surfaces with a vacuum cleaner that contains a high-efficiency particulate air (HEPA) filter.

VEGETATIVE CELLS

Microbial cells that are in the growth and reproductive phase of the growth cycle. (Block, 2001)

VERIFICATION SAMPLING

Use of chemical and/or biological indicators to document that fumigation has been successful.

WARM ZONE

The transition area between the Exclusion and Support Zones. This area is where responders enter and exit the Exclusion Zone and where decontamination activities take place. (EPA, 2004)

WEAPON OF MASS DESTRUCTION (WMD)

Any nuclear, radiological, chemical, or biological substance that is intentionally introduced to cause disease or harm in humans, animal, or plants, or damage to property. (Note: The National Response Framework has a longer, legal definition.)

WIPE SAMPLING

Collecting environmental surface samples by rubbing a thin, flat piece of wet, absorptive material on a small area of a non-porous surface.

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About this Report

This guidance describes a general risk management framework for decision-makers in planning and executing activities required for response and recovery from a biological incident in a domestic, civilian setting. This report was developed by the Subcommittee on Decontamination Standards and Technology (SDST), and reviewed and approved by the Office of Science and Technology Policy and the National Science and Technology Council.

About the National Science and Technology Council

The National Science and Technology Council (NSTC) was established by Executive Order on November 23, 1993. This cabinet-level council is the principal means by which the President coordinates science, space, and technology policies across the Federal Government. NSTC coordinates diverse paths of the Federal research and development enterprise.

An important objective of the NSTC is the establishment of clear national goals for Federal science and technology investments in areas ranging from informationtechnologies and health research to improving transportation systems and strengthening fundamental research. The Council prepares research and development strategies that are coordinated across the Federal agencies to form a comprehensive investment package aimed at accomplishing multiple national goals.

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About the Office of Science and Technology Policy

The Office of Science and Technology Policy (OSTP) was established by the National Science and Technology Policy, Organization and Priorities Act of 1976. OSTP's responsibilities including advising the President in policy formulation and budget development on all questions in which science and technology (S&T) are important elements; articulating the President's S&T policies and programs; and fostering strong partnerships among Federal, State, and local governments, and the scientific communities in industry and academe. Every fiscal year, OSTP and the Office of Management and Budget (OMB) issue a memorandum entitled "Administration Research and Development Budget Priorities." The memorandum highlights the Administration's research and development priorities and emphasizes improving management and performance to maintain excellence and leadership in science and technology.

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