

# Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans

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Homeland  
Security

## Handling Instructions

Information contained in this draft annex is subject to the restrictions outlined in the Response and Recovery Federal Interagency Operational Plans. Distribution of this document is limited and not releasable to the public or to any public web site (public availability to be determined under 5 U.S. Code §552). Although this is an interagency annex, dissemination must be approved by the Department of Homeland Security (DHS).

## Use of this Document

This annex provides guidance and serves as a reference for federal agency planning efforts involving biological incidents. Other stakeholders (e.g., local, state, tribal, territorial, and insular area governments; nongovernmental organizations; voluntary agencies; and the private sector) engaged in their own planning will find this document useful in enhancing their understanding of how the Biological Incident Annex will be implemented and how their planning efforts can be complementary.

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Thank you for your continued support of DHS and assistance throughout this process.

## Rescission Notice

Publication of this Biological Incident Annex to the Response and Recovery Federal Interagency Operational Plans thereby rescinds the following documents: 2008 Biological Incident Annex to the National Response Framework.



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## Annex Overview

This Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plans (FIOPs) replaces the 2008 Biological Incident Annex to the National Response Framework (NRF). The BIA serves as the Federal organizing framework for responding and recovering from a range of biological threats. The BIA also serves as a reference for state, local, tribal, and territorial



**Figure 1: Biological Incident Annex Structure**

(SLTT) authorities and private sector organizations to conduct adaptive planning, consistent with hazard and risk analysis for specific biological threats in their communities. For the purpose of this annex, a biological incident refers to the occurrence of cases or outbreaks involving an infectious agent that affects people, regardless of natural or deliberate cause, for which response needs have the potential to overwhelm state and local resources and for which the Department of Health and Human Services (HHS), to lead all federal public health and medical efforts, deems that, in consultation with other relevant agencies, interagency support is or will be required.

The BIA was designed to be scalable, flexible, and adaptable to a wide range of biological incidents regardless of cause, size, location, or complexity. Response to a biological incident should be well coordinated across the U.S. Government and must be integrated with U.S. counterterrorism law enforcement response, when appropriate. Coordination across consequence management and counterterrorism communities will help ensure risk-informed decision making.

The BIA is composed of a base document and a branch plan (**Figure 1**). The base document is applicable to all biological incidents, whereas the branch plan focuses on suspected or actual intentional attacks affecting the United States. The Intentional Biological Incident Branch details the importance of establishing operational coordination with the Prevention Mission Area regarding the response to imminent biological terrorist threats or incidents.<sup>1</sup> This annex is supplemental to, and not duplicative of, the FIOPs and other subordinate plans.

Although the BIA provides guidance for the whole community, it focuses intentionally on the requirements of those involved in delivering core capabilities at the federal level. The BIA does not alter or impede the ability of any SLTT or federal agency<sup>2</sup> to execute authorities or meet responsibilities under applicable laws, executive orders, and directives.

The BIA is an annex to both the Response and Recovery FIOPs. The FIOPs provide detail regarding agency roles and responsibilities and critical tasks and identify resourcing and sourcing

<sup>1</sup> Planners should also anticipate the execution of additional plans of the counterterrorism community during any response to biological threats or incidents, which also contain descriptions of the roles and responsibilities of federal, state, and local agencies.

<sup>2</sup> For this annex, “federal agency” includes any Federal Executive Branch department or agency including boards, commissions, government corporations, and any independent agencies of the U.S. Government that have authority for, or provide support to, the response to and recovery from a biologic incident.

requirements for delivery of core capabilities. The BIA utilizes the same concepts of operation for delivering response and recovery core capabilities but highlights the unique attributes of a biological incident, including acts of terrorism. This annex supersedes the previous BIA (April 2008) to the NRF.

Actions described in this annex may take place with or without a Presidential Stafford Act declaration or a public health emergency declaration by the Secretary of HHS.

The term “response” within this annex refers to those activities and capabilities within the Response and Recovery Mission Areas, commonly identified as “consequence management” that are exclusive of any law enforcement and criminal investigation activities and capabilities otherwise described within the Prevention Mission Area. The term “consequence management” is used to describe those Response and Recovery Mission Area activities that include securing the incident site, assessing the dispersal of biological material, enhancing first responder capabilities, ensuring availability of decontamination and site remediation resources, providing biological medical triage capabilities, and increasing population resilience and recovery capabilities. All references to law enforcement “crisis management” or criminal investigative activities and capabilities within this annex are clearly identified.

## Base Annex

### Situation

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Public health emergencies can occur anywhere and regularly within the United States, sometimes impacting multiple geographic regions simultaneously. Greater movement of people, animals, and goods across international borders increases the risk of exposure to health threats originating outside the United States. While public health emergencies regularly require a coordinated response, this annex addresses biological pathogens presenting in humans that threaten to significantly impact the United States and have the potential to overwhelm state, local, tribal, and territorial (SLTT) resources and for which the lead agency,<sup>3</sup> in this case assumed to be the Department of Health and Human Services (HHS), deems that interagency support is or will be required.

Planning and preparedness for a biological incident require consideration of the characteristics unique to biological events such as the potentially contagious nature of an incident, specialized medical countermeasures or lack thereof, or long-term contamination. It should be anticipated that the roles and responsibilities of the public health and medical community and the emergency management community will intersect. The time frame in which to provide initial health and medical response and the large number and variety of response partners will require advanced planning as well as close coordination during the incident, in order for both entities to operate successfully.

Response and recovery for biological incidents are complex and challenging for the whole community. Response/recovery and knowledge for a specific biological incident may not be on the same time line. Novel and re-emerging pathogens, including those that are difficult to detect and/or treat can spread throughout the globe quickly, posing threats to national security which will require federal intervention and coordination. Each type of pathogen poses unique response and recovery challenges that the United States may be forced to confront. Environmental shifts, disasters, or other incidents can change disease patterns, raising the risk of a biological incident. Genetic changes may alter the characteristics (i.e., virulence and transmissibility) of common pathogens, potentially resulting in increased morbidity and/or mortality. Widespread and improper use of antibiotic, anti-viral, antifungal, and anti-parasitic treatments or other medical countermeasures (MCM) are accelerating the emergence of drug-resistant pathogens. Zoonotic diseases, where a virulent pathogen may move from animal to human communities, also require a level of collaboration and coordination between multiple agencies for response and recovery.

Managing large-scale public health emergencies and coordinating the response policy related to those events increasingly requires simultaneous domestic and international actions that are often interconnected. Recent experiences, including the global spread of the H1N1 (2009) influenza

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<sup>3</sup> Presidential policy provides for the identification of a lead federal agency when the President has not declared a major disaster or emergency under the Stafford Act and when federal roles and responsibilities related to incident response are unclear. This annex assumes that HHS will act as the lead federal agency for biological incidents.

virus, the emergence of MERS-CoV, the outbreak of Ebola Virus Disease in West Africa, Zika Virus Disease, H7N9 Influenza, and a range of natural disasters with public health consequences (e.g., the Haiti earthquake, the Fukushima nuclear accident), have shown that public health and medical emergencies in one part of the world can quickly develop into international health security crises posing a risk to populations everywhere.

Both state and non-state actors have expressed interest in the intentional use of pathogens as weapons. It is the policy of the United States, that until otherwise determined, any weapon of mass destruction incident, to include a biological incident,<sup>4</sup> will be treated as a potential terrorist incident.<sup>5</sup>

Incidents may be complicated by incomplete information, particularly the uncertainty in detection and recognition that an incident is occurring. State and federal entities must work within the resource constraints of the impacted area(s) and may confront difficult challenges such as the potential for human-to-human transmission, a particularly virulent pathogen, and/or a pathogen engineered to be antibiotic resistant. For a biological incident, response and recovery activities are typically managed at the state and local level. Federal assistance under HHS' authorities and under the Stafford Act is provided upon request from and in support of SLTT authorities. The incident could develop into a large-scale response and recovery incident requiring significant state and federal assistance and capability.

Ultimately, a biological incident may diminish the ability of response entities to respond to the emergency. The risks to first responders and receivers posed by certain pathogens are high. In addition, the recovery from a biological incident may span months or even years; seamless, ongoing federal coordination is vital.

Public fear typically characterizes biological incidents, so coordinated messaging and information that adheres to principles of risk communication, even in areas unaffected by the incident, are crucial. Behavioral health impacts may be significant in impacted populations. In some situations, large numbers of concerned citizens may seek medical assistance, which, if not mitigated by behavioral and medical triage, can quickly overwhelm the ability of medical facilities to assist the sick and wounded. Significant mental health impact (e.g., depression, anxiety, post-traumatic stress disorder) could overwhelm existing behavioral health counseling professionals and facilities and will call for less traditional methods of delivering psychological support.

While developing this annex, the planning team recognized the difficulty of preparing a general biological incident annex that would be appropriate to a wide range of scenarios and leverage the commonalities between them. Furthermore, not all infectious diseases are life threatening or lethal. However, it is fair to say that there are a set of core capabilities, that if well executed, will go far to mitigate the effects of a biological incident. Preparing for, responding to, and

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<sup>4</sup> It is understood that all biological incidents may not be intentional and all intentional biological incidents may not be terrorism.

<sup>5</sup> The Attorney General of the United States, generally acting through the Director of the Federal Bureau of Investigation Director, will determine whether a particular situation is to be treated as an actual terrorist incident.

recovering from a biological incident spans Prevention, Response, and Recovery Presidential Policy Directive-8 Mission Areas and further complicates annex development to ensure seamless coordination.

## **Purpose**

The Biological Incident Annex (BIA) provides hazard-specific supplemental information to the Response and Recovery Federal Interagency Operational Plans (FIOP). Federal interagency partners can respond in a lead role or in support to SLTT governments to save lives, protect property and the environment, ensure economic stability, and meet basic human needs when there is a threat of or an actual biological incident.

The BIA addresses pertinent core capabilities of lead federal agencies (See **Table 1**), including unique aspects of biological incidents that are not addressed in the Response and Recovery FIOPs. The BIA acknowledges the differences in operational phase structures between federal agencies and aligns coordination to foster effective communication among federal, SLTT, and private sector organizations. The complex nature of biological incident response and recovery efforts between agencies within the Federal Government will require effective communication, coordination, and collaboration. The intergovernmental collaboration could begin slowly and mount steadily depending on how the incident spreads or occurs. Therefore, a coordinated response will serve as a check and balance strategy within the interagency to help ensure an appropriate level of response, as well as help to ease public fear and chaos. Finally, the BIA aims to serve as a reference point for regional and SLTT authorities and private sector organizations to conduct adaptive planning efforts, based on their hazard and risk analysis, for specific biological pathogens that are a threat to their communities and public health.

This annex also describes operational coordination and information sharing mechanisms within the Prevention Mission Area when federal crimes of terrorism involving biological pathogens are suspected. In addition, the BIA ensures response, recovery, and prevention activities and decisions are informed and coordinated from the regional to the national level. This annex—

- Describes the process, methods, coordination of core capabilities, and organizational constructs for federal agencies to respond to biological incidents and provide recovery support under federal authorities.
- Provides information not addressed in the Response and Recovery FIOPs that is specific and unique to federal biological incident response and recovery processes, assets, resources, and teams.
- Acknowledges differences in operational phase structures between federal agencies and aligns coordination to foster effective communication, coordination, and collaboration among federal, SLTT, and private sector organizations.
- Details the mechanisms and structures for information sharing and coordination within the Prevention Mission Area involving suspected terrorist incidents.
- Serves as a reference point for regional SLTT authorities and private sector organizations to conduct adaptive planning efforts, based on their hazard and risk analysis, for specific biological pathogens that are a threat to their communities and public health.

## Scope

- This annex applies to the federal response to all suspected or confirmed biological incidents, including naturally occurring and intentional acts. It incorporates national capabilities and requirements that are fully executable during a biological incident anywhere in the United States or U.S. territories, including those originating abroad that have the potential to spread among the U.S. population.

This annex maps to the Response and Recovery FIOPs as follows:

- Identifies top-level decision-making processes.
- Spans response through recovery actions.
- Accounts for international aspects of a biological incident as they relate to and influence domestic response.
- Addresses the human-animal interface as it pertains to a biological incident.

This annex does not impede federal departments/agencies from exercising authorities to perform agency responsibilities under law or from taking appropriate independent emergency actions pursuant to their own statutory authority. In addition, this annex does not address—

- International response operations.
- Foreign animal diseases of livestock and poultry and other animal-specific and plant-borne biological hazards that pose a limited threat to human populations.
- Biological toxins (e.g., ricin, saxitoxin, mycotoxins) not associated with active infections

## Facts, Assumptions, and Critical Considerations

The following information represents facts, planning assumptions, and critical considerations that contribute to the development of an operational environment for the BIA and are supplemental to those outlined in the Response and Recovery FIOPs. Additional facts, assumptions, and considerations that pertain to the specifics of an intentional incident are delineated in the Intentional Biological Incident Branch later in this annex.

### Facts

- **Primary Responsibilities:** State and local governmental public health agencies have primary responsibility and authority for public health response to biological incidents within their jurisdictions and can implement quarantine and movement restrictions that can vary, based in part, from federal guidance issued by the Centers for Disease Control and Prevention (CDC).
- **Reporting Requirements<sup>6</sup>:** As a party to the International Health Regulations (IHR), the United States is obligated to report to the World Health Organization (WHO) via the U.S.

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<sup>6</sup> In the instance of a criminal investigation/act or threat of terrorism, the Federal Bureau of Investigation (FBI) shall be consulted before releasing potentially sensitive law enforcement information.

IHR National Focal Point any public health incident that may result in international disease spread or that may require a coordinated international response. Further, the United States has agreed to develop, strengthen, and maintain its capacity to respond promptly and effectively to public health risks and Public Health Emergencies of International Concern (PHEIC) as set out in the IHR, which seeks to minimize disruptions to international travel and trade.

- **Biological Incidents:** The nature of biological incidents continues to evolve; they may result from either natural, accidental or intentional sources, and may include genetically engineered pathogens.
- **Contagious Pathogens:** The greatest biological threat to response and recovery is presented by highly virulent pathogens (or infectious diseases) spread by indirect contact (this includes: airborne transmission, transmission through contaminated objects, vector-borne diseases, and transmission through contaminated food and water, among others) for which there are no MCM.
- **Biological Pathogens:** Most biological incident pathogens are readily cleared from the environment (exclusive of water borne); some select pathogens are environmentally persistent and may require specific decontamination methods.
- **Animal Populations:** If the pathogen has an animal reservoir, infection control, including MCM, isolation, or depopulation, can extend to the animal population in question.
- **Incident Presentation:** Initial surreptitious incident presentation may hamper recognition (e.g., many illnesses have similar initial symptoms and are undiagnosed or improperly diagnosed until the disease and time progress).
- **Non-pharmaceutical Intervention:** For some pathogens, there will be no immediate therapy or prophylaxis (e.g., medication/vaccination) and; therefore, non-pharmaceutical interventions will be the predominant intervention.
- **Epidemiological Investigations:** The public health epidemiological investigation will be used to identify the causative agent, source of the exposure, and populations at risk.
- **MCM Stockpile:** MCM have been identified and stockpiled to reduce the health impacts of a limited number of known threats.
- **MCM Distribution:** Availability, overwhelming public demand, and requests beyond impacted areas will make MCM distribution challenging.<sup>7</sup>

## Planning Assumptions

In absence of fact, planning assumptions represent information presumed to be true and are necessary in order to facilitate planning. Assumptions are a baseline set for planning purposes, and they do not take the place of specific activities or decision points that would occur during an incident. During response and recovery operations, assumptions may be validated as facts.

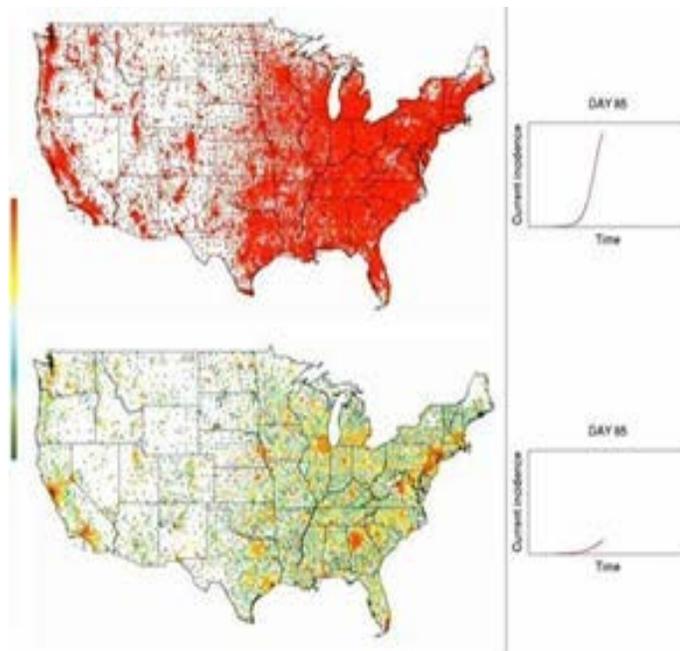
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<sup>7</sup> Challenges addressed in federal and regional MCM plans.

- **Situational Awareness:** Full information about the biological threat may not be immediately available and may take hours (e.g., pathogen identification), days (e.g., exposure areas and/populations), or months (e.g., attack and secondary attack rates, lethality, susceptibility to countermeasures) to unfold. Situational awareness will largely depend on the type of agent and its epidemiologic characteristics. Decisions will need to be made without complete information.
- **Incident Cause:** The cause of a biological incident (e.g., intentional, accidental, or naturally occurring) may not be readily apparent; the possibility the incident was caused by a criminal act will be considered in the response.
- **Disproportionate Impacts:** Responders and first receivers may be disproportionately impacted depending on the agent and the nature of the event.
- **Criminal Investigations:** Any potentially intentional biological threat or incident will require a joint criminal and epidemiological investigation. The Federal Bureau of Investigation (FBI) will coordinate criminal investigative activities with appropriate SLTT and federal partner agencies such as HHS, Department of Homeland Security (DHS), Environmental Protection Agency (EPA), U.S. Department of Agriculture (USDA), and other partners as appropriate.
- **Disease Transmission:** A contagious disease incident may include waves of secondary and tertiary infections within the original outbreak region and beyond. Disease transmission (i.e. epidemic curve) may vary depending on the source of the agent and how it is transmitted (including animal reservoirs). This may present challenges in planning for these incidents in a linear, phased fashion. “Waves” of infections and recurrence demonstrate how different levels of impacts on the country could be possible and how strictly aligning response to planning phases (i.e. 1a-c, 2a-c, 3) can be challenging. **Figure 2** shows the hypothetical spread of a moderately contagious pandemic flu in the United States. Each dot represents a census tract and changes color from green to red as more people in that tract become infected. The dots change back to green as people recover. With no intervention (top), the pandemic peaks around day 85. With distribution of 10 million doses per week of a vaccine that is poorly matched to the emerging virus (bottom), the pandemic peaks around day 108.<sup>8</sup>

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<sup>8</sup> All graphics are courtesy of the Proceeding of the National Academy of Sciences.



**Figure 2: Hypothetical spread of Moderately Contagious Pandemic Flu in United States**

- **Disease Origin:** The geographic origin of the incident may not be readily apparent; the first detected cases may not be in the location of the initial release or exposure. Incidents that originate abroad have the potential to spread quickly to the domestic U.S. population.
- **Significant Resource Shortfalls:** The size, scope, and/or complexity of a biological incident may overwhelm existing state and local capabilities and resources, causing significant strain on the whole community.
- **Healthcare Response:** Individual practitioners, healthcare organizations, healthcare coalitions, and nongovernmental organizations (NGOs) will all be an integral part of a public health response.
- **MCM Development and Production:** For pathogens with no pre-established MCM, development and production would occur as quickly as possible but may take considerable time.
- **Long-Term Recovery:** The impacts of a biological incident can cascade nationally, even for a localized event. Recovery of the impacted populations and environments may take many years.

## Critical Considerations

The following critical considerations are supplemental to those outlined in the Response and Recovery Federal Interagency Operational Plans:

- **Detection:** Biological detectors are not deployed in all metropolitan areas throughout the United States. Thus, detection and confirmation of a biological incident may likely take longer in cities without environmental detection systems. Detectors do not detect all biological agents or pathogens. Furthermore, existing environmental detection

capabilities could require up to 36 hours between deployment of a pathogen and confirmation that an attack has actually occurred.

- **Coordinating Structures:** In the case of a suspected or actual biological terrorist threat, close coordination between the public health and the counterterrorism community will be required throughout the incident. Public health, emergency management, and law enforcement stakeholders will require close collaboration on the ground at the incident level, all the way through the national multi-agency coordination centers. A biological incident will require a coordinated response among SLTT governments, NGOs, the private sector; and international partners.
- **Decision Coordination:** Interdependent decisions of mission areas should be coordinated to avoid unintended consequences. Interdependent decisions include, but are not limited to, pre-positioning of MCM, security of points of entry or enhanced screening, public messaging, operations to resolve the threat, etc.
- **Legal and Policy Decisions:** During a response where federal or SLTT authorities conflict or intersect, critical legal and policy decisions will be required (such as movement restrictions, civil order).
- **Public Information:** Despite the initial lack of availability of incident information, the public will still demand authoritative and knowledgeable information in a developing situation. In situations in which there is a suspected or actual biological terrorist threat, the President of the United States has directed the Secretary of Homeland Security and the Attorney General to coordinate with each other to execute key responsibilities that provide public information and warning to the Nation regarding terrorist threats and attacks.<sup>9</sup>
- **Complex Medical and Health Information:** Communications must synthesize complex medical and health information to promote public compliance with guidance. Information from SLTT, federal, and private sector partners will be necessary to develop a full understanding of risks, identify appropriate response actions, and provide accurate risk communications.
- **International Partners:** The United States engages in several international partnerships on preparedness and response for biological incidents.<sup>10</sup> International partners may request information or assistance from the United States, or the United States may request information or assistance from international partners. For foreign requests for assistance,<sup>11</sup>

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<sup>9</sup> Whenever there is a suspected or actual terrorist threat or incident, the Terrorism Incident Law Enforcement and Investigation Annex, as well as other applicable national policies, including Presidential policy directives, should be consulted to identify necessary coordination mechanism.

<sup>10</sup> The United States is part of key multilateral partnerships such as the Global Health Security Initiative, to work with like-minded countries to strengthen health preparedness and response globally to chemical, biological, radiological, and nuclear threats and pandemic influenza. On a regional level, the U.S.' health security efforts include the North American Plan for Animal and Pandemic Influenza or the health security aspects of the U.S./Canada Beyond the Border Initiative.

<sup>11</sup> Policy Framework for Responding to International Requests for Public Health Emergency Medical Countermeasures from the U.S. Department of Health and Human Services. This Framework established the International Sharing of Medical Countermeasures Policy Group (ISMPG)—a U.S. Government (USG) interagency group that analyzes international requests for MCMs and develops recommendations for U.S.

the U.S. may also need to assist foreign governments (as requested) in an effort to contain the spread of a biological incident to the United States by controlling it at its source. Each department and agency will consider specific requests for their resources. Politically sensitive requests or requests for scarce resources may be elevated to the National Security Council (NSC) through the Presidential Policy Directive (PPD-1 process or its successor. HHS has a series of Frameworks<sup>12</sup> that can be used to address requests for public health and medical resources.

- **Foreign Offers of Assistance:** Foreign offers of assistance will be made to the Federal Government and will be managed in accordance with the International Assistance System Concept of Operations.
- **Continuity of Operations (COOP)/Continuity of Government (COG):** The Implementation of COOP planning and COG activities is anticipated depending on the pathogen's impact on the workforce. Prioritization of capabilities will be necessary to balance competing missions and maximize efficiency.
- **Workforce Protective Actions:** Each federal agency is responsible for maintaining and implementing workforce protective actions. Coordination of workforce directives across agencies may increase compliance, effectiveness, and perceptions with staff and the public. Consistency with guidance for the private sector and the public should be established as well.
- **Resistant Pathogens:** There is the potential for pathogens to be resistant to MCM, limiting the availability of prophylaxis and treatment options.
- **Immunity of Populations:** There will be limited, if any, immunity in the population to some novel emerging infections.
- **Limited MCM:** Available but limited MCM may fall short of the required demand due to a variety of factors (e.g., geographical variance in the severity of the outbreak, logistical issues, disruption to pharmaceutical production). MCM may be exhausted. Further complications may arise from existing drug shortages as mentioned in Executive Order 13588, Reducing Prescription Drug Shortages (Oct. 31, 2011).
- **Medical Countermeasures Dispensing:** SLTT entities may lack the capability to immediately provide MCM and personal protective equipment (PPE) and may require assistance, which may include federal options consistent with the Federal Interagency Concept of Operations-Rapid Medical Countermeasures Dispensing.
- **Public Safety:** Both federal and state authorities must consider public safety and security during implementation of response and recovery measures (e.g., security at MCM dispensing areas and of healthcare and public health critical infrastructure).

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action—for which the Office of Planning and Policy, Division of International Health Security serves as the Executive Secretariat.

<sup>12</sup> Department of Health and Human Services Policy Framework for the Deployment of Personnel during International Medical and Public Health Emergencies: This Framework established the HHS International Policy Group for Personnel Sharing (HIPPS)—a USG interagency group that analyzes international requests for public health and medical personnel and develops recommendations for U.S. action—for which the Office of Policy and Planning, Division of International Health Security serves as the Executive Secretariat.

- **New Therapies:** Unique therapeutic and unapproved or novel therapies and diagnostic tests may need to be used after appropriate regulatory authorization (e.g., Emergency Use Authorization).
- **Contact Tracing:** Contact Tracing involves the identification and diagnosis of persons who may have come into contact with an infected person. Individuals or populations who have traveled to other states or countries since exposure may complicate and slow the contact tracing process.
- **Waste Management:** The pathogen type can have an impact on hazardous waste processing and disposal. Management of large quantities of hazardous waste will prove challenging and further drain resources. See **Appendix 9** for further Waste Management considerations.
- **Responder Exposure:** Responders may be placed at risk if not adequately protected. For example, they may be exposed to individuals with contagious illness. Alternatively, they could become contaminated with an intentionally disseminated agent before recognition of its presence has occurred.
- **Fatality Management:** Fatality management resources will likely be strained by both naturally occurring and intentional incidents. For the former, regular processing mechanisms are likely overwhelmed due to large numbers of human remains, which are possibly hazardous due to the presence of the biological causative agent(s). For the latter, evidence taken from human remains might have to be recovered and preserved as part of ongoing law enforcement investigations.
- **Behavioral Health Impacts:** Public concern for exposure, without demonstration of illness, and the desire for preventive prophylaxis will all amplify the demand for medical and health resources. Due to the characteristics of biological incidents, behavioral health impacts should be anticipated; negative perception of individuals, families, communities, ethnic/racial groups, or even certain professions that may become associated with the pathogen via media and other reports is a significant concern.
- **Transportation Protocols.** Appropriate protocols may be necessary when transporting persons from areas affected by a biological pathogen. Protocols will delineate the screening and follow-up requirements for unexposed or asymptomatic persons who are being repatriated back to the U.S. and the transportation requirements for exposed, symptomatic, or infected persons within the U.S., as well as U.S. citizens and healthcare workers from overseas.<sup>13</sup>
- **Decontamination:** A few agents could require long-term or permanent closure of buildings or public spaces in the instance of a wide-area dissemination. Decontamination may take an extended period of time, closing affected areas to individuals and businesses.
- **Animal Care:** Aside from zoonotic potential, animals present complexities in managing a biological incident as personnel for their care may be unavailable and disposition decisions for those animals that are exposed will impact their owners' behavior.

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<sup>13</sup> If U.S. citizens exposed abroad require transportation to a healthcare facility in the United States; emergency repatriation will be coordinated between the U.S. Department of State and the Department of Health and Human Services.

- **Children and Youth Task Force:** Children and youth may become concerned by the impacts of the incident and may be confused by messaging related to the incident. The Health and Social Services Recovery Support Function (RSF) may need to convene specific groups of relevant personnel to address the health, behavioral health, and social services needs of impacted children and the adults who support them.
- **National/Global Markets:** Hazard impacts may affect national and global markets. The resultant commercial implications (e.g., supply chain) will challenge response and recovery actions.
- **Non-pharmaceutical Interventions (NPI):** NPIs (e.g., social distancing, quarantine, travel restrictions, school closures) may have unintended consequences and require judicial implementation. Considerations include civil rights and civil liberties, financial impacts, implementation challenges, consistent applications, and efficacies.
- **Travel Restrictions:** Both federal and state authorities permit public health actions (e.g., travel restrictions) in specific situations. Interstate coordination may be vital. In accordance with IHR, response to public health incidents should minimize impact on travel and trade.
- **Resource Competition:** Resources may be limited regardless of pathogen (natural or intentional). Competition between various governmental levels and the private sector can be anticipated and should be coordinated to promote the most judicious distribution of these resources.

## Mission

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The mission of the Federal Government during a biological incident is to save lives; reduce human suffering; protect property and the environment; restore critical infrastructure; reestablish an economic and social base; control the spread of disease; and support community efforts to overcome the physical, emotional, and environmental impacts of the biological incident. This federal mission is contingent upon coordination with and the success of the whole community response.

## End State

The desired end state of federal response and recovery operations to a biological incident is achieved when—

- Federal lifesaving and life-sustaining assistance to SLTT and private sector entities are provided.
- SLTT governments can provide individuals and families with the means to rebound from their losses in a manner that sustains their physical, emotional, social, and economic well-being.
- Critical infrastructure capability and capacity are restored.
- Public safety and health protection assurances are reestablished.
- Response and recovery worker safety and health protection assurances have been reestablished.

- Measures are in place to enable and restore commercial activity to meet the demand of the population. Economic impacts are minimized locally, nationally, and internationally.
- Exposed populations are fully identified and have received appropriate MCM or other interventions to protect or restore health.
- Behavioral/mental health needs of victims, responders, and other affected populations have been addressed.
- The public has been provided the necessary information to protect against or recover from the biological incident.
- Pathogen transmission has ceased within and outside U.S. borders.
- Environmental assurances can be made that contaminated areas have been assessed for safety, need for decontamination, and appropriateness for re-occupancy.
- Persistent disease threats to humans from animals or any other sources have been addressed and threats from reservoirs mitigated.
- Appropriate care is identified for dependents (e.g., elderly, children) and animals without caretakers as a result of the incident.
- All levels of communities have been addressed: elderly, children, people with access and functional needs, people with English as a second language, people with low literacy, and people with chronic conditions.; sustainable activities are in place.

## **Primary Authorities and Relevant Declarations**

There are numerous federal authorities applicable to biological incidents, and a detailed but non-exhaustive list is contained in **Appendix 1: Authorities and Other References**. This annex does not alter or impede the ability of any federal departments and agencies to exercise their authorities or to perform their responsibilities under the law. This annex does establish parameters and methods for inter-agency coordination.

The agencies with primary authority to implement federal support to and management of the Prevention, Protection, Response, and Recovery Mission Areas are listed in **Table 1**.

While the focus of this annex is a domestic biological incident, it is essential to consider the intersections between domestic and international response activities. As specified in the National Response Framework (NRF) International Coordination Support Annex, the Department of State has the lead foreign policy role in supporting U.S. Government (USG) agencies and managing the international aspects of a domestic incident. As noted in **Table 1**, HHS is the lead agency for all activities described in the base annex, and the FBI is the lead agency for all activities described in the Branch Plan.

Though **Table 1** lists lead federal authorities, it is clear that other federal departments and agencies have significant roles in each of the incident types (See **Appendix 2: Roles and Responsibilities of Federal Agencies with Primary Authority for Response to a Biological Incident**). Due to these potential complexities, it is the responsibility of the lead agency to establish inter-agency coordination mechanisms as soon as possible during incidents. For some incidents (e.g., intentional, or naturally occurring both domestically and internationally) there

may be two lead agencies for different mission areas (crisis versus consequence management). Coordination between these is required as well.

**Table 1: Federal Agencies with Primary Authority for a Biological Incident**

Incident Type, Location	Lead Agency
<b>Response and Recovery (Consequence management for Human disease):</b> a) Naturally occurring, domestic b) Intentional, domestic c) Naturally occurring, international with potential domestic impact d) Intentional, international with potential domestic impact	a) HHS b) HHS c) DOS/HHS <sup>14</sup> d) DOS
<b>Prevention and Protection (Crisis management):</b> e) Domestic or foreign origin	e) DOJ/FBI
Note: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.	

At all times, federal agencies may take appropriate independent emergency actions within the limits of their own statutory authority to protect the public, mitigate immediate hazards, and gather information concerning the emergency to avoid delay. Coordination of these activities with other relevant departments and agencies remains critical.

### Major Declarations of Relevance

In a biological incident, the following declarations may be issued and may influence the response and recovery to the incident. It is important to consider that many prior biological incidents have been addressed without any of the following declarations. States or territories can also issue their own public health emergency declarations at their discretion.

#### *HHS Declaration of Public Health Emergency*

Section 319 of the Public Health Services Act (PHSA) authorizes the Secretary of HHS to determine that a Public Health Emergency (PHE) exists, if the Secretary determines a disease or disorder presents a PHE or that a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. If the Secretary issues this declaration, it would authorize the Secretary to take appropriate actions consistent with other authorities to respond to the emergency, temporarily suspend or modify certain legal requirements, and expend available funds in the PHE Fund to respond to the PHE. The Secretary has broad authorities to respond to a public health emergency, regardless of whether a formal PHE is declared.

<sup>14</sup> HHS serves as the technical lead for issues related to consequence management for human disease including public health and medical services, fatality management, and response health and safety, among others. The Department of State coordinates diplomatic engagement and communications with foreign governments and leads humanitarian assistance efforts as needed.

### *Presidential Declaration of a National Emergency*

Section 201 of the National Emergency Act (NEA) authorizes the President to declare a national emergency. Under NEA Section 301, statutory emergency authorities enabled by the national emergency declaration cannot be exercised until the President specifies the provisions of law under which the President or other officials will act. Such specification may be made either in the declaration or in subsequent Executive Orders published in the Federal Register and transmitted to Congress.

### *Stafford Act Declaration*

Historically, and due to the way the legislation is written, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) is less commonly used for biological incident response. It is possible it could be utilized in certain situations. When the President of the United States issues a declaration under the Stafford Act in response to a biological incident, coordination of interagency partners and tasking through mission assignments will occur through the National Response Coordination Center (NRCC) or the Regional Response Coordination Center (RRCC) of the affected jurisdictions under this Act's authorities. The NRF and National Disaster Recovery Framework (NDRF), as well as the associated FIOP and this annex, serve as the guidance to provide the appropriate federal assistance.

### *World Health Organization Declaration of Public Health Emergency of International Concern*

A Public Health Emergency of International Concern (PHEIC) is defined by the International Health Regulation (2005) as any extraordinary event which is determined to constitute a public health risk to other countries through the international spread of disease and to potentially require a coordinated international response. All parties are required to notify the WHO through their IHR National Focal Points; the Director-General of the WHO determines whether an event constitutes an actual PHEIC. In accordance with IHR the United States would have 48 hours to assess and determine whether a potential PHEIC notification should be sent to the WHO. If the severity or impact of the biological incident poses a significant threat (through international spread) or may require a coordinated international response to contain, the Director-General of the WHO may declare the event a PHEIC.

## **Execution**

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### **Concept of Operations**

Biological incidents are primarily managed and monitored by public health agencies at the SLTT levels of government. As incidents change in size, scope, and complexity, a higher level of coordination among public health, emergency management, and law enforcement communities may be required in the form of supplemental and complementary support. During a biological incident, the public health agency at the local or state level is normally the lead response agency (for the geographic area). When federal public health and medical support is required for response and recovery efforts, HHS is the lead agency and originator for federal agency-to-agency operational support tasks. Many conceivable instances will not result in a PHE or Stafford Act declaration, yet additional resources and coordination support may be facilitated by the Federal Emergency Management Agency (FEMA) and the interagency to deliver

supplemental support to the lead public health agencies. Depending on the situation, other federal agencies may play a lead coordinating role, with HHS retaining its lead functional responsibilities to deliver public health and medical capabilities.

### Steady State

Steady state and enhanced steady state operations encompass surveillance and information gathering by multiple federal agencies and numerous SLTT entities. Some of this surveillance occurs in the realm of day-to-day public health activities. Syndromic surveillance, disease reporting, and public health investigations of unusual cases occur as a part of these regular ongoing activities. Multiple federal agencies are tasked to seek out and report any abnormalities (e.g., environmental sampling) or unusual cases of concern as part of their daily work, in order to prevent and detect biological threats.

Steady state and enhanced steady state operations involve a number of departments and agencies, each with a role in surveillance and threat awareness, as well as the coordination of myriad sources of information, to include potential international sources of information regarding diseases. For further information, see **Appendix 3: Information and Surveillance**.

### Biological Agent Detection

Detection is defined as identification of a biological pathogen of concern. There are numerous ways in which initial detection could occur, including presentation of disease in humans or animals (domestically or internationally), detection through syndromic surveillance, alerts from environmental surveillance systems or international partners, and normal operations and surveillance efforts conducted by law enforcement or other departments and agencies. Details are provided in **Appendix 3: Support and Coordination Elements. Table 2** provides examples of some potential sources of initial information with follow-on verification processes. It should be noted that in some instances, detection can predictably occur after the outbreak/incident is well underway resulting in numerous infections prior to initial detection.

**Table 2: Examples of initial Detection of a Biological Pathogen**

Source of Information	Examples of Initial Information Received	Verification Processes
Individual practitioner or healthcare facility laboratory	<ul style="list-style-type: none"> <li>• Suspected sentinel case reported through local public health</li> <li>• Confirmed sentinel case reported through local public health</li> </ul>	<ul style="list-style-type: none"> <li>• Private sector, Laboratory Response Network (LRN), or CDC laboratory confirmation may be required</li> </ul>
Individual facility, local or state health department surveillance systems	<ul style="list-style-type: none"> <li>• Influx of patients with similar symptoms indicating potential disease pathogen</li> </ul>	<ul style="list-style-type: none"> <li>• Private sector, LRN, or CDC laboratory confirmation may be required</li> <li>• Epidemiologic investigation to confirm patterns of similarity</li> </ul>

Source of Information	Examples of Initial Information Received	Verification Processes
Identification of atypical pathogens by a private sector laboratory	<ul style="list-style-type: none"> <li>Individual not originally suspected but “surprise” diagnosis received through secondary testing</li> </ul>	<ul style="list-style-type: none"> <li>LRN or CDC laboratory confirmation will be required</li> </ul>
Novel emerging or re-emerging infection, potentially reportable or officially reported under IHR from overseas source	<ul style="list-style-type: none"> <li>New pathogen or pathogen of concern evolving in a situation in which spread to United States is possible</li> </ul>	<ul style="list-style-type: none"> <li>Multiple international partners as well as international assistance provided by U.S. Government</li> </ul>
Zoonotic outbreak identified by private sector, SLTT, or federal providers or laboratories	<ul style="list-style-type: none"> <li>Zoonotic pathogen identified in an animal population with potential for causing concerning human disease</li> </ul>	<ul style="list-style-type: none"> <li>USDA, CDC, SLTT, National Animal Health Laboratory Network, or private sector laboratory confirmation all possible</li> </ul>
Law enforcement and intelligence	<ul style="list-style-type: none"> <li>Credible threat of deployment of pathogen of concern</li> </ul>	<ul style="list-style-type: none"> <li>Law enforcement investigations paired with public health expertise</li> </ul>
Public media	<ul style="list-style-type: none"> <li>Announced identification of pathogen of concern</li> </ul>	<ul style="list-style-type: none"> <li>Multiple entities/processes at various levels potentially involved</li> </ul>
BioWatch or other environmental sampling	<ul style="list-style-type: none"> <li>Pathogen of concern detected in environment leading to a BioWatch Actionable Result or BAR</li> </ul>	<ul style="list-style-type: none"> <li>BioWatch has internal verification processes and may conduct additional sampling</li> <li>If additional environmental verifications are indicated, follow-on testing of BAR related samples are coordinated with CDC</li> <li>If another environmental sample, may require U.S. Government support to SLTT sample to verify</li> </ul>

Many of these potential examples can include a complex set of activities, some in which federal partners are either primarily responsible for or provide support to SLTT entities and the private sector. Coordinated collection of data elements from disparate sources, analysis of data elements, and modeling can be required to further elucidate the initial data points.

Incidents involving biological pathogens occur regularly but usually do not rise to the level of requiring the coordination of multiple federal agencies and departments. Notification,

coordination, and collaboration efforts are ongoing, occurring as part of regular public health activities. These occur across the horizontal and vertical partners to detect and confirm the presence of a biological pathogen of concern. As these efforts expand across these levels and it becomes more apparent that multi-agency coordination may be required, the lead agency may determine that a biological incident (as defined in this annex) is occurring. This determination, denoted as “incident recognition,” may be determined based on the need to expand current response communications, capabilities, operations, and resources. The HHS decision-making process for this transition to unified coordination is outlined in the next section.

## **Incident Recognition/Initial Decision-Making Process**

Within HHS, the Assistant Secretary for Preparedness and Response (ASPR) is the lead for coordinating the federal public health and medical preparedness and response and recovery to biological incidents and other public health emergencies. The ASPR also has responsibilities for providing departmental resources to assist federal and SLTT government requests for public health and medical assistance during biological incidents. The Disaster Leadership Group (DLG) is a policy group that the ASPR uses to convene and collaborate with senior leadership and their designated subject matter experts (SMEs) across HHS Operating Divisions (OPDIVs) and Staff Divisions to discuss policy issues and develop solutions to support preparedness, response, and recovery related to a national incident or event. This would include suspected or known biological agent attacks. During or following such incidents, the lead federal agency should work with the White House National Security Council staff to convene the Domestic Resilience Group (DRG)<sup>15</sup> Interagency Policy Committee to enhance interagency coordination among federal partners.

The DLG ensures a coordinated, HHS-wide, strategic approach among the executive leadership of HHS operating divisions and staff divisions. In some instances, the HHS DLG could expand to include leaders from additional federal departments and agencies as necessary.

The initial decision for interagency coordination may be apparent if certain parameters exist, such as—

- Departments and agencies agree, through the interagency policy process described in PPD-1, or its successor, that enhanced interagency coordination is recommended.

The ASPR is responsible for determining, in consultation with other agencies as relevant, when interagency coordination related to a biological incident is necessary.

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<sup>15</sup> The Domestic Resilience Group (DRG) Interagency Policy Committee coordinates homeland security policy development and implementation across the United States Government in the areas of domestic preparedness, incident management, response, recovery, resilience, and continuity for all hazards. During domestic incidents and international incidents with homeland security implications, the DRG may evaluate policy issues regarding the response to, recovery from, and management of the consequences or potential consequences of an incident; coordinate policy recommendations and decisions to enhance the Federal Government’s response and recovery efforts; and enhance common situational awareness.

- The lead agency has exhausted or has insufficient domestic incident management capacity to meet incident demand, necessitating augmentation.
- The incident has the potential to increase in magnitude and complexity such that it requires substantial survivor mass care services, logistics architecture, public safety and security, emergency communications, and other elements outside of the abilities in HHS.
- Existing obligations require the U.S. Government to report certain developments through international mechanisms (IHR, International Food Safety Authorities Network, World Organization of Animal Health).

If the need for interagency coordination is not immediately apparent, the ASPR will consider all known information including input from other federal agencies as appropriate. Information to be evaluated may include the following:

- Epidemiology, ecology, and impact of the disease and its effects on high-risk groups or populations.
- Availability and deployability of effective medical and NPI and countermeasures.
- Effectiveness of medical countermeasures.
- Immediate and short-term needs of local public health authorities and medical facilities.
- Need for health risk communication and public affairs coordination.
- Data regarding the effectiveness of public health interventions.
- Impacts on long-term community resiliency and recovery.
- Need for, and availability of, international assistance.
- Impacts on international relationships, foreign travel, and global trade.
- Need to support law enforcement, criminal investigation, and interdiction activities while simultaneously mitigating public and worker health impacts.
- Gaps in current knowledge and needs for immediate and long-term biological research.

Many additional factors will also be considered when making a decision on enhanced coordination, some of which may include:

- International emergence of a highly infectious disease with high mortality.
- Identification and/or confirmation of human cases of a novel virus infection within or near the national, regional, or local jurisdiction area of responsibility.
- Actionable finding by National Biosurveillance Integration System (NBIS).
- BioWatch Actionable Result (BAR) received or declared by one or more SLTT jurisdictions.
- Confirmed case of human or animal illness involving a select agent or toxin (see: [www.selectagents.gov/SelectAgentsandToxinsList.html](http://www.selectagents.gov/SelectAgentsandToxinsList.html)).
- Efficient, sustained, and/or increasing numbers of human-to-human transmission of a novel virus.
- Intelligence reporting of an impending bio-attack.
- Potential or actual PHE declaration or emergency management declaration.

- Exceeding public health capabilities and resources or expanding geographic impact necessitating the local, tribal, county, parish, territory, or state to request public health assistance from its neighbors or elevated supporting agency.
- Report of a case of disease caused by a very uncommon biological agent or presented in a very unusual manner (e.g., *Bacillus anthracis*).
- Simultaneous occurrence of similar illness in non-contiguous areas, unusual geographic, or seasonal distribution.
- Positive alert for the anthrax organism by Postal Service Biohazard Detection System.
- Detection of a mail piece(s) proven to contain a dangerous biological agent.

## Notification

There are numerous notification methodologies utilized at the federal level that could play a role in a biological incident. **Table 3** lists examples of information sharing processes with descriptions of when they are utilized. For purposes of this annex, notification is most appropriately utilized to describe the process in which the lead agency “notifies” interagency partners when unified coordination is required. HHS maintains pre-designated points of contact among the interagency but may also request DHS/FEMA to assist with obtaining appropriate department and agency representation during initial unified coordination efforts. In addition, the lead agency should notify the DRG and other entities (e.g., WHO) as appropriate and per statutory requirements for notification. Initial biological incident notification will include all Emergency Support Function (ESF) #8 departments and agencies.

The activation notification to relevant interagency partners for a biological incident will include—

- Initial incident summary
- List of departments and agencies requested to participate
- Level/types of anticipated unified coordination (see below)
- Initial timing/schedule of meetings/calls

**Table 3: Examples of National-Level Notification Modalities<sup>16</sup>**

Information Sharing Process	Description
Biological Incident Notification and Assessment (BINA) Protocol	The BINA Protocol provides a consistent means for National Security Council (NSC) staff to convene agencies pursuant to the interagency policy process outlined in PPD-1, providing the Federal Government the ability to rapidly develop a common understanding of an evolving, potentially high consequence biological incident or threat, allowing for rapid decision-making and a coordinated action among agencies and as directed by the President.

<sup>16</sup> These modalities provide examples of various ways to collect and share information from, and with, interagency partners as well as SLTT representatives.

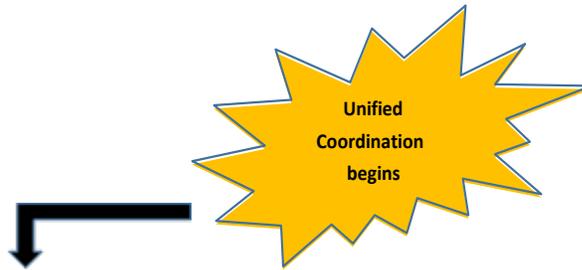
Information Sharing Process	Description
BioWatch National Conference Call	Occurs within 2 hours of the BAR declaration and after the local jurisdictional BioWatch Advisory Committee (BAC) call. It begins with a summary of laboratory testing data and a summary of the current local situation by the BAC chair and other local public health, law enforcement, and emergency management representatives to provide situational awareness of follow-on activities and potential requests for assistance from other federal agencies (DHS, CDC, FBI, EPA, or the Strategic National Stockpile [SNS]) and a decision regarding the next conference call time.
National Biosurveillance Integration System (NBIS) Protocol	Mechanism to bring federal NBIS partners together on a short-notice teleconference to share information on a potentially significant biological incident. It can be initiated at the request of any NBIS partner and is an example of a unique capability of the National Biosurveillance Integration Center (NBIC) that helps enable national biosurveillance integration. The Protocol is activated when a situation meets one or more of the threshold criteria and is requested by a NBIS agency.
Health Alert Network (HAN)	CDC’s primary method of sharing public health information with public information officers, federal and SLTT-area public health practitioners, clinicians, and public health laboratories. There are jurisdictional HAN programs from 50 states and the District of Columbia, 8 territories as well as Chicago, Los Angeles, and New York City metropolitan areas.
Epidemic Information Exchange (EpiX)	Epi-X is a web-based communications solution for public health professionals. Through Epi-X, CDC officials, state and local health departments, poison control centers, and other public health professionals can access and share preliminary health surveillance information—quickly and securely. Users can also be actively notified of breaking health events as they occur. Key features of Epi-X include unparalleled scientific and editorial support, controlled user access, digital credentials and authentication, rapid outbreak reporting, and peer-to-peer consultation.
Clinician Outreach and Communication Activity (COCA)	Provides timely, accurate, and credible information to clinicians related to emergency preparedness and response and emerging public health threats. COCA fosters partnerships with national clinician organizations to strengthen information-sharing networks before, during, and after a PHE.
HHS Public Affairs Conference Line (PACL)	Provides a conference line to allow telephone connectivity for public affairs staff supporting ESF #8. This conference line provides HHS public affairs personnel to work from dispersed sites during the crisis yet be able to receive guidance or direction or to provide information to those needing it.
National Incident Coordination Conference Line (NICCL)	While DHS traditionally leads the NICCL for transmission and exchange of critical and timely incident information among federal authorities, HHS, when needed, can coordinate communications information related to the public health and medical aspects of a response, particularly in a public health-specific emergency such as a pandemic disease. DHS coordinates similar processes for private and state entities through the Private-sector Incident Coordination Conference Line and State Incident Coordination Conference Line, respectively.
National Public Health Information Coalition (NPHIC)	Leverages a network of state and local public health communicators to exchange information and increase the likelihood of consistent messaging and communication activities between federal and SLTT-area governments regarding the emergency and its impact on health.

Initial notifications related to intentional incidents and the PPD-25 process are further outlined in the Intentional Biological Incident Branch to this plan.

## Activating Unified U.S. Government Coordination

### Operational Phases during a Biological Incident

There are multiple ways in which a biological incident can unfold. As noted above, many departments and agencies can be involved at a steady state in public health actions and even more as a biological pathogen is detected. Some activities may be occurring before this annex is applicable, and some departments or agencies may have initiated response while others have not. For simplicity’s sake, the transition from phase 1c to 2a for a biological incident as defined in this annex is the point in time in which unified interagency coordination has formally been initiated.



Phase 1			Phase 2			Phase 3
Primarily Pre-Incident			Begins when an Incident Occurs Upon Notification			Sustained Operations
<b>1a</b>	<b>1b</b>	<b>1c</b>	<b>2a</b>	<b>2b</b>	<b>2c</b>	<b>3a</b>
Normal Operations	Increased Likelihood or Elevated Threat	Near Certainty or Credible Threat	Activation, Situational Assessment,	Employment of Resources and Stabilization	Intermediate Operations	Long-Term Recovery Operations

Figure 3: Operational Phases During a Biological Incident

For purposes of this annex, activation is defined as the point in time in which the lead agency notifies interagency partners of a request to initiate unified coordination. This distinction is made due to the numerous potential roles and responsibilities of various departments and agencies (see **Appendix 2: Roles and Responsibilities of Federal Agencies with Primary Authority for Federal Response to a Biological Incident**).

### Unified Coordination

Biological incidents may evolve in unique ways, providing a challenge for interagency coordination. The differences between given biological incidents mean that there are a number of ways to coordinate federal activities related to biological incident response. As noted above, some departments or agencies will be responding as part of their statutory authorities before unified coordination is initiated by the lead federal agency. As part of that initial response, they might be engaging with entities external to the federal government. There are several critical decisions that the lead federal agency should make early in the interagency coordination process. The discussion of unified coordination in this document should be considered a starting point,

but unified coordination must adhere to the basic tenets of the National Incident Management System (NIMS) and be scaled appropriately to the incident response.

### *Integration Mechanisms and Operational Tempo*

In the early stages of an incident, a formally staffed Unified Coordination Group (UCG) at the national level may not be required. Instead, interagency coordination may be as simple as formalized communications (e.g., weekly meetings) coordinated by the lead federal agency with little to no staff dedicated to the incident outside of their typical work responsibilities. This operational tempo may increase to more frequent meetings and more formal staffing of a UCG, depending on incident parameters and as determined by the lead federal agency. Conversely, the incident may dictate the immediate establishment of a robust national-level UCG (or UCGs at various government levels—see below).

The majority of biological incidents will entail, at a minimum, communications between HHS and DHS/FEMA (to ensure linkage of the health and emergency management communities). Coordination between HHS, DHS/FEMA, and other departments and agencies involved will occur as necessary.

It is important to note that interagency coordination, whether basic communication or a formalized through the UCG, may be required independent of any formal declaration (see Primary Authorities and Relevant Declarations).

For some limited outbreak scenarios, the lead federal agency may be able to provide initial estimates of anticipated duration of the UCG.

### *Purpose and Roles of UCG*

The purpose of a UCG is to integrate and synchronize the response and recovery activities of relevant federal departments and agencies. When established, a national-level UCG will assist the lead federal agency and senior response official in executing the following responsibilities:

- Developing goals and objectives for the federal response to the biological incident;
- Identifying gaps that response efforts should address and resources to fill those gaps;
- Identifying federal capabilities to assist SLTT officials in responding to the incident;
- Coordinating response and recovery strategy and operations with federal, state, local, tribal, and territorial officials as well as private sector and non-governmental entities;
- Coordinating with senior USG officials in order to raise and resolve resource and policy issues related to response and recovery;
- Facilitating information sharing with federal and SLTT officials, as appropriate, including development and dissemination of a Senior Leadership Brief or other information aggregation document, that is accessible to all federal agencies with roles and responsibilities related to response and recovery activities;
- Developing guidance and messages for dissemination to the public and external stakeholders; and
- Developing metrics to define and measure progress on goals and achievements.

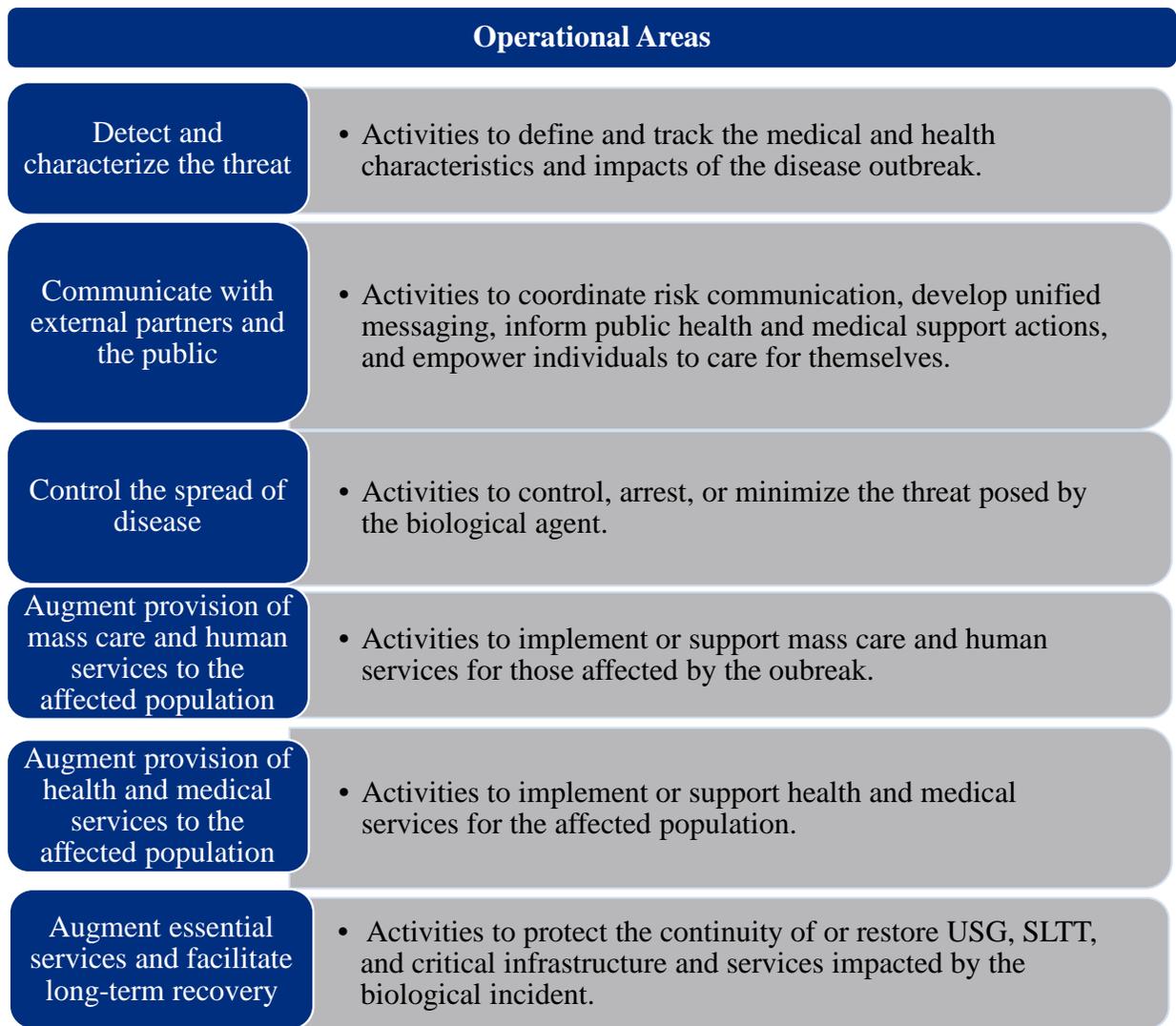
### *Construct of UCG*

The lead federal agency is responsible for determining the relevant departments and agencies required for participation in unified coordination as well as the level of unified coordination needed. As noted above, at a minimum, all ESF #8 supporting departments and agencies will be notified of any biological incident meriting unified coordination.

A singular coordination structure must be modular, scalable, and flexible and able to operate across all phases of an incident. As incidents evolve, there may be a need to expand the UCG to involve additional interagency partners or to implement unified coordination structures at the regional or local levels. Similarly, efforts at each level may be scaled back as incident parameters dictate. An organizational chart that is consistent with NIMS and Incident Command Structure (ICS) principles will be developed, tailored to the incident, and focused on positions necessary to accomplish the goals and objectives.

For consequence management, there are six operational areas for consideration around which the UCG response to a recognized biological incident will be organized. These areas form the core of the response and recovery operations to a biological incident and integrate emergency management, public health, and medical functions. Federal departments/agencies with equities in any of these operational areas would then provide qualified and sufficient representation to the UCG to ensure effective collaboration, coordination, and information sharing.

The operational areas are listed in the **Figure 4** below. More expansive definitions are provided in the following section.



**Figure 4: Operational Areas**

Building on the operational areas, organizational elements may be applied to assemble a national-level UCG. The operational areas provide a starting point for constructing a UCG and may be added to, modified, or omitted within a UCG construct based on the circumstances and requirements of a specific incident response. Branches may be staffed with units to execute national-level objectives and maintain span of control.

The UCG leadership may include a Senior Response Official (HHS) and a Deputy Response Official, the latter of which may be staffed by FEMA or another federal agency with primary authority for a portion of the response.

The Command Staff Elements may include, but is not limited to, Press/Media Affairs, Legal Advisor, Legislative Affairs, and Intergovernmental Affairs.

The Operations Section can be designed utilizing the operational areas but does not need to mirror them exactly. For example, an operations section could possess a Public Health Branch, a Mass Care and Human Services Branch, a Health and Medical Branch, and a Recovery Branch.

Other functional elements include a Planning Section with robust Situation and Resource Units, and Logistics and Finance Sections. The breadth of each of these elements will be dictated by the nature of the incident.

### *Location*

Just as the configuration and operational tempo of the UCG can vary depending on incident parameters, so can the location of the UCG. Depending on incident parameters, different levels of unified coordination may be required (e.g., local, regional, national).

A formal, national UCG for a biological incident could be established in one of several forms, at the direction of the lead federal agency:

- Assignment of emergency management personnel and others to form a UCG at the HHS Secretary's Operations Center (SOC).
- Assignment of emergency management personnel and others to form a UCG at the CDC Emergency Operations Center (EOC).
- Establishment of a robust UCG at the FEMA NRCC.

Regional-level UCGs may be located in the HHS or FEMA region(s) significantly affected by a large-scale biological incident. Regional-level UCGs would coordinate and collaborate with private sector and non-governmental organizations to support affected states/territories.

Local-level UCGs may be required in those jurisdictions significantly affected by a large-scale biological incident. A local UCG develops response actions to biological incidents while overseeing implementation of those response actions ultimately aimed at providing effective federal support to the jurisdiction.

It is important to understand that depending on the nature of the biologic incident, each one of the above UCG models could be implemented individually or in unison. Given the wide range of potential biological scenarios, flexibility in implementation is critical and attention to staffing needs is imperative.

Any established UCG will integrate with other operating bodies such as the CDC's EOC or other department operating centers.

In most cases, exclusive of a Stafford Act declaration, support provided between agencies is governed by the Economy Act. Certain agencies may have other legal authorities that they can rely upon to provide support to or receive support from other agencies.

In the event of a Stafford Act Declaration, responding departments or agencies provide representatives to the NRF and NDRF elements (e.g., Joint Field Office, National Operations Center [NOC]) when appropriate. In addition, during Stafford Act incidents, FEMA may issue mission assignments to federal agencies to support response and recovery activities.

## **Federal to SLTT Coordination**

The mechanisms employed for coordination between SLTT and private sector counterparts can expand and contract in accordance with the level of operational coordination taking place at the

national level. The following table identifies what parallel degrees of coordination at the national and state and local levels may look like.

**Table 4: Federal to State and Local Coordination by Incident Type<sup>17</sup>**

Scenario	National	State/Local
Steady State	CDC coordinates with state and local health departments; HHS Regional Emergency Coordinators (REC) work with state(s) and coordinates with FEMA on a regular basis.	State and local public health coordinates with CDC; state and local emergency management coordinates with FEMA Region; FEMA Region coordinates with FEMA Headquarters; Homeland Security Advisors and Fusion Centers.
Small-Scale Incident	Unified coordination at the federal level, HHS REC coordinates with FEMA Regional Administrator	State and local government engages with HHS REC; state and local government continues to coordinate with CDC.
Large-Scale Incident	National-level UCG established with a Federal Health Coordinating Officer (FHCO) designated for affected state(s)	State-level UCG may be established
Large-Scale, Widespread Incident	National-level UCG	Regional-level UCG may be established with FHCO covering a region
International Incident	National-level unified coordination; State(s) would be encouraged to prepare for appearance of domestic cases	Federal Government has limited authority to implement public health actions; once border screening (if applicable) is completed, National unified coordination works with state public health agencies to implement response

See **Appendix 5: State and Local Functional Capabilities** for a recommended unified coordination structure at the local level that is scalable to incorporate additional functional responsibilities for managing a significant public health or medical incident.

<sup>17</sup> For a suspected terrorist incident, the Federal Bureau of Investigation (FBI) serves as the Lead Federal Agency for law enforcement investigation at the national level.

## Operational Areas

While FIOPs identify key elements for all-hazard response and recovery operations, the BIA identifies six operational areas (**Figure 4**) in response to a biological incident. These areas form the basis for the response and recovery operations to a biological incident. The operational areas can be used to organize response and recovery operations at any level.

The following operational areas identify key considerations that are specific to a biological incident and supplement the overarching mission objectives, critical tasks, and goals identified in the Response and Recovery FIOPs.

Activities specific to a biological incident are organized into six areas: (1) Detect and characterize the threat, (2) Communicate with external partners and the public, (3) Control the spread of disease, (4) Augment the provision of mass care and human services to affected populations, (5) Augment the provision of health and medical services to affected populations, and (6) Augment essential services and facilitate long-term recovery.

In providing assistance to state and local authorities, the federal government can contribute personnel, resources, and other support to assist and coordinate a larger-scale (multi-state) response, national response, or international response. While the BIA is intended to cover response and recovery to any biological incident, it is not all inclusive, and additional operational activities may be required. Departments and agencies may become involved in a biological incident under their own mission and authorities, as part of a UCG led by the lead federal agency, or under a Stafford Act declaration.

### Detect and Characterize the Threat

There are numerous biological incident detection methods, including presentation of disease in humans or animals (domestically or internationally) through case reporting, alerts from environmental surveillance systems or international partners, and normal operations and surveillance efforts conducted by law enforcement or other departments and agencies.

In some instances, detection may predictably occur after the outbreak/incident is well underway, resulting in numerous infections prior to agent identification. The potential lack of full information about the biological threat may further complicate decision-making, resulting in leaders making partially informed decisions for an extended period.

This functional area is characterized by all ongoing efforts to define and track the medical and health characteristics of the disease outbreak. This can include a complex set of activities that the federal partners are either primarily responsible for or provide support to SLTT entities and the private sector. In addition, coordinated collection of data elements from disparate sources, analysis of data elements, and modeling are included within this functional area.

#### Key Objectives

- Coordinate data feeds from multiple surveillance and detection systems used for biological threats.
- Support or implement surveillance and detection systems.

- Confirm the initial threat/hazard and maintain situational awareness and interagency sharing of information.
- Continue to assess the size, scope, and impact of the incident as it progresses.
- Support initial and ongoing decision making, using evolving threat/hazard information.

#### *Key Federal Roles Responsibilities*

- Confirm *initial* incident/disease outbreak and diagnosis. Biological incident detection can be a complex and dynamic process that may originally be categorized as “presumed” before “confirmed.” The following are examples of information sources the U.S. Government (USG) may be primarily responsible for, may have a role in supporting, or may collect to confirm or inform initial threat identification:
  - Sentinel case suspected or confirmed in private sector and reported to appropriate SLTT public health entity.
  - Influx of patients with similar disease symptoms indicating new disease pathogen
  - Identification of novel or atypical pathogen in federal or SLTT laboratory (e.g., Laboratory Response Network [LRN]).
  - Notification by international partner of a pathogen threat overseas.
  - Zoonotic outbreak with potential for human spread.
  - Credible threat of deployment of pathogen of concern.
  - Announced release of deployment of pathogen of concern.
  - Environmental surveillance system (e.g., BioWatch) detects pathogen of concern.
- Coordinate multiple surveillance systems and critical information collection. Depending on the pathogen and its origins, numerous federal entities have primary responsibility for initial coordination of surveillance systems and sharing of critical information with USG and SLTT partners to support initial and ongoing decision making, utilizing evolving threat information.
- Support SLTT epidemiological efforts, including support for epidemiologic investigations.
- Support to laboratories through the Integrated Consortium of Laboratory Networks (ICLN), which is a federal partnership between DHS, Department of Defense (DoD), HHS, USDA, Department of Energy, Department of Interior (DOI), Department of Justice (DOJ), Department of State (DOS), and EPA to coordinate laboratory response capabilities during a crisis. The ICLN includes the following networks: Department of Defense (DoD) Laboratory Network, Environmental Response Laboratory Network, Food Emergency Response Network, Laboratory Response Network, National Animal Health Laboratory Network, National Plant Diagnostic Network, and the Veterinary Laboratory Investigation and Response Network.
- Coordinate information to determine intentionality and support of criminal investigations. For details see **Branch 1: Intentional Biological Incident**.
- Conduct ongoing situational assessments to continually assess size, scope, and impact of the biological incident, as required. The government may help to establish parameters to monitor as well as support or primarily conduct some of this data collection. Examples of incident parameters requiring monitoring or sampling may include:

- Epidemiologic, laboratory, clinical, and other relevant data needs to be collected to help inform the public health actions and potential gaps.
- Changes to assumed characteristics of agent (e.g., enhanced resistance, change in spread).
- Public health authority actions implemented (and effectiveness in limiting spread versus social disruptions/costs).
- Areas of environmental contamination.
- Reportability to the WHO under the IHR.
- For threats that originate internationally, ongoing liaison and participation in the management of USG international response efforts to ensure capture of appropriate threat information as it pertains to potential domestic impacts.
- Carry out data analysis and modeling. Review and analysis of data collected from numerous sources can, in some instances, provide significant insight into the disease process. Modeling capabilities exist within the Federal Government; therefore, the government may primarily conduct some of these activities or support others' efforts. A critical task is to coordinate different modeling efforts to ensure unity of effort on models utilized to support decision making.

## **Communicate with External Partners and the Public**

Coordination of public and external communications is a key component of an effective biological incident response.

### *Key Objective*

- Coordinate risk communication to develop a unified message across a range of media and involved entities to inform the public and external partners.

### *Key Federal Roles/Responsibilities*

- Provide timely and coordinated messaging to the public for both warning and guidance throughout the incident.
- Provide behavioral health messaging to the public, healthcare workers, and responders to the incident.
- Coordinate associated messaging for all of above through inter-agency process. Response and recovery outcomes for a biological incident are significantly tied to public reception and compliance with public health guidance on personal protective measures and access to health and medical interventions.

## **Control the Spread of Disease**

The Federal Government carries out national-level functions and supports state and local governments to halt the spread of disease through the coordination and implementation of MCM and NPIs.

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is the interagency medical countermeasure coordinating body for the USG led by the ASPR. The PHEMCE coordinates the development, acquisition, stockpiling, and use of medical products

that are needed to effectively respond to a variety of high-consequence public health emergencies, whether naturally occurring or intentional. Pharmaceutical interventions can include the development, acquisition, and distribution of both medications and vaccinations.

NPIs include an expansive array of activities, including public health interventions to limit spread of disease, environmental controls, PPE, and personal hygiene activities. All of these activities may need to occur in multiple disparate geographic locations or potentially nationwide. As with other functional areas, some capabilities are primarily the responsibility of the Federal Government, whereas others reside at various levels of government with the Federal Government providing support.

### *Key Objectives*

- Research and develop appropriate pharmaceutical and non-pharmaceutical interventions.
- Support or implement pharmaceutical and non-pharmaceutical interventions.
- Control spread of disease across borders into and out of the United States.
- Implement zoonotic control measures.

### *Key Federal Roles/Responsibilities*

- Research and develop pharmaceuticals and vaccines.
- Provide recommendations and guidance on research and development of PPE and associated infection control practices (e.g., cleaning/disinfection methods healthcare facilities as well as transportation sector). **NOTE:** PPE practices have traditionally focused on the healthcare community, but specialty recommendations may be needed for different sectors such as law enforcement, other responders, or for caretakers supporting homebound patients. Development of these recommendations will include adequate representation from the disciplines in question.
- Provide recommendations and guidance on waste management and requirements for decontamination of individuals, animals, and the environment.
- Provide support to deploy medical countermeasures (e.g., SNS and MCM efforts); this includes a layered approach using regional and national rapid MCM planning. Additionally, the UCG may identify additional federal-to-federal requirements for further MCM support coordination.<sup>18</sup>
  - Federal dispensing support will begin in Phase 2 of the response, after the confirmation of an intentional release or emerging infectious disease and the decision to distribute and dispense MCM has been made.
- Assist foreign governments with an outbreak (as requested) in an effort to control spread to the United States by controlling it at its source. Though domestic support to an international response is covered in the NRF International Coordination Support Annex, the linkages to this international effort must be made to a domestic response. The USG has a series of frameworks that can be used without linkages to a domestic response.

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<sup>18</sup> Federal Interagency Concept of Operations- Rapid Medical Countermeasures Dispensing, September, 2011.

- Control the spread of disease across borders. Once an outbreak has occurred in a foreign country, there may be interventions that can prevent disease spread to the United States. Though not all infectious diseases are susceptible to border interventions, activities such as screening, isolation, and quarantine at the border can be helpful for some. This requires a significant coordinated effort (e.g., by HHS/CDC, DHS/CBP, U.S. Coast Guard, and OHA).<sup>19</sup>
- Assist prevention of *interstate* spread of disease. The USG is authorized to take measures to prevent the spread of communicable disease between states.
- Assist prevention of *intrastate* spread of disease through—
  - Research and development of recommendations for NPIs that can be deployed by SLTT governments. NPIs or public health actions can have significant social and economic impacts. The USG, in the development of recommendations, will work with SLTT governments and the private sector to gauge these impacts.<sup>20</sup>
  - Support (resources) to the implementation of NPI.
- Support PPE needs, which can involve utilization of the Defense Production Act (DPA).
- Provide recommendations and/or support for—
  - Decontamination of patients, as necessary.
  - Identification of environmental contamination controls.
  - Development of recommendations and/or provision of support for hygiene practices/surface decontamination.
- Support and implement environmental response and remediation (both indoors and outdoors) when there is persistent contamination.
  - Conduct environmental response and remediation under federal authorities.
  - Support SLTT environmental remediation efforts.
  - Provide scientific and technical expertise and operational support for all phases of consequence management, including sampling, characterization, prioritization, decontamination, and clearance (tactical options for screening, sampling, monitoring, decontamination, and clearance).
  - Provide guidance and support for biologically-contaminated waste management.
- Support and implement zoonotic control measures such as vaccination, isolation, euthanasia, and carcass disposal.
- Support long-term public health capacity to guard against the re-emergence of disease.

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<sup>19</sup> To date, screening has been scientifically difficult to defend, given the tools employed and the overarching goal of not hindering the safe and efficient movement of people and goods. However, screening can be a powerful tool for ensuring the entry of persons arriving in the United States with potential exposure into existing surveillance systems. This requires not only coordination of the interagency but also with SLTT public health authorities.

<sup>20</sup> Given the propensity for different states to implement public health interventions at varying levels, there may exist a role for the Federal Government to coordinate among states to integrate these efforts.

## Augment the Provision of Mass Care and Human Services to the Affected Population

The Federal Government assists locally led response and recovery efforts to establish mass care services and support impacts on social services. Unique considerations for emergency assistance will arise during a biological incident due to limitations posed by issues such as contamination and communicable disease spread.

### *Key Objectives*

- Support or implement mass care activities.
- Guide SLTT governments and NGOs to operate shelters safely and in a manner that limits disease spread, where possible.
- Support or implement human services.

### *Key Federal Roles/Responsibilities*

- Develop recommendations for mass care services (e.g., for implementation by NGOs) or support actual implementation of these activities. Practical guidance may be difficult to develop due to the implications of a contagious disease incident. Actual implementation may be challenging as well (e.g., Voluntary Organizations Active in Disasters [VOAD] policy restrictions).
- Provide resources for potential expansion of basic medical care support for individuals with disabilities and others with access and functional needs to help reduce burden on high-demand components of healthcare infrastructure. Multiple potential resources could be utilized:
  - The Commissioned Corps of the US Public Health Service
  - Service Access Teams
  - Individual Assistance-Technical Assistance Contract
  - Delivery services
  - NGOs or VOADs such as the Red Cross and Salvation Army
- Provide guidance for regular shelters (with infectious disease considerations) during a simultaneous disaster or for shelters designed to assist with response to the outbreak to assist with public distancing.
- Assist SLTT governments with housing requirements that have occurred as a result of public health actions (e.g., quarantine).
- Provide resources to support SLTT commodity distribution to special needs populations, as needed.
- Address care needs and placement/disposition for dependents (e.g., children) and animals of people who become temporarily or permanently incapacitated due to the biological incident.
- Augment SLTT capabilities to identify and support management and care of dependents at congregate care facilities when normal caregivers are absent (e.g., nursing homes, prisons, and congregate animal facilities such as zoos, etc.).
- Support long-term social services to promote resilience, health, and well-being.

## Augment Provision of Health and Medical Services to the Affected Population

SLTT or private entities may experience shortfalls in the availability of personnel, material, space, and systems required to meet the demands on medical and health systems during a biological incident, particularly a contagious disease outbreak. It is important to note that the majority of healthcare services provided in the United States are provided by the private sector. The Federal Government will support affected areas with available federal resources and assist in their prioritization and coordination throughout the incident progression.

### Key Objectives

- Provide available federal surge capacity to implement or support health and medical services.
- Implement or support fatality management.

### Key Federal Roles/Responsibilities

- Health services assistance/augmentation to include:
  - Guidance
  - Tools
  - Subject matter expertise/technical assistance
  - Assistance to integrate health services with other non-medical disciplines (e.g. emergency management, law enforcement)
  - Other support not already covered under other operational areas
- Medical services assistance/augmentation: Healthcare delivery is predominantly conducted in the private sector. There are delivery mechanisms which exist within the Federal Government (e.g., Veterans Affairs Medical Centers) that require integration and support as well. The government can provide medical assistance in the form of:
  - Guidance
  - Tools
  - Resource support to healthcare facilities
    - Personnel
    - Supplies (e.g., PPE, ventilators, pharmaceuticals)
    - Facilities
  - Patient transportation (e.g. movement of patient populations away from an area of outbreak to open space for care of infected/ill)
- In certain select cases, there may be medical services that the Federal Government is primarily responsible for (e.g., the repatriation of Federal Government employees with exposure to highly infectious/virulent pathogens). There are both international and domestic implications for this type of activity, highlighting again the need for coordination of these two response efforts.
- Support behavioral health and mental health requirements for communities.
- Support fatality management:
  - Provide evidence collection guidance during an intentional biological incident.
  - Technical assistance and personnel for support activities including:
    - Temporary morgue facilities
    - Victim identification services

- Processing
- Preparation
- Disposition of remains
- Veterinary medical support, including triage and treatment.
- Support long-term basic behavioral health services to affected populations as effects may not be well known in advance of an incident due to the rare or novel nature of the threat.<sup>21</sup>
- Assist SLTT entities with monitoring and long-term medical care of exposed and potentially exposed due to complications/chronic effects related to recovery from the biological agent.
- Support long-term health and medical services to promote resilience, health, and well-being.

### **Augment Essential Services and Facilitate Long-Term Recovery**

The operation of critical infrastructure may be limited during a biological incident due to personnel/operator illness/exposure or infrastructure contamination. Economic activity may be restricted by official or non-official limitations on contact and movement. The combined effects of critical infrastructure interruptions could disrupt supply chains, security, and provision of basic resources to the general public. Longer term activities may be required after a biological incident to support community resiliency.

#### *Key Objectives*

- Ensure continuity of USG operations and safety of personnel.
- Restore critical infrastructure systems as quickly as possible to limit cascading effects.
- Provide an environment in which businesses can continue to operate or return to normal operations.
- Support or restore transportation pathways and infrastructure to facilitate supply chains and movement of people.
- Facilitate the movement/delivery of supplies critical to response and recovery.
- Secure critical infrastructure assets that are still in operation (e.g., public transportation).

#### *Key Federal Roles/Responsibilities*

- Both focal and widespread incidents can challenge continuity of federal operations, depending on locations. Coordinated efforts to ensure continuity can include prioritization of resources (e.g., PPE), coordination of messaging to ensure consistency, and NPI implementation in the federal work place, as well as other activities.
- Support to addressing impacts caused by implementation of NPIs (e.g. travel restrictions and other public health actions).
- Support movement of critical supplies.

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<sup>21</sup> This responsibility will be coordinated through the Health and Social Services RSF; also, refer to the Disaster Behavioral Health Concept of Operations.

- Support movement and disposal of particularly hazardous waste, including granting of special permits.
- Support infrastructure systems:
  - Coordinate critical infrastructure assessments (potential sources include a combination of sector-specific agencies, Sector Coordinating Councils, and Government Coordinating Councils; related ESFs and RSFs; and the National Interagency Coordination Center).
  - Recommend prioritization of MCM dispensing to critical infrastructure operators in order to maintain operability and support the response. Cascading effects could include disruptions to supply chains, essential personnel, and security staff.
  - Support cleanup and remediation of infrastructure facilities for an incident with persistent contamination, including the provision of guidance and recommendations.
- Support economic recovery:
  - Assist SLTT jurisdictions in returning economic and business activities (including food and agriculture) as illness, quarantine, business closings, and other social distancing interventions will have had major impacts to populations, business functions, and economic activity.
  - Support social service and economic support programs as prolonged community-wide interventions (e.g., NPIs) can create significant personal, local, and regional economic impacts and increase requirements.<sup>22</sup>

## **Key Federal Response and Recovery Decisions**

Federal decisions regarding the following key issues are to be made in close coordination with SLTT decision makers and whole community stakeholders to ensure a unity of effort in the response to and recovery from a biological incident. The following table illustrates key topics relevant to biological incident response and recovery and associated key federal decisions associated with each.

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<sup>22</sup> These responsibilities will be coordinated by the Economic and Health and Social Services RSFs.

**Table 5: Key Federal Response and Recovery Decisions**

Topic	Decision Point
<p><b>National Declarations:</b> Declaring a national or public health emergency allows funding and response and recovery resources from the Federal Government.<sup>23</sup></p>	PHE declaration by Secretary of HHS
	Presidential declaration under the Stafford Act
	Presidential declaration of a National Emergency
	Stafford Declarations along with PHE declaration
<p><b>Operational Coordination:</b> Unified coordination is deemed necessary based on international or domestic incident parameters.</p>	Formally establish unified coordination at the national and/or regional level
	Establish UCG at the national level.
	Establish UCG at the state and regional level
<p><b>Public Information and Warning:</b> Providing honest, accurate, timely, and frequent information in many accessible formats is critical to the success of response and recovery from a biological incident. Coordinated messaging with all affected jurisdictions will be necessary.</p>	Prepare public messaging with fundamental information about the biological incident, safe work practices, and PPE for first responders and hospital first receivers, and steps the public should take to protect itself
	Establish a national Joint Information Center in support of the UCG to coordinate messaging with SLTT regarding topics such as NPI, MCM, decontamination, etc.
	Consider use of Integrated Public Alert and Warning System
<p><b>PPE:</b> Federal agencies will need to actively coordinate and prioritize PPE purchasing and logistics based on incident priorities. Contracts and other mechanisms that restrict local access to PPE should be reviewed and modified as necessary during an incident. Agencies must plan in advance for the PPE needs of their response and recovery workers.</p>	Make recommendations to prevent worker injury and illness
	Prioritize PPE purchasing and distribution
	Consider deployment of technical assistance in support of responder health and safety such as

<sup>23</sup>The Secretary of HHS has broad authority to respond to a public health emergency, regardless of whether he or she makes a formal Public Health Emergency declaration.

Topic	Decision Point
	National Institute for Occupational Safety and Health, and DOL/OSHA multidisciplinary teams
<p><b>Defense Production Act (DPA) Resource Adjudication:</b> There will likely be scenarios in which multiple departments and agencies use DPA priority rating for the same resources (e.g., PPE, MCM, etc.). Adjudication of these resources should be coordinated across the involved departments and agencies in accordance with the process outlined in Executive Order 13603, National Defense Resources Preparedness (Mar. 16, 2012).</p>	Assist in the prioritization and allocation of resources subject to the DPA priority ratings
	Initiate use of DPA for PPE, vaccines, and other resources
<p><b>Screening:</b> Certain contagious pathogens may necessitate screening of travelers to control disease spread.</p>	Determine when screening at international and/or interstate borders is indicated and likely to be beneficial
	Determine when to begin and end international and/or interstate border screening
	Determine locations, protocols, and SLTT support necessary for screening
<p><b>Medical and Non-Pharmaceutical Interventions (NPI):</b> If available and/or effective against the infectious agent, demand for MCMs may be high. HHS, through its agencies has the responsibility to specify the appropriate MCM for the affected population.</p>	Determine necessity and feasibility for NPI
	Determine/confirm the appropriate regulatory approach to facilitate use of an MCM (e.g., Emergency Use Authorization)
	Make recommendation to SLTT for NPI implementation
	Determine resources support required for SLTT implementation
	Determine necessity for and coordinate deployment of SNS resources
	Determine prioritization of funding to affected areas/states
Determine appropriate methods of support to SLTT establishment of supply chains and delivery	

Topic	Decision Point
	<p>Determine the need for Emergency Use Authorization</p> <p>Determine need for private sector funding and methods to establish new medical countermeasures</p> <p>Determine need for countermeasures in animal population and veterinary medical support to protect human health</p>
<p><b>Health and Medical Services:</b> Limited capability exists within the Federal Government to deliver medical care, but there may be situations in which the Federal Government can support SLTT in the delivery of medical care.</p>	<p>Determine need for public health support personnel, teams, etc.</p> <p>Determine need for diagnostic personnel teams, resources, etc.</p> <p>Determine need for medical providers</p> <p>Determine need for assistance in processing deceased (e.g., Disaster Mortuary Operations Response Teams)</p> <p>Determine need for personnel to assist with MCM distribution and dispensing</p>
<p><b>Modeling:</b> Modeling can be of assistance in projecting disease outbreak and/or dispersal.</p>	<p>Determine utility of modeling and coordinate model development across federal departments and agencies and the private sector</p>
<p><b>Decontamination Standards and Clearance Goals:</b> The Incident Command /Unified Command (IC/UC) coordinates with the appropriate SLTT public health agencies to determine final clearance goals. This decision is a judgment as to whether the criteria for decontamination verification and clearance have been met. Federal departments and agencies will work closely with state and local officials to implement existing guidance and to develop and communicate acceptable clearance levels to guide recovery. If a response is taken pursuant to Comprehensive Environmental Response,</p>	<p>In coordination with SLTT; determine acceptable clearance level</p> <p>In coordination with SLTT, make ultimate clearance decision regarding the success of remediation</p>

Topic	Decision Point
<p>Compensation, and Liability Act (CERCLA), offsite disposal of CERCLA waste is subject to the offsite rule, 40 CFR 300.440.</p>	
<p><b>Infrastructure Remediation:</b> State and local decision makers may require support regarding prioritization of infrastructure remediation. The federal role is to provide technical assistance and support including modeling, measurement, and sampling to state and local governments to support decision making.</p>	<p>Assist IC/UC in prioritization of infrastructure remediation</p>
	<p>Stand up a technical working group of multi-disciplinary technical experts to provide input for planning and implementing remediation</p>
<p><b>Waste Management:</b> The Hazardous Materials Regulations promulgated by the U.S. Department of Transportation (DOT) (HMR; 49 CFR 171-180) regulate “hazardous materials,” which means a substance or material that the Secretary of Transportation has determined is capable of posing an unreasonable risk to health, safety, and property when transported in commerce and has been designated as hazardous under section 5103 of Federal Hazardous Materials Transportation Law (49 U.S.C. 5103). The term includes hazardous substances, hazardous wastes, marine pollutants, elevated temperature materials, materials designated as hazardous in the Hazardous Materials Table (see 49 CFR 172.101), and materials that meet the defining criteria for hazard classes and divisions in 49 CFR part 173. The waste generated in the care of persons with suspected or known exposure to a Category A substance (“contaminated waste”) is also subject to procedures set forth by federal, state, and local regulations. The Pipeline and Hazardous Materials Safety Administration (PHMSA) within the DOT is responsible for regulating and ensuring the safe and secure</p>	<p>Tailor Pre-Incident Waste Management Plans as identified in <b>Appendix 9</b> to incident specific conditions</p>
	<p>Provide additional resources to implement waste management and disposal operations</p>

Topic	Decision Point
<p>movement of hazardous materials across all modes of transportation.</p> <p>Generally, waste that has been inactivated is considered medical waste under the federal Resource Conservation and Recovery Act. As medical waste, the waste is subject to State regulations regarding its handling and management. However, the ultimate disposal facilities must meet minimum federal requirements including the Resource Conservation and Recovery Act (40 CFR 264 and 265).</p> <p>If a response is taken pursuant to CERCLA, offsite disposal of CERCLA waste is subject to the offsite rule, 40 CFR 300.440.</p>	
<p><b>Relocation, Alternative Housing, and Reoccupancy:</b> Long-term and permanent housing solutions may require unique consideration and implementation compared to other major disasters due to long-term denial of use. While state and local governments hold the authority and responsibility for relocation and housing decisions, federal departments and agencies may offer decision support and implementation resources. Support for the needs of large displaced populations will require closely coordinated decision making and communications with both impacted and host jurisdictions. Reoccupancy decision making and timing is integrally linked to remediation planning.</p>	<p>Support SLTT officials in decision making and implementation of relocation, alternative housing, and reoccupancy strategies</p>
<p><b>Patient Transportation:</b> A biological incident will require transport of patients from incident site(s) to hospitals. When the need arises, certain decisions will be required by the Federal Government.</p>	<p>Determination of repatriation need and methodology</p> <p>Determination of movement need and methodology between designated facilities</p>

## Administration, Resources, and Funding

### Administration

The PHS Act directs HHS to lead all federal public health and medical response to public health emergencies while also providing authorities to extend temporary assistance to requesting states or local governments to meet health emergency capability requirements. However, HHS does not receive appropriations for a dedicated response fund and may need additional funding to provide support during a large biological incident.

The Economy Act enables other federal departments and agencies to obtain reimbursement from HHS for the performance of supplemental actions in support of HHS's lead responsibility to respond to the biological incident. Other authorities exist that enable HHS to coordinate a response such as (1) PHSA authorities to issue grants and a surge workforce capability; (2) the Public Readiness and Emergency Preparedness Act that addresses certain medical countermeasure liability concerns; (3) the Social Security Act to waive Medicare, Medicaid, Children's Health Insurance Program and certain Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule requirements; and (4) the Federal Food Drug and Cosmetic (FD&C) Act to address issues related food safety and medical products such as drugs, vaccines, and devices, including diagnostics.

The declaration of a PHE is made by the HHS Secretary as a means to trigger the availability of special funding (if Congress chooses to appropriate funds to the Public Health Emergency Fund), regulatory waivers, grant making, or other emergency measures to aid or speed the response to an incident.

The Financial Management Support Annex to the NRF provides basic financial management guidance for all federal departments and agencies that provide support for incidents that require a coordinated federal response.

For response and short-term recovery activities associated with this annex, the Stafford Act establishes management and oversight responsibilities for all administrative and logistical requirements that support response and short-term recovery operations. FEMA is the primary agency for funding associated with Stafford Act declarations.

### Resources

Federal departments and agencies are responsible for personnel augmentation to support operations under this plan. Each federal department and agency possesses individual policies for personnel augmentation that is predicated on its authorities, various policies, memorandums of understanding, and mutual aid agreements. Federal departments and agencies must ensure that their employees who are engaged in incident response activities are able to perform in accordance with standard resource typing guidelines and operational requirements. See **Appendix 6: Federal Response Capability Inventory**.

## Funding

Federal funding to support federal response operations will be consistent with applicable laws and authorities as detailed within the NRF Financial Management Support Annex. There are generally two types of funding sources available for the coordination of federal resources: Stafford Act and Non-Stafford Act funding.

When a major disaster or emergency under the Stafford Act that involves a biological incident(s) is declared by the President, a separate set of programs and frameworks for cost reimbursement can be applied. Funding sources for Stafford and Non-Stafford Act incidents are detailed in **Table 6**.

**Table 6: Funding Sources for Stafford and Non-Stafford Act incidents**

	Types of Funding	Administered By	Description
PHEF	Supplemental appropriations can be sought from Congress	HHS	The Public Health Emergency Fund (PHEF) is a no-year fund at the U.S. Treasury to provide funding in the event of a public health emergency. The PHEF has no balance and can only be accessed in a declared public health emergency. In addition, there are no other immediate and flexible no-year funding sources available to ensure a timely response to an urgent event and no such fund for an event that does not meet the threshold for a public health emergency declaration.
Non- Stafford Act	Appropriated Funds	Each Department/Agency	As established by Congress (most federal agencies do not have disaster response appropriations and specific guidance from agency financial management offices should be obtained).
	Economy Act, 31 U.S.C. 1535-1536: Federal-to-Federal):	DHS	A federal entity with primary responsibility and statutory authority for handling an incident (i.e., the requesting agency) that needs support beyond its normal operations may request DHS coordination and facilitation through the NRF.

	Types of Funding	Administered By	Description
Stafford Act	Pandemic Coverage: (Emergency Assistance for Human Influenza Pandemic Disaster Assistance Policy 9523.17. November 25, 2009)	FEMA	Direct federal assistance is available through Public Assistance grants for Stafford Act declarations related to pandemic influenza. Assistance provided by FEMA under the Stafford Act in response to a pandemic influenza declaration may not duplicate assistance provided or available under the authority of other federal agencies, including HHS.
	Mutual Aid Agreements for Public Assistance and Fire Management Assistance Disaster Assistance Policy 9523.6. August 13, 2007	FEMA	FEMA will reimburse for services provided through written mutual aid agreements, such as the Emergency Management Assistance Compact, for aid provided to states where there has been a presidential declaration, the activities and costs directly relate to the incident and eligible work, and costs are reasonable.
	Disaster Relief Fund (Robert T. Stafford Relief and Emergency Assistance Act of 1988)	FEMA	Disaster relief funding limits established by Congress

### Coordination of Benefits

Financial assistance following a biological incident poses a risk for duplicate services and financial support. A coordinated system to deconflict survivor assistance will be required. ESF #6, the Health and Social Services RSF, Economic RSF, the Small Business Administration, FEMA, the Department of Housing and Urban Development, and others may establish a benefits workgroup to avoid duplicate services and financial support while ensuring streamlined assistance to survivors.

## Oversight, Coordinating Instructions, and Communications

### Oversight

During a federal biological incident response, HHS is responsible for coordinating the Federal Government's response in support of the affected SLTT officials.

Other federal departments and agencies will perform roles and responsibilities congruent with their statutory authority in coordination with HHS as lead federal agency. The White House National Security Council Staff provides policy coordination and deconfliction, as required.

### Coordinating Instructions

HHS's Emergency Management Group (EMG) is the primary HHS element for resource coordination at the national/headquarters level. The EMG provides public health and medical coordination and incident support functions to the regions and/or joint field office, conducts operational planning, deploys national-level resources, and collects and disseminates incident information to maintain a common operating picture.

*Consistent with the NRF and in accordance with Homeland Security Presidential Directive (HSPD)-5, the Secretary of DHS, through the FEMA Administrator or other appropriate officials, will coordinate the federal government's resources utilized in response to or recovery from a biological incident when required by HSPD-5. In cases of intentional acts or threats giving rise to a biological incident, the Secretary will coordinate, as necessary, with the Attorney General.*

### Telecommunications and Operational

Immediate action should be taken to identify communication systems for public messaging to provide clear, factual, and timely guidance to the public. Communication systems for federal, state, and local agencies should coordinate to maintain situational awareness and permit timely assessments of the status of critical services, resources, and infrastructure.

FEMA's Integrated Public Alert and Warning System provides significant capability for public messaging including capability to broadcast an alert message to all cellular phones in a given area as a Wireless Emergency Alert, access to the Emergency Alert System, National Oceanic and Atmospheric Association All Hazards Weather Radio network, and internet connected alerting tools.

The HHS Secretary or designee serves as the primary spokesperson for the public health and medical response, supported by subject matter experts within the department.

Maintenance and sharing of current and accurate information across the Federal Government is a priority during a biological incident. Multiple federal agencies support response/recovery to a biological incident, and interagency information sharing will be imperative in order to coordinate

federal teams and assets throughout a diverse environment under a range of different timelines and authorities.

Consideration of the early establishment of a Joint Information Center (JIC) is critical. Additionally, the collection and dissemination of numerous data elements from across SLTT governments is critical.

Coordination of risk communications through a single federal spokesperson is critical. Federal response-related announcements to the public are coordinated by the Secretary of DHS through the national JIC, where HHS has public affairs representation. The HHS Assistant Secretary for Public Affairs (ASPA) assumes the lead in media response for public health, coordinated with and through the JIC. Depending on the nature of the incident, HHS ASPR may designate one of the HHS agencies (e.g., CDC, National Institutes of Health, Food and Drug Administration) to take the lead on public affairs activities with the responsibility of consulting with the HHS ASPR as they move forward to manage the incident communications. In the instance of a terrorist incident, the FBI shall be consulted before issuing sensitive media/press releases.

In incidents where the DHS National JIC is activated, the DHS NOC provides direct support through situational awareness, information sharing and executive communications.

The appropriate spokesperson will be determined based on the nature of incident but may be from HHS, DHS, the White House NSC, SLTT, or elsewhere, in accordance with applicable Presidential policy directives.

## **Appendix 1: Authorities and Other References**

Authorities applicable to this annex include Presidential Policy Directive (PPD)-8 (National Preparedness), PPD-25 (classified), Homeland Security Presidential Directive (HSPD)-5 (Management of Domestic Incidents), the Homeland Security Act of 2002, the Post-Katrina Emergency Management Reform Act (PKEMRA) of 2006, the Pets Evacuation and Transportation Standards Act of 2006, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), the Sandy Recovery Improvement Act of 2013, the Atomic Energy Act, the PHSA, and numerous federal criminal statutes. Certain federal agencies are authorized to respond directly to specific biological incidents. Nothing in this annex alters or impedes the ability of federal agencies to carry out their respective authorities and associated responsibilities under the law.

This annex does not alter or impede the ability of any state, local, tribal, territorial (SLTT), and insular-area government or federal departments and agencies to exercise their authorities or to perform their responsibilities under the law. Federal departments and agencies may take appropriate independent emergency actions pursuant to their own statutory authorities and those described in national policy. This annex does not create new authorities nor change existing ones.

Federal agencies may take appropriate independent emergency actions within the limits of their own statutory authority to protect the public, mitigate immediate hazards, and gather information concerning the emergency to avoid delay. Key authorities applicable to this annex include the following.

### **Public Health and Medical Authorities and References**

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The authorities that guide the structure, development, and implementation of the Response and Recovery Federal Interagency Operational Plans (FIOPs) and this annex are statutes, executive orders, regulations, presidential directives, memorandums of understanding, and memorandums of agreement. Congress has provided the broad statutory authority necessary for this plan, and the President has issued executive orders and presidential directives to supply policy direction to departments and agencies of the Executive Branch. Certain federal agencies are authorized to respond directly to specific biological incidents and/or acts of bioterrorism.

### **Occupational Safety and Health Act**

The Occupational Safety and Health Act of 1970<sup>24</sup> (OSH Act) was passed to prevent workers from being killed or seriously harmed at work. This law created the Occupational Safety and Health Administration (OSHA), which sets and enforces protective workplace safety and health standards. OSHA also provides information, training, and assistance to employers and workers.

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<sup>24</sup>Occupational Safety and Health Act of 1970, Public Law 91-596 (as amended at 29 U.S.C. 651-678).

Under the OSH Act, employers in all 50 states and U.S. territories have the responsibility to provide a safe workplace. Basic program elements for federal employee occupational safety and health programs and related matters are set out in 29 CFR 1960. OSHA's role primarily is to provide oversight and guidance for federal departments' and agencies' individual occupational safety and health programs through the Designated Agency Safety and Health Official and agency safety and health management staff.

During disaster response and recovery operations, even when OSHA is operating in a technical assistance and support mode, the agency's established standards remain in effect, and OSHA retains its ability to enforce the standards under its legal authority. Although some states operate their own OSHA-approved occupational safety and health programs (state plans), OSHA's federal offices provide coordination, technical assistance, support services, and oversight in all 50 states, U.S. territories, and the District of Columbia.

Executive Order (EO) 12196 extends protections for private sector employees provided under the OSH Act to federal employees. Generally, federal employer responsibilities under the EO and OSH Act apply no matter where the federal employee is located (e.g., outside the continental U.S.). The EO and OSH Act do not cover uniformed military personnel, U.S. Coast Guard personnel, members of the National Oceanic and Atmospheric Administration Commission Corps or U.S. Public Health Service (PHS) commissioned corps serving on active duty, or certain private sector employees in certain contexts (e.g. flight crews in operation).

## **Public Health Service Act**

PHSA<sup>25</sup> forms the foundation of the Department of Health and Human Services (HHS) legal authority for responding to public health emergencies (PHE). Among other things, it authorizes the HHS Secretary to lead all federal public health and medical response to public health emergencies and incidents covered by the National Response Framework; to direct the U.S. PHS and other components of the Department to respond to a public health emergency; to declare a PHE and take such actions as may be appropriate to respond to the PHE consistent with existing authorities; to assist states in meeting health emergencies; to control communicable diseases; to maintain the Strategic National Stockpile (SNS); to provide for the operation of the National Disaster Medical System (NDMS); to establish and maintain a Medical Reserve Corps; and to potentially provide targeted immunity for covered countermeasures to manufacturers, distributors, certain classes of people involved in the administration of a program to deliver covered treatments to patients, and their employees.

Section 311 of the PHSA provides the Secretary of HHS with authority to extend temporary assistance to states or localities to meet health emergencies at the request of states or local authorities, including utilizing HHS personnel, equipment, medical supplies, and other resources, when state resources are overwhelmed by an emergency situation. The HHS Secretary may authorize assistance regardless of a formal PHE or Stafford Act declaration.

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<sup>25</sup> Public Health Service Act of 1944, Pub L. No. 78-410 (as amended at 42 U.S.C. §§ 201 et seq.)

Under Section 319 of PHSa, when the Secretary has declared a PHE, he or she can take appropriate actions consistent with other authorities to respond to the emergency, including, making grants, entering into contracts, and investigating the cause, treatment, or prevention of the disease or disorder. In addition, the Secretary may access the Public Health Emergency Fund (PHEF) if appropriated by Congress. Under 42 U.S. Code § 247d, the Emergency Fund is made available without fiscal year limitation if a PHE has been declared by the HHS Secretary. Funding is authorized to be appropriated to the PHEF as may be necessary to respond to (1) a disease or disorder that presents a PHE or (2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks.

The SNS is authorized under Section 319F-2 of the PHSa and is maintained by the HHS Secretary to provide for the emergency health security of the United States. The Secretary of HHS may deploy the stockpile to respond to an actual or potential PHEs, or to otherwise protect public health and safety, or as required by the Secretary of the Department of Homeland Security (DHS) to respond to an actual or potential emergency.

Under section 361 of the PHSa the Secretary of HHS is authorized to take measures to prevent the entry and spread of communicable diseases from foreign countries into and out of the United States and between states. Under Title 42, parts 70 and 71 of the Code of Federal Regulations (CFR), The Centers for Disease Control is authorized to detain, medically examine, and release persons arriving into or exiting the United States and traveling between states who are suspected of carrying these communicable diseases.

The Secretary of HHS may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings.

## **Federal Food, Drug, and Cosmetic Act**

The Federal Food, Drug, and Cosmetic Act<sup>26</sup> (FD&C Act) is the foundation for Food and Drug Administration (FDA) authority and responsibility to protect and promote the public health by, among other things, ensuring the safety and effectiveness of human and veterinary drugs, biological products, and medical devices, and ensuring the safety and security of the nation's food supply. During a biological incident, medical products regulated by the FDA may need to be used to mitigate the health impact and with certain flexibilities. For example, under section 564 of the FD&C Act, the FDA Commissioner may authorize the use of certain unapproved drug, device, or biological products (medical countermeasures [MCMs]) or unapproved uses of approved MCMs under an emergency use authorization (EUA). When certain conditions are met, the FD&C Act authorizes the HHS Secretary to declare circumstances exist justifying EUA of unapproved drugs, devices, or biological products or of approved drugs, devices, or biological products for an unapproved use.

The FDA Commissioner may issue an EUA for an MCM. When certain conditions are met, the FD&C Act authorizes the HHS Secretary to declares that circumstances exist justifying the

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<sup>26</sup> Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717 (as amended at 21 U.S.C. §§ 301-399f).

emergency use emergency use authorization (EUA) of (“EUA declaration”) under section 564 of the FD&C Act. The EUA declaration must be based on one of four determinations under section 564, unapproved drugs, devices, or biological products or of approved drugs, devices, or biological products for an unapproved use. Once a Secretarial determination is made, the Commissioner of the FDA may issue an EUA for particular products. In addition, the FDA Commissioner must conclude that certain other statutory criteria for issuance and conditions are met (e.g., the Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency if it is reasonable to believe the product may be effective in diagnosing, treating, or preventing a serious or life-threatening diseases or conditions caused by a chemical, biological, radiological, or nuclear (CBRN) threat agents or emerging infectious disease when, among other criteria, there are no adequate, approved, and available alternatives to the product). An EUA will no longer remain in effect when the HHS EUA declaration that supports it is terminated (e.g., because the emergency or threat circumstances have ceased to exist) or when it is revoked by FDA (e.g., to protect the public health or safety because it is determined that the criteria for issuance are no longer met) or revocation is appropriate to protect public health or safety. Section 564 of the FD&C Act was amended by the Project BioShield Act of 2004 to add the EUA authority, which was later amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA).

Once a Secretarial determination is made, the Commissioner of the FDA may issue an EUA for particular products, assuming other statutory criteria and conditions are met. The Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents or emerging infectious disease when, among other criteria, there are no adequate, approved, and available alternatives. An EUA can be revoked when it is determined that the criteria for issuance are no longer met or revocation is appropriate to protect public health or safety. Section 564 of the FD&C Act was amended by the Project BioShield Act of 2004 and the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA).

## **Project BioShield Act**

In 2004, The Project BioShield Act<sup>27</sup> amended the PHS Act and the FD&C Act to provide flexible authorities to expedite and enhance research, development, procurement, and stockpiling of MCM for CBRN threat agents and authorized funding for procurement of those MCM. The Act also provided HHS with broader ability to quickly authorize use of certain MCM during emergencies. The authorities enacted under the Project BioShield Act were further clarified and expanded under Pandemic and All-Hazards Preparedness Act (PAHPA), Pub. L. No. 109-417, and PAHPRA, Pub. L. No. 113-5.

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<sup>27</sup> Project BioShield Act of 2004, Pub. L. No. 108-276 (as amended at 21 U.S.C. § 360bbb-3; 42 U.S.C 247d-6a, 247d-6b).

## **Pandemic and All-Hazards Preparedness Act**

The PAHPA of 2006 amended the PHS Act and designates the Secretary of HHS to lead all federal public health and medical response to public health emergencies and incidents. It also established within HHS, a new Assistant Secretary for Preparedness and Response, and provided new authorities for a number of programs, including the advanced development and acquisition of MCM. PAHPA placed the NDMS under the purview of HHS and called for the establishment of a quadrennial National Health Security Strategy. It also authorizes the Secretary to establish an interagency agreement with any federal agency to assume control of emergency public health and medical response assets, as necessary, in the event of a public health emergency, except members of the armed forces under the authority of the Secretary of Defense.

## **Pandemic and All-Hazards Preparedness Reauthorization Act**

PAHPRA amended the PHS Act to reauthorize funding for public health and medical preparedness programs (i.e., the Hospital Preparedness Program and Public Health Emergency Preparedness Cooperative Agreement) and for the purchase of MCM. The legislation increases the flexibility of Project BioShield as well as state health departments in dedicating staff resources to meeting critical community needs in a disaster. Also, PAHPRA enhances the authority of the FDA to support stakeholder preparedness for rapid MCM responses in advance of a PHE by amending the EUA authority to permit issuance of an EUAs in advance of an emergency when there is a significant for potential for a public health emergency. PHEs, and PAHPRA also providing additional MCM emergency use authorities under the FD&C Act to facilitate the use of approved MCM products such as the authority for FDA to issue emergency dispensing orders without having to issue an EUA emergency use instructions

## **Public Readiness and Emergency Preparedness Act**

The Public Readiness and Emergency Preparedness Act<sup>28</sup> (PREP Act) of 2005 amended the PHS Act to authorize the HHS Secretary to issue a declaration that provides immunity from liability (except for willful misconduct) to covered persons against legal claims arising from administration or use of MCM recommended by the Secretary to address pandemic or epidemic diseases or threats, or CBRN threats to health that the Secretary determines constitute a present or future PHE. Covered persons can include manufacturers; researchers, distributors, states, local governments, private sector partners, and others involved in countermeasure programs; qualified persons who prescribe, administer, or dispense countermeasures; officials, agents, employees of all of these groups, and the U.S. Government. A PREP Act declaration is specifically for the purpose of providing immunity from liability and is different from, and not necessarily dependent on, other emergency declarations. The PREP Act also authorizes a fund in the U.S. Treasury to provide compensation to eligible individuals for physical injuries or death directly caused by administration or use of MCM covered by the declaration.

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<sup>28</sup> Public Readiness and Emergency Preparedness Act (PREP Act), Pub. L. No. 109-148 (42 U.S.C. 247d-6d, 247d-6e).

## Social Security Act

The Social Security Act (Section 1135: Authority to Waive Requirements during National Emergencies) authorizes the Secretary of HHS to temporarily waive or modify certain requirements enumerated in the Act of Medicare, Medicaid, and Children's Health Insurance Programs during certain emergencies. Section 1135 waivers require both (1) a declaration of national emergency or disaster by the President under the National Emergencies Act (NEA) or the Stafford Act and (2) a PHE determination by the Secretary under the PHS Act. Waivers may be requested by affected health care providers in the emergency area during the emergency period. The Secretary may make a waiver retroactive to the beginning of the emergency period or any subsequent date thereafter. The waiver generally expires at the termination of the applicable declaration of emergency or disaster under the NEA or Stafford Act or determination of the termination of a PHE under the PHS Act. In addition, the Secretary may specify that the waivers terminate 60 days from publication, which may be extended, provided that neither the original 60-day period nor any extension extends beyond termination of the applicable declaration or determination.

Waivers related to the Emergency Medical Treatment and Labor Act are subject to different requirements, except in the case of a PHE involving pandemic infectious disease and terminate 72 hours after a hospital has activated its disaster plan or, in the case of a PHE involving pandemic infectious disease, until the termination of the declaration of the PHE.<sup>29</sup> While the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is not suspended during an emergency, disaster, or PHE, the HHS Secretary may waive certain provisions of the Rule under section 135(b)(7) of the Social Security Act, as amended by the Project BioShield Act, and section 1135(b)(7) of the Social Security Act. Any such waivers expire 72 hours after a hospital has activated its disaster plan.<sup>30</sup>

## National Emergencies Act

NEA<sup>31</sup> authorizes the President to declare a national emergency. A declaration under NEA triggers emergency authorities contained in other federal statutes. Past NEA declarations have addressed, among other things, the imposition of export controls and limitations on transactions and property from specified nations.

## The Health Insurance Portability and Accountability Act of 1996

Protecting public health, including through public health surveillance, program evaluation, terrorism preparedness, outbreak investigations, and other public health activities, often requires

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<sup>29</sup> [https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09\\_52.pdf](https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf).

<sup>30</sup> [http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures\\_in\\_emergency\\_situations/1068.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/disclosures_in_emergency_situations/1068.html).

<sup>31</sup> National Emergencies Act, Pub. L. 94-412, 90 Stat. 1255, enacted September 14, 1976, codified at 50 U.S.C. § 1601-1651.

access to or the reporting of the protected health information of individuals. This information is used to identify, monitor, and respond to disease, death, and disability among populations.

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and certain others to have access to protected health information for public health purposes and the importance of public health reporting by covered entities to identify threats to the public and individuals. Thus, the Privacy Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

## **Other Authorities and References**

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### **Presidential Policy Directive-1: Organization of the National Security Council System**

This PPD outlines the organization of the National Security Council (NSC) system. The document contains headings on the NSC, the NSC Principals Committee, the NSC Deputies Committee, and interagency policy committees. This document is the first in a series of PPDs that, along with Presidential Study Directives, replaces National Security Presidential Directives as instruments for communicating presidential decisions about national security policies of the United States. This Directive supersedes all other existing presidential guidance on the organization of the NSC system.

### **Presidential Policy Directive-8: National Preparedness**

PPD-8, signed in March of 2011 by President Barack Obama, directed the systematic development of a series of policy and planning documents to enhance national preparedness across five mission areas: Prevention, Protection, Mitigation, Response, and Recovery. PPD-8 also called for the development of a National Planning System to integrate planning across all levels of government with the use of private and nonprofit sectors to deliver key capabilities.

### **Presidential Policy Directive-44: Enhancing Domestic Incident Response**

PPD-44 (November 2016) makes improvements to the way the Federal Government coordinates internally when responding to complex and unique incidents where Federal agency leads are not identified in statute or policy. During such incidents, the PPD provides for the identification of a lead federal agency and senior response official to lead coordination of the Federal Government's incident response. Given FEMA's experience and important role in assisting the American people during crises, the PPD states that FEMA may assist the lead agency in coordinating the Federal incident response. The PPD does not change the way that state, local, tribal, or territorial officials respond to incidents and does not alter the way that FEMA coordinates the provision of Federal assistance under the Stafford Act.

### **National Response Framework**

The National Response Framework (NRF) is one of five elements of the National Planning System and is composed of a base document; Emergency Support Function annexes; and support

annexes that describe the doctrine for how the nation builds, sustains, and delivers the response core capabilities identified in the National Preparedness Goal. The NRF describes doctrine for managing any type of disaster or emergency regardless of scale, scope, and complexity. This Framework explains common response disciplines and processes that have been developed at all levels of government (SLTT, insular area, and federal) and have matured over time.

## **National Disaster Recovery Framework**

The National Disaster Recovery Framework (NDRF) provides guidance that enables effective recovery support to disaster-impacted states, tribes, and local jurisdictions. It provides a flexible structure that enables disaster recovery managers to operate in a unified and collaborative manner. It also focuses on how best to restore, redevelop, and revitalize the health, social, economic, natural, and environmental fabric of the community and build a more resilient nation.

## **Response Federal Interagency Operational Plan**

The Response FIOP describes the concept of operations for integrating and synchronizing existing national-level federal capabilities to support SLTT plans and is supported by federal department-level operational plans, where appropriate. The concept of operations and supporting tasks contained in the Response FIOP are scalable, flexible, and adaptable, allowing the FIOP to be used regardless of cause, size, location, or complexity. Concepts of operations and/or tasks may be modified, added, or deleted depending upon the incident.

## **Recovery Federal Interagency Operational Plan**

The Recovery FIOP describes how the Federal Government delivers core capabilities for the Recovery Mission Area. It is an all-hazards plan that provides guidance for the implementation of the NDRF. The mission of the Recovery FIOP is to provide guidance to enable more effective delivery of recovery support to disaster-impacted SLTT jurisdictions. It provides a flexible structure that enables disaster recovery managers to operate in a unified and collaborative manner while preserving the civil rights and civil liberties of all community members.

## **Presidential Policy Directive-2 National Strategy for Countering Biological Threats**

This Strategy addresses the challenges from proliferation of biological weapons or their use by terrorists. It highlights the beneficial nature of advances in the life sciences and their importance in combating infectious diseases of natural, accidental, and deliberate origin. It also outlines how the risks associated with misuse and potential consequences of a biological incident require tailored actions to prevent biological threats. The Strategy emphasizes the need to (1) improve global access to the life sciences to combat infectious disease regardless of its cause; (2) establish and reinforce norms against the misuse of the life sciences; and (3) institute a suite of coordinated activities that collectively will help influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences. Through the seven objectives identified in this Strategy the United States Government will work with domestic and international partners to protect against misuse of the life sciences that may support biological weapons proliferation and terrorism.

## Homeland Security Presidential Directive-5: Management of Domestic Incidents

HSPD-5 enhances the ability of the United States to manage domestic incidents by directing the establishment of a single, comprehensive National Incident Management System. This management system provides a consistent nationwide approach to prepare for, respond to, and recover from domestic incidents. The system allows all levels of government throughout the nation to work together efficiently and effectively.

In HSPD-5, the President designated the Secretary of Homeland Security as the principal federal official for domestic incident management. As such, the Department Homeland Security (DHS) Secretary is responsible for coordinating preparedness activities and operations within the United States to respond to and recover from terrorist attacks, major disasters, and other emergencies. As part of these responsibilities, the Secretary coordinates federal entities to ensure federal unity of effort for domestic incident management.<sup>32</sup> The DHS Secretary coordinates the Federal Government's resources utilized in response to or recovery from terrorist attacks, major disasters, or other emergencies if and when any one of the following four conditions applies: (1) a federal department or agency acting under its own authority has requested the assistance of the Secretary, (2) the resources of state and local authorities are overwhelmed and federal assistance has been requested by the appropriate state and local authorities, (3) more than one federal department or agency has become substantially involved in responding to the incident, or (4) the Secretary has been directed to assume responsibility for managing the domestic incident by the President.

It is within the purview/at the discretion of the Secretary of Homeland Security as to how he/she will execute their HSPD-5 responsibilities.

## HSPD-10: Biodefense for the 21st Century

HSPD-10 (April 2004) provides a comprehensive framework for the nation's biodefense program and outlines its essential pillars as well as specific directives to further strengthen the gains that have been made in this area. The Directive's pillars include—

- *Threat Awareness*, which includes biological weapons-related intelligence, assessments, and anticipation of future threats.
- *Prevention and Protection*, which includes interdiction and critical infrastructure protection.
- *Surveillance and Detection*, which includes attack warning and attribution.
- *Response and Recovery*, which includes response planning, mass casualty care, risk communication, medical countermeasures, and decontamination.

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<sup>32</sup>This does not include those activities that may interfere with the authority of the Attorney General or the FBI Director as described in PPD-8, or other applicable Presidential policy directives.

## **HSPD-18: Medical Countermeasures against Weapons of Mass Destruction**

HSPD-18 (January 2007) addresses the need to be prepared for an attack by terrorist forces or hostile states using weapons of mass destruction. It acknowledges that having sufficient resources on hand at all times and at all places is not realistic. The policy set forth in HSPD-18 is “a two-tiered approach for development and acquisition of MCM, which will balance the immediate need to provide a capability to mitigate the most catastrophic of the current CBRN threats with long-term requirements to develop more flexible, broader spectrum countermeasures to address future threats.” Tier I is a focused development of agent-specific MCM, and Tier II concerns the development of a flexible capability for new MCM. HSPD-18 provides that DHS shall develop and update at least every two years, a strategic, integrated all-CBRN risk assessment and continue to issue Material Threat Determinations for those CBRN agents that pose a material threat to national security.

## **Homeland Security Presidential Directive-21: Public Health and Medical Preparedness**

HSPD-21 (October 2007) mandates the development of a national strategy for public health and medical preparedness that built upon principles set forth in HSPD-10. HSPD-21 identifies four critical components of public health and medical preparedness—biosurveillance, countermeasure distribution, mass casualty care, and community resilience—and establishes federal agency planning requirements in each of these areas. The directives establish a formal mechanism for an annual review of the SNS composition. The directives also address planning in the areas of risk awareness, education and training, and disaster health systems. The directive outlines the requirement for DHS, in coordination with HHS, to communicate risks to public health posed by relevant threats and establishes a mechanism to provide up-to-date and specific public health threat information to qualified heads of state and local governments.

## **Executive Order 13527: Medical Countermeasures Following a Biological Attack**

The order serves as the framework for the federal government to plan and prepare for the timely provision of MCM in the event of a biological attack. This policy seeks to (1) mitigate illness and prevent death, (2) sustain critical infrastructure, and (3) complement and supplement SLTT government MCM distribution capacity.

## **Comprehensive Environmental Response, Compensation, and Liability Act**

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as Superfund, was enacted to provide response authorities to actual or potential releases (1) of hazardous substances or (2) of pollutants or contaminants that may present an imminent and substantial danger to public health or welfare. CERCLA’s implementing regulation is the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR Part 300). A biological agent would be considered a “pollutant or contaminant” when it meets the definition in CERCLA. For an actual or threatened release to the environment,

CERCLA provides the Environmental Protection Agency (EPA) and the United States Coast Guard (USCG) with the authority to gather information, collect samples, and take action to contain and mitigate the threat. The EPA's and/or USCG's environmental assessment, decontamination/cleanup, and waste management activities may be conducted under CERCLA or, if there is a Stafford Act declaration, under an Emergency Support Function #10 mission assignment.

## **Resource Conservation and Recovery Act**

The Resource Conservation and Recovery Act (RCRA) is the federal statute passed in 1976 that regulates hazardous waste generation, storage, transportation, treatment, and disposal. The RCRA amendments of 1984 (the Hazardous and Solid Waste Amendments) incorporate the minimization of the nation's reliance on land disposal of hazardous waste. U.S. regulations under the RCRA<sup>33</sup> (<http://www.epa.gov/rcra>) require that all solid and hazardous wastes are handled in a manner that minimizes harm to humans and the environment. Many states are authorized or approved to administer the RCRA programs and to ensure compliance, and states may regulate solid and hazardous wastes under their own authorities as well. Most if not all states require that biological agents are either destroyed on site before disposal as solid unregulated waste, or packaged as regulated medical waste, or handled as a special Category A infectious [CU1] substance and transferred to a licensed third party for decontamination via autoclaving or incineration. RCRA also establishes standards for landfills, incinerator ash, and solid waste, all of which will likely be involved in a biological incident response.

## **Homeland Security Act of 2002**

The Homeland Security Act of 2002<sup>34</sup> created DHS as an executive department of the U.S. Government. The Act consolidated component agencies, including the Federal Emergency Management Agency (FEMA), into the Department. The Secretary of Homeland Security is the head of the Department and has direction, authority, and control over it. All functions of all officers, employees, and organizational units of the Department are vested in the Secretary. The mission of the Department includes preventing terrorist attacks within the United States, reducing America's vulnerability to terrorism, and minimizing the damage and recovering from attacks that occur.

## **Post-Katrina Emergency Management Reform Act**

The PKEMRA<sup>35</sup> clarified and modified the Homeland Security Act with respect to the organizational structure, authorities, and responsibilities of FEMA and the FEMA Administrator. Enacted as part of the DHS Appropriations Act of 2007, the PKEMRA is intended to address various shortcomings identified in the preparation for and response to Hurricane Katrina. The act enhanced FEMA's responsibilities and its autonomy within DHS. Per PKEMRA, FEMA is to lead and support the nation in a risk-based, comprehensive emergency management system of

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<sup>33</sup> <http://www.epa.gov/rcra>.

<sup>34</sup> Homeland Security Act of 2002, Pub. L. No. 107-296 (codified as amended at 6 U.S.C. §§ 101-629).

<sup>35</sup> Post-Katrina Emergency Management Reform Act (PKEMRA) of 2006, Pub. L. No. 109-295.

preparedness, protection, mitigation, response, and recovery. Under the act, the FEMA Administrator reports directly to the Secretary of Homeland Security. FEMA is now a distinct entity within DHS, and the Secretary of Homeland Security can no longer substantially or significantly reduce the authorities, responsibilities, or functions of FEMA—or the capability to perform them—unless authorized by subsequent legislation. The Act further directed the transfer to FEMA of many of the functions of DHS’s former Preparedness Directorate.

## **Robert T. Stafford Disaster Relief and Emergency Assistance Act**

The Stafford Act<sup>36</sup> authorizes the programs and processes by which the Federal Government provides disaster and emergency assistance to state and local governments, tribal nations, eligible private nonprofit organizations, and individuals affected by a declared major disaster or emergency. The Stafford Act covers all hazards, including natural disasters and terrorist incidents.

At the request of the Governor of an affected state, or a chief executive of an affected Indian tribe, the President may declare a major disaster or emergency if an incident is beyond the combined response capabilities of the state, tribal, and jurisdictional governments. Among other things, this declaration allows federal assistance to be mobilized and directed in support of state, tribal, and jurisdictional response efforts. Under the Stafford Act (42 U.S.C. §5191(b)), the President can also declare an emergency without a gubernatorial request if primary responsibility for response rests with the Federal Government because the emergency involves a subject area for which the United States exercises exclusive or preeminent responsibility and authority. In addition, in the absence of a specific request, the President may provide accelerated federal assistance and federal support where necessary to save lives, prevent human suffering, or mitigate severe damage and notify the state of that activity.

## **The Economy Act**

In the absence of, or in addition to, the Stafford Act, the Economy Act can be used by lead federal agencies to request support from other federal agencies. However, use of the Economy Act is limited to circumstances in which the head of the requesting federal agency determines that the support cannot be provided by contract as conveniently or cheaply by a commercial enterprise.

## **Defense Production Act**

The Defense Production Act<sup>37</sup> (DPA) is the primary source of presidential authority to expedite and expand the supply of critical resources from the U.S. industrial base to support the national defense and homeland security. In addition to military, energy, and space activities, the DPA definition of “national defense” includes emergency preparedness activities conducted pursuant

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<sup>36</sup> Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. L. No. 93-288 (as amended primarily at 42 U.S.C. §§ 5121-5207).

<sup>37</sup> Defense Production Act of 1950, as amended (50 U.S.C. § 4501 et seq.).

to Title VI of the Stafford Act; protection and restoration of critical infrastructure; and efforts to prevent, reduce vulnerability to, minimize damage from, and recover from acts of terrorism within the United States. The President's DPA authorities are delegated to the heads of various federal departments in Executive Order 13603.<sup>38</sup> DPA, however, does not necessarily increase the production of critical resources if those production lines are already operating at a maximum capacity and the demand for such resources are high, resulting in significant national shortages.

### **The 9/11 Commission Act of 2007**

The Implementing Recommendations of the 9/11 Commission Act (9/11 Commission Act) established within the DHS National Biosurveillance Integration Center (NBIC). The Center is tasked with enhancing the capability of the Federal Government to rapidly identify, characterize, localize, and track biological events of national concern by integrating and analyzing data related to human health, animal, plant, food, and environmental monitoring systems and to disseminate alerts if any such events are detected. A central responsibility is to develop and oversee the National Biosurveillance Integration System (NBIS), a federal interagency consortium and information management concept that was established to integrate and analyze biosurveillance-relevant information to achieve earlier detection and enhanced situational awareness. NBIC has identified the following federal agencies as NBIS partners: The Departments of Agriculture, Commerce, Defense, Energy, Health and Human Services, Interior, Justice, State, and Transportation, as well as Veterans Affairs, the U.S. Postal Service, and the EPA and SLTT agencies who are provided access to information and analysis and are allowed to contribute data.

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<sup>38</sup> Executive Order 13603 of March 16, 2012: National Defense Resources Preparedness.

## Appendix 2: Roles and Responsibilities of Federal Agencies with Primary Authority for Federal Response to a Biological Incident

This section details the roles and responsibilities of federal departments and agencies that may be involved in the response and recovery to a biological incident. This list is not exhaustive and merely represents the most prominent stakeholders and leaders; additional departments and agencies may be called upon to support these primary response and recovery organizations.

### Federal and Regional Government Offices

Federal response and recovery support following a biological incident must be coordinated closely with state and local governments and jurisdictional federal agencies located in the areas affected by the incident. The following departments, agencies, and offices may play a role in response and recovery:

- Department of Health and Human Services (HHS)
  - Indian Health Service (HIS)
  - Assistant Secretary for Preparedness and Response (ASPR)
  - Centers for Disease Control and Prevention (CDC)
  - Food and Drug Administration (FDA)
  - Administration for Children and Families (ACF)
  - Health Resources and Services Administration (HRSA)
  - National Institutes of Health (NIH)
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
  - Centers for Medicare Medicaid Services (CMS)
  - Health Resources and Services Administration (HRSA)
- Department of Homeland Security (DHS)
  - Federal Emergency Management Agency (FEMA)
  - U.S. Coast Guard (USCG)
  - Customs and Border Protection (CBP)
  - National Protection and Programs Directorate (NPPD)
  - Office of Health Affairs (OHA)
- Department of Justice (DOJ)
  - Federal Bureau of Investigation (FBI)
- U.S. Department of Agriculture (USDA)
  - Animal and Plant Health Inspection Service (APHIS)
  - Food Safety and Inspection Service (FSIS)
  - Food and Nutrition Service (FNS)
- Environmental Protection Agency (EPA)
- General Services Administration (GSA)
- Department of Defense (DoD)
- Department of State (DOS) and U.S. Agency for International Development (USAID)
- Department of Transportation (DOT)

- Office of the Secretary/Office of Intelligence, Security, and Emergency Response
- Federal Aviation Administration (FAA)
- National Highway and Traffic Safety Administration (NHTSA)
- Pipeline and Hazardous Materials Safety Administration (PHMSA)
- Department of the Interior (DOI)
  - National Park Service (NPS)
  - U.S. Geological Survey (USGS)
  - Fish and Wildlife Service (FWS)
- Department of Commerce (DOC)
  - National Oceanic and Atmospheric Administration (NOAA)
- Department of Labor (DOL)
  - Occupational Safety and Health Administration (OSHA)
  - Employment Training Administration (ETA)
- Office of Personnel Management (OPM)
- Department of Veterans Affairs (VA)

A detailed description of each department and agency and its potential roles and responsibilities related to a biological incident are outlined in **Appendix 6: Federal Department/Agency Roles and Responsibilities**.

Federal regional offices may closely coordinate with state and local jurisdictions to identify response and recovery requirements and establish standardized early warning protocols as they pertain to a biological incident occurring within local jurisdictions. For example, HHS Regional Emergency Coordinators will coordinate with CDC, HHS ASPR Emergency Management Group, and their counterparts at the National Operations Center (NOC), Office of Health Affairs (OHA), and FEMA. Regional health administrators, regional advisory councils, and regional directors may work with state, local, tribal, and territorial (SLTT) senior health officials and representatives from health associated nongovernmental organizations to support decision-making and provide guidance.

## **Department of Health and Human Services**

HHS is the U.S. Government's (USG) principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.

The mission of HHS is to enhance the health and well-being of Americans by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services.

In addition to federal statutes, a number of National Strategies and Presidential Directives establish HHS as the lead federal department responsible for the protection of the health of the civilian population against both intentional and accidental or naturally occurring threats. It is also responsible for coordinating with other federal agencies and impacted SLTT, private sector, and nongovernmental partners, as appropriate, in responding to a biological incident. The Secretary of HHS leads all federal public health and medical response to public health and medical emergencies covered by the National Response Framework (NRF).

## Assistant Secretary for Preparedness and Response

ASPR was created under the Pandemic and All Hazards Preparedness Act (PAHPA) in the wake of Hurricane Katrina. The Office of the ASPR leads the nation and its communities in preparing for, responding to, and recovering from the adverse health effects of public health emergencies and disasters. ASPR focuses on public health and medical preparedness planning and response; assisting locally led recovery efforts in the restoration of the public health, health care, and social services networks of impacted communities; building federal emergency medical operational capabilities; medical countermeasures research, advance development, and acquisition; and grants to strengthen the capabilities of hospitals and health care systems in public health emergencies and medical disasters. The ASPR leads the Public Health Emergency Medical Countermeasures Enterprise, which is comprised of the CDC, NIH, FDA and interagency partnership with the VA, DoD, DHS, and USDA. Additionally, the ASPR, in collaboration with the CDC and in coordination with the Secretary of Homeland Security, exercises the responsibilities and authorities of the HHS Secretary with respect to the Strategic National Stockpile (SNS). The office provides federal support, including medical professionals through ASPR's National Disaster Medical System (NDMS), to augment state and local capabilities during an emergency or disaster.

Under the Public Health Service Act, HHS is the lead agency for Emergency Support Function (ESF) #8 of the NRF. Consistent with provisions established in statutes under the PAHPA and Pandemic and All-Hazards Preparedness Reauthorization Act, the Secretary of HHS delegates to ASPR the leadership role for all health and medical services support function in a health emergency or public health incident and lead responsibility within the department for emergency preparedness and response policy coordination and strategic direction. Additionally, HHS/ASPR manages the International Health Regulations (IHR) National Focal Point, consisting of the ASPR, the IHR program, and the HHS Secretary's Operations Center, which serves as the official pathway for notifications to the World Health Organization of incidents that may have potential international impact.

ASPR consists of the following offices:

- Biomedical Advanced Research and Development Authority (BARDA)
- Office of Emergency Management (OEM)
- Office of Acquisition Management, Contracts, and Grants
- Office of Policy and Planning (OPP)
- Office of Financial Planning and Analysis
- Office of the Chief Operating Officer

Though all offices will likely have a role in major incidents, the offices of BARDA, OEM, and OPP, in particular, have highly specific functions during a biological incident.

### *ASPR: Biomedical Advanced Research and Development Authority*

BARDA facilitates the advanced research, development, and acquisition of medical countermeasures (MCM) for chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases, including pandemic influenza and biological threats that threaten the U.S. civilian population. BARDA establishes systems that encourage and facilitate the

development and acquisition of MCM such as vaccines, therapeutics, and diagnostics as well as innovative approaches to meet the threat of CBRN agents and emerging infectious diseases, in support of the mission and priorities of the HHS.

*ASPR: Office of Emergency Management*

OEM is responsible to ASPR for implementing and operationalizing pertinent authorities directed by the Public Health Services Act (PHSA), as amended, and OEM is responsible to ASPR for implementing and operationalizing pertinent authorities directed by the PHSA, as amended by PAHPA and the Pandemic and All-Hazards Preparedness Reauthorization Act. OEM supports ASPR's role as the principal advisor to the Secretary of HHS on all matters related to federal public health and medical emergency management for public health emergencies. Specific to the Biological Incident Annex, the Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives (CBRNE) Branch provides subject matter expertise and decision-maker support for incidents involving CBRNE agents. During a biological incident, OEM assists the Secretary of HHS and ASPR in the execution of their responsibilities to lead the federal public health and medical response to emergencies under ESF #8 of the NRF in support of federal, and SLTT requests and leads the Health and Social Services Recovery Support Function (RSF) of the National Disaster Recovery Framework (NDRF) to assist locally led recovery efforts in the restoration of the public health, health care, and social services networks of affected individuals and communities.

OEM manages a diverse portfolio of programs to ensure that ASPR has the plans, procedures, logistical support, systems, and training to support domestic and international emergency operations and response needs and enhance the preparedness of the nation's healthcare system. OEM also manages the NDMS, a federally coordinated system that augments the nation's medical response capability. The NRF employs NDMS under ESF #8, to support federal agencies and SLTT governments in the management and coordination of the federal medical response to public health emergencies and federally declared disasters including a biological incident. NDMS teams include medical assistance, veterinary, mortuary, and international medical surgical teams.

OEM provides decision support tools and analysis to facilitate and enable the tracking of public health and medical emergencies in a specified community, coordinates and supports national volunteer health professionals through the Medical Reserve Corps and the Emergency System for Advance Registration of Volunteer Health Professionals initiative, facilitates and leads the coordination activities of the federal health and social services efforts under the RSF of the NDRF, and links stakeholder partners to resources via open and direct communication at all levels of response.

*ASPR: Office of Policy and Planning*

ASPR/OPP advises ASPR and HHS leadership during both domestic and international public health emergencies, and develops policies to address response-specific challenges as needed. ASPR/OPP maintains the IHR Program, which manages the U.S. assessment and notification process for potential public health emergencies of international concern (PHEIC) as well as other emergency communications, including CBRN events, and the sharing of routine public health information with the World Health Organization and other IHR national focal points worldwide.

In addition, ASPR/OPP coordinates with international partners to execute the ASPR's mandate to provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response. As a result, OPP, in collaboration with OGA, CDC, DOS and other stakeholders, coordinates and makes recommendations about HHS response activities to affected nations, including international deployments of both medical countermeasures from the SNS and HHS public health and medical personnel.<sup>39 40</sup> In addition, OPP, in close coordination with other USG agencies, assists in, coordinating HHS activities during responses to international CBRN events and influenza pandemics.<sup>41 42</sup>

### *U. S. Centers for Disease Control and Prevention*

The CDC is an operational component of HHS that is responsible for the nation's health protection. The CDC's administration, scientists, and staff track diseases, research outbreaks, and respond to emergencies to protect the nation from health, safety, and security threats, both foreign and in the U.S.

The following critical functions may be executed by the CDC to effectively prepare for, respond to, and recover from a biological incident:

- Conduct epidemiologic and surveillance activities to define cases, identify the populations at risk, and determine the source of exposure.
- Provide laboratory support for the identification, confirmation, characterization, and drug susceptibility of the biological agent.
- Provide environmental assessment consultations and/or conduct environmental sampling to support epidemiologic and surveillance activities and identify exposures pathways to support implementation of intervention strategies.
- Provide guidance on identification, diagnosis, and clinical management of human cases.
- Distribute MCM as required/directed.

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<sup>39</sup> Policy Framework for Responding to International Requests for Public Health Emergency Medical Countermeasures from the U.S. Department of Health and Human Services. This Framework established the International Sharing of Medical Countermeasures Policy Group (ISMPG)—a USG interagency group that analyzes international requests for MCMs and develops recommendations for U.S. action—for which the OPP Division of International Health Security serves as the Executive Secretariat.

<sup>40</sup> Department of Health and Human Services Policy Framework for the Deployment of Personnel during International Medical and Public Health Emergencies. This Framework established the HHS International Policy Group for Personnel Sharing (HIPPS)—a USG interagency group that analyzes international requests for public health and medical personnel and develops recommendations for U.S. action—for which the OPP Division of International Health Security serves as the Executive Secretariat.

<sup>41</sup> The International CBRN response protocol provides principles, guidance, and considerations for a USG response to a catastrophic, international CBRN incident. The protocol is designed to support, not supplant, existing USG coordination processes and procedures by adding CBRN-specific considerations including unique USG assistance and advisory options. It will also be used only when no other CBRN-related guidance is available or normal government-to-government support procedures cannot be applied (such as during war or when international response plans and agreements exist).

<sup>42</sup> The PI Framework outlines the interagency process by which the USG will receive, consider, communicate about, decide upon, and respond to international requests for public health and medical assistance during influenza pandemics. The PI Framework does not apply to routine seasonal influenza activities.

- Provide guidance on use of MCM (e.g., antimicrobials, vaccines, and immunotherapeutics) that may be utilized for prophylaxis and treatment.
- Develop effective infection control practice recommendations for healthcare settings.
- Prevent the entry of communicable disease into the United States through quarantine/isolation measures that may be used at U.S. Ports of Entry.
- Provide guidance on non-pharmaceutical mitigation strategies to assist with the containment and control of infectious agents.
- Conduct assessments and identify mitigation solutions for worker safety and health issues related to exposure to the biological agent and other hazards workers face during response and recovery options.
- Provide technical assistance to SLTT, federal, and international partners to support public health activities.
- Disseminate key public health and risk mitigation messages to the public to provide timely, accurate, clear, consistent, credible, and easily accessible information relevant to the information needs of all stakeholders.
- Provide guidance on threats to human health from exposed animals, their clinical management, and appropriate control measures in animal populations.
- Provide rapid and sustained public health assessment, leadership, expertise, and support by deploying personnel both to the impacted area and to the CDC Emergency Operations Center (and other emergency operation centers) for technical and administrative mission and Drug Administration.

The FDA is an agency within HHS that is responsible for, among other things, protecting the public health by assuring the safety, effectiveness, quality and security of human and veterinary drugs, vaccines, and other biological products as well as medical devices. FDA's Medical Countermeasures Initiative (MCMi), led by the Office of Counterterrorism and Emerging Threats (OCET), provides strategic leadership and coordination for FDA's counterterrorism and emerging threat portfolios and works to identify and resolve complex scientific and regulatory challenges facing medical countermeasure development, approval, availability, and security. OCET coordinates FDA's MCMi, facilitates relevant intra- and interagency counterterrorism communications, and coordinates MCMi emergency use, including Emergency Use Authorization (EUA), activities. The FDA has a number of authorities related to providing access to investigational and/or unapproved, or unapproved uses of approved, medical products for emergency use. For example, under an EUA, the FDA Commissioner may allow emergency use of an unapproved medical product (e.g., drug, vaccine, diagnostic) or an unapproved emergency use of an approved medical product to diagnose, treat, or prevent a serious or life-threatening disease or condition caused by a CBRN threat agent, including an emerging infectious disease, when there is no adequate, approved, and available alternatives and when all other statutory criteria under section 564 of the FD&C Act are met.

## **Department of Homeland Security**

The Secretary of DHS is the principal federal official for domestic incident management. The Secretary is responsible for coordinating federal operations within the United States to prepare for, respond to, and recover from terrorist attacks, major disasters, and other emergencies,

including biological incidents. DHS provides biosurveillance capabilities to detect an intentional aerosolized biological agent dispersion and to coordinate information sharing with federal partners on health-related threats to humans, animals, and plants. The DHS Secretary coordinates the federal response as provided in HSPD-5 and noted in **Table 1**.

OHA serves as the department's medical and public health advisor to the Secretary of Homeland Security, the FEMA Administrator, and all DHS components. Specifically, OHA manages the BioWatch program and the National Biosurveillance Integration Center (NBIC). In addition, OHA provides departmental-level workforce guidance and medical support, to include medical countermeasures.

The Office of the Chief Human Capital Officer serves as the Designated Agency Safety and Health Official and is the principal technical adviser for occupational safety and health protection matters on behalf of DHS. Personnel protective equipment guidance is not the responsibility of this office.

DHS serves as an information conduit across multiple agencies and to the National Security Council for—

- Operational coordination
- Situational awareness and decision support through the National Biosurveillance Integration Center/Information System (NBIC/NBIS)
- Public information and warning messaging
- Detection of ongoing threats through the BioWatch program

### *Federal Emergency Management Agency*

FEMA is an operational component of DHS that coordinates ESFs, RSFs, and funding support to impacted areas during Stafford Act disasters. For biological incidents, FEMA primarily manages coordinating centers, funding sources, non-medical supply resourcing, and supporting ESFs/RSFs.

FEMA's Administrator is the principal advisor to the President, the Secretary of Homeland Security, and the Homeland Security Council regarding emergency management. The FEMA Administrator's duties include assisting the President, through the DHS Secretary, in carrying out the Stafford Act; operating the National Response Coordination Center; supporting all ESFs and RSF's; and preparing for, protecting against, responding to, and recovering from an all-hazards incident. A Federal Coordinating Officer, appointed by the President in a Stafford Act declaration, coordinates federal activities in support of the states and tribal and territorial governments. Reporting to the Secretary of Homeland Security, the FEMA Administrator is also responsible for managing the core DHS grant programs that support homeland security activities.

FEMA develops with OPM and federal departments and agencies DHS Surge Capacity Force personnel requirements.

### *United States Coast Guard*

The USCG will conduct ports and waterways coastal security, search and rescue, and marine safety missions during a biological incident. These missions include exercising of port state

control authorities, enforcement of security zones, alien migrant interdiction, and counter-terrorism operations. In addition, the USCG under its cognizant authority shall enforce quarantines, per direction of the CDC, in the maritime environment. In addition, the Coast Guard Deployable Specialized Forces, including the National Strike Force and Marine Security Response Teams, provide highly trained, experienced personnel and specialized equipment to USCG and other federal agencies to facilitate preparedness for and response to biological incidents in order to protect public health and the environment. USCG On-Scene Coordinators are responsible for coordinating the removal of oil and hazardous substances in the Coastal Zone.

#### *United States Customs and Border Protection*

For biological incidents suspected or detected inside or at U.S. borders or those individuals that may travel to the United States from abroad, CBP may detain and/or quarantine individuals until medical authorities have been alerted. CBP may deny the admission of an alien not lawfully admitted for permanent residence who is infected with a communicable disease of public health significance.

#### *National Protection and Programs Directorate*

NPPD works with partners at all levels of government and from the private and non-profit sectors to share information and build greater trust to make secure critical infrastructure and key resources. Protective Security Advisors forge strong relationships with federal and SLTT government mission partners and private sector stakeholders to enhance public/private collaborative efforts to protect critical infrastructure. The Private Security Advisors will remain focused on contingency outreach to owners and operators of critical infrastructure regarding the evolving biological incident.

NPPD will sustain communications with the respective sector coordinating councils and sector-specific government coordinating councils on appropriate information sharing related to the evolving biological incident.

## **Department of Justice**

#### *Federal Bureau of Investigation*

The Attorney General, generally acting through the FBI Director, leads and coordinates the operational law enforcement response, on-scene law enforcement, and related investigative and appropriate intelligence activities related to terrorist threats and incidents. This includes the coordination of the law enforcement activities to detect, prevent, preempt, and disrupt terrorist threats. The FBI, acting primarily through its Joint Terrorism Task Forces (JTTF), has lead responsibility for investigative activities involving federal crimes of terrorism. This includes the receipt and resolution of suspicious activity reporting of terrorist activities or acts in preparation of terrorist activities. The Attorney General, generally acting through the FBI Director, has primary responsibility for searching for, finding, and neutralizing weapons of mass destruction (WMD) within the U.S. and its territories. The FBI On-Scene Commander is responsible for leading and coordinating the federal operational law enforcement response and investigative activities necessary to prevent or resolve terrorist threats or incidents. The FBI On-Scene Commander retains the authority to take appropriate law enforcement actions (tactical-response, render safe, and bomb-management operations) at all times during the response. Additionally,

the FBI On-Scene Commander has primary responsibility to conduct, direct, and oversee crime scenes, to include those involving WMD, their security, and evidence management through all phases of the response.

All information regarding biological threats that have a potential impact on the United States will be immediately passed to the FBI to conduct a timely Threat Credibility Evaluation in order to assess the credibility and severity of the WMD threat and consider initiation of the appropriate WMD counterterrorism response protocols.

In the case of substantial credible threats or incidents, the FBI will notify appropriate senior leaders of departments and agencies, to include the National Counterterrorism Center, DHS, HHS, USDA, and DoD and will stand up the interagency Weapons of Mass Destruction Strategic Group (WMDSG). The WMDSG supports efforts to successfully resolve imminent WMD terrorist threats or incidents while simultaneously coordinating its information with the nationwide effort to save lives and protect property.

The FBI also has a WMD Coordinator assigned to each of its field offices. WMD Coordinators are responsible for managing the office's WMD program and serve as a point of contact for emergency responders and public health at the state and local level in a threat scenario or incident potentially involving a WMD. In such an incident, the WMD Coordinator serves as a conduit for obtaining federal assistance for operational response direction and threat evaluation support.

Terrorist threat-related information collected domestically, including suspicious activity reporting involving suspected federal crimes of terrorism, will be shared comprehensively and immediately with the FBI JTTF so that threats can be investigated and resolved. Terrorist threat-related information will also be shared promptly with National Counterterrorism Center and in addition, as authorized by law, with the Terrorist Screening Center, DHS, and DoD. Specific terrorism-related threat information and the collection and investigative activities related thereto will be coordinated with and through the FBI JTTFs. Decisions on where to perform tests on collected materials/evidence are made by the FBI during the Threat Credibility Evaluation based on the nature of the material. The Laboratory Response Network (LRN), in coordination with CDC, is used to test for the presence of specific panel of biological threat agents in the majority of cases. All positive LRN-tested samples are considered preliminary for the purposes of future use in a criminal investigation, and samples/items are sent to other laboratories for confirmatory analysis. Any agency or organization that identifies an unusual or suspicious item (e.g., mail package) or test result should contact the FBI to ensure coordination of appropriate testing. All relevant threat and public health assessments should be provided to the NOC. Test results on human samples from non-LRN facilities are considered a "first pass" or "screening" test.

## **U.S. Department of Agriculture**

USDA serves as the USG's primary agency for the security and resilience in the commercial production of food and consequence management of outbreaks and/or attacks that may occur in animals used in the commercial production of food. The USDA, HHS, DHS, and the FBI collaborate through surveillance systems with states and private industries to protect the nation's food supply from terrorist threats and to prepare for and respond to catastrophic disasters. In

biological incidents affecting human health, USDA may provide technical and animal health assistance to HHS, if requested and resources are available.

Several federal agencies have the authority to declare emergencies in their jurisdictional area with or without local emergency declarations. The USDA is one of those federal agencies that has some of the most relevant food and agricultural emergency declaration authority and subsequent agency specific disaster loan programs. USDA Secretarial agricultural disaster declarations include emergency, extra-ordinary emergency and agricultural disaster declarations.

USDA's National Animal Health Laboratory Network laboratories perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for foreign animal diseases, protecting human health by decreasing the risk of zoonotic diseases (those that can affect animals and humans) and diseases transmitted between wildlife and livestock.

USDA and DOI coordinate ESF #11, Agriculture and Natural Resources, which provides nutritional assistance; responds to animal and agricultural health issues; provides technical expertise in support of animal and agricultural emergency management; ensures the safety and defense of the nation's supply of meat, poultry, and processed egg products; and protects natural, cultural, and historical resources. ESF #11 can provide support during a biological incident.

When a veterinary response is required during a biological incident, assets may be requested from the National Veterinary Stockpile.

#### *Animal and Plant Health Inspection Service*

APHIS works closely with DHS FEMA to provide assistance and coordination during all-hazards emergencies. APHIS may provide technical assistance to include coordinating with nonprofit and private organizations and government departments or agencies to support the rescue, care, shelter, and essential needs of owners and their household pets and service and assistance animals. APHIS may provide epidemiology and diagnostic support during a biological incident. APHIS maintains the National Veterinary Stockpile to address foreign animal disease in livestock and poultry.

#### *Food Safety and Inspection Service*

FSIS is the public health regulatory agency within the USDA responsible for ensuring that the nation's commercial supply of meat, poultry, and processed egg products is safe, wholesome, and correctly labeled and packaged. FSIS works to lower the incidence of pathogens that cause foodborne illness and limit the occurrence of outbreaks in the products it regulates. FSIS performs food safety inspection activities at more than 6,000 establishments nationwide, maximizes domestic and international compliance with food safety policies, promotes food defense practices and principles, enhances public education and outreach to increase safe food-handling practices, and strengthens collaboration among internal and external stakeholders and other public and private sector partners to prevent foodborne illness.

### **Department of the Interior**

DOI serves as the point of contact for and can respond to wildlife disease emergencies, including zoonoses, through the DOI Office of Emergency Management, PWS, NPS, and the USGS. DOI provides assistance through mapping, modeling, monitoring, testing of wildlife (terrestrial and

marine), and designing sampling strategies for wildlife and environmental reservoirs. USGS has tools and capabilities to help assess how environmental processes (e.g., soil geochemistry, hydrologic flows, water quality, etc.) influence the occurrence, viability, and transmission of zoonotic or vector-borne disease agents. USGS provides guidance for disease prevention, control, and eradication of zoonotic diseases in wildlife and the environment.

The FWS National Wildlife Refuge System's Wildlife Health Office and the NPS Wildlife Health Branch and Office of Public Health conduct critical work in health and disease surveillance, response and management to support the National wildlife refuges and parks, respectively. The FWS National Wildlife Refuge System's Wildlife Health Office and the NPS Wildlife Health Branch and Office of Public Health conduct critical work in health and disease surveillance, response, and management to support national wildlife refuges and parks, respectively. DOI also is an operating division for HHS for the recruitment, placement, and management of U.S. Public Health Services Officers assigned to its bureaus to provide public health capacity to support disease prevention, detection and management. These officers, managed by the NPS's Office of Public Health, respond to and prevent infectious diseases and outbreaks and develop and implement disease surveillance systems. Furthermore, officers conduct onsite evaluations regarding control measures to manage public health hazards related to water supplies, waste water systems, and food service facilities.

## **Environmental Protection Agency**

EPA is the lead agency for environmental cleanup and remediation in the inland zone, including indoor cleanups, if appropriate, under the specific federal authorities being invoked. The EPA through its federal On-Scene Coordinators also provides technical assistance and operational support for sampling, characterization, decontamination, clearance, and waste management efforts; federal contractors; and EPA special teams, specifically its CBRN Consequence Management and Advisory Team; and Environmental Response Laboratory Network. If there is potential for environmental contamination due to a biological incident, HHS collaborates with EPA in developing and implementing sampling strategies and sharing results. EPA may conduct environmental response activities under the Comprehensive Environmental Response Compensation, and Liability Act or an ESF #10 mission assignment for responses conducted under the Stafford Act.

## **Department of Defense**

DoD has significant resources that may be accessed to respond to domestic emergencies and, in the case of a biological incident, provides a spectrum of capabilities that protect not just DoD, but the general public as well.

To ensure advanced warning of threats, the Defense Intelligence Agency/National Center for Medical Intelligence (NCMI) provides intelligence assessments of foreign health threats, including pandemic warning, to prevent strategic surprise across the broad threat spectrum. NCMI assesses risk and projects the impact of incidents to deliver decision advantage to U.S. warfighters, defense planners, and DoD policymakers.

DoD, via the Defense Health Agency, Public Health Division, Armed Forces Health Surveillance Branch (AFHSB), conducts comprehensive health surveillance of DoD forces. The AFHSB serves a key role in biosurveillance to detect disease and to understand the threats from endemic

and emerging infectious diseases relevant to DoD forces. Though the focus is on infectious disease threats relevant to DoD forces, the AFHSB serves as a significant source of information to inform the larger U.S. biosurveillance mission and to maintain situational awareness.

In order to ensure that DoD has the ability to assist the response to and recovery from a biological incident, the protection of DoD personnel, installations, and other assets to provide mission assurance is the first priority for DoD. Under immediate response authority, DoD officials may, under imminently serious conditions and if time does not permit higher authority approval, provide an immediate response, when requested, to save lives, prevent human suffering, or mitigate great property damage. Normally, DoD provides defense support of civil authorities to support the response and to minimize the consequences of the incident, when requested by a lead agency and approved by the Secretary of Defense. DoD's response capabilities may include specialized MCM research, diagnostics, emergency medical and lifesaving capabilities, logistics, and transportation support. Depending on the size and scope of the incident, DoD may be requested to employ additional command and control capabilities to facilitate the management of DoD assets and to support the larger response effort.

DoD has limited medical services capabilities beyond those authorized for the DoD health care system. These systems would which likely would be equally affected during a large-scale (regional epidemic/ pandemic) biological incident but may be able to provide surge capabilities (laboratory, emergency care, logistics, etc.) for more finite incidents. Additionally, when requested, DoD may provide medical logistic support and general support, such as transportation, to enable civil responders.

The Posse Comitatus Act (18 U.S.C. §1385) generally prohibits DoD military forces from conducting civilian law enforcement activities such as search, seizure, and arrest in the absence of specific constitutional or statutory authority to engage in such activities. One such authority, 10 U.S.C. §382, permits DoD to provide support to the DOJ under certain circumstances in emergency situations involving WMD, including biological weapons and materials.

DoD may also support DOJ and/or other law enforcement agencies and/or other authorities with logistical support such as sheltering and transportation. Upon a determination that a biological incident was the result of an intentional attack, DoD emergency assistance may include the operation of equipment to monitor, contain, disable, or dispose of biological weapons involved or elements of the weapons.

Lastly, DoD's capabilities in biological forensics and technical analysis may be called upon to support the FBI in determining whether an incident is natural, accidental, or intentional. This forensic capability allows DoD to provide expert advice, technical assistance and, if necessary, operational support to the attribution assessment process.

## **Department of State**

As the USG's lead coordinating agency for foreign relations, DOS is responsible for all communication and coordination during any domestic incident between the USG and foreign governments. Specifically, DOS coordinates support to foreign missions in the U.S. regarding consequence management efforts of a biological incident in the United States. DOS coordinates the U.S. support for foreign missions in the United States in mitigation, preparedness, and response operations to a biological incident that has the potential to adversely impact the United

States or U.S. interests. In addition, DOS facilitates consular access for foreign missions in the event of foreign national casualties and injuries, facilitating communication with first responders, hospitals, and morgues as well as facilitating other logistics, such as shipments of remains.

Overseas, DOS coordinates requests to foreign countries for support of U.S. citizens located outside of the United States, primarily through the U.S. missions abroad (embassies and consulates). As the President's representative in a foreign country, the Chief of Mission (COM) is responsible for the security of all USG personnel and their families on official duty abroad in that respective country. The COM is supported in security, health, crisis planning, and risk management by the Emergency Action Committee, comprised of consular, security, management, medical, environmental, and other subject matter experts. Through the Emergency Action Plan, DOS maintains formal processes for crisis management and coordination at U.S. missions abroad for incidents that affect the mission or the host country, including biological incidents.

### *United States Agency for International Development*

USAID/Office of Foreign Disaster Assistance (OFDA) is the federal lead for managing the provision of USG international humanitarian assistance and disaster response as specified under the Foreign Assistance Act of 1961 in that USAID's Administrator is the President's Special Coordinator for International Disaster Assistance as established in section 493 of the Foreign Assistance Act. With a mandate to save lives and reduce human suffering, USAID/OFDA's approach to a biological response will focus on providing lifesaving assistance (food, water, shelter, and medicine) to the population that is affected by the incident as afforded in USAID's broad authority to provide disaster assistance pursuant to section 491 of the Foreign Assistance Act.

USAID/OFDA provides yearly guidance to all posts for disaster planning and response outlining the support from USAID/OFDA before, during, and after the occurrence of natural and man-made disasters abroad. USAID coordinates international assistance in the case of an overseas disease outbreak as well as in the case of the United States requesting international assistance with a disease scenario in this country. Procedures highlight the need for continuous collaboration in the planning process for disaster response as well as regular and sustained communication between mission disaster relief officers and USAID/OFDA regional staff to ensure timely, appropriate, and effective U.S. Government emergency response and humanitarian assistance.

### **Department of Transportation**

The DOT Pipeline and Hazardous Materials Safety Administration (PHMSA) is responsible for regulating and ensuring the safe and secure movement of hazardous materials to industry and consumers by all modes of transportation, including pipelines. To minimize threats to life, property, or the environment due to hazardous materials-related incidents, PHMSA's Office of Hazardous Materials Safety develops regulations and standards for the classifying, handling, and packaging of over one million daily shipments of hazardous materials within the United States.

DOT regulations assign the responsibility to the shipper (e.g., hospital) for complying with the proper packaging and transport of hazardous materials, including regulated medical waste.

However, there are individual states that may have additional rules, and thus, appropriate state regulations may apply in a biological incident response and recovery operation.

The FAA has broad authority for management of the navigable airspace of the United States and to oversee the safety of U.S. operators, U.S.-registered civil aircraft, and FAA-certificated airmen worldwide. More specifically, the FAA also has an existing regulation that authorizes it to issue temporary flight restrictions in the vicinity of disasters and hazards. See 14 CFR 91.137. Additionally, the FAA has occupational health and safety jurisdiction over most of the working conditions of aircraft cabin crewmembers (including, but not limited to, flight attendants) while they are working on board aircraft in operation. In 2014 FAA entered into an MOU with OSHA, which states that OSHA can apply its occupational safety and health standards regarding hazard communication, bloodborne pathogens exposure, and occupational noise exposure to the working conditions of aircraft cabin crewmembers while they are on board aircraft in operation (except flight deck crew). The FAA also enforces PHMSA's Hazardous Materials Regulations in the aviation mode.

The FAA maintains an agreement with the CDC to ensure the agencies relay notifications of reports they receive regarding deaths, suspected cases of communicable disease, or other public health risks on board aircraft. The agreement also ensures the preparedness and plans for response to such contingencies

The National Highway Traffic Safety Administration (NHTSA), in coordination with CDC and other federal partners, promulgates guidance for prehospital care. Through the Federal Interagency Committee on Emergency Medical Services, NHTSA identifies current practice, training, and equipping issues and in conjunction with federal and private sector partners develops materials and policies to fill those gaps.

## **United States Department of Labor**

OSHA assures safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. OSHA has the authority to provide technical assistance and support to other federal agencies and SLTT agencies, including state-run occupational safety and health programs (state plans), as requested.

OSHA leads implementation of the NRF Worker Safety and Health Support Annex preparedness and response actions to protect response workers. OSHA can provide technical assistance and support to protect response and recovery works workers, including through the following: Risk assessment and management; identification, assessment, and control of health and safety hazards; development and oversight of site health and safety plans; site safety monitoring; worker exposure monitoring, sampling, and analysis; personal protective equipment selection, including respirator fit-testing, and decontamination; and incident-specific worker safety and health training. During a biological incident, CDC should consult OSHA and National Institute for Occupational Safety and Health when working with SLTT senior health officials to protect first responders, first receivers, critical infrastructure/key resource workers, and public health workers.

## Employment Training Administration

ETA administers Federal Government job training and worker dislocation programs, federal grants to states for public employment service programs, and unemployment insurance benefits. These services are primarily provided through state and local workforce development systems.

SLTT governments have primary responsibility for operational coordination (including the private sector) within their respective geographic regions. The Federal Government may either provide support to the individual SLTT entities or have a primary role in coordinating between them. In addition, there is a primary role for the Federal Government in interstate activities involving travel and trade in which transmission of communicable disease may occur.

## State, Local, Tribal, and Territorial Governments

SLTT governments are primarily responsible for detecting and responding to disease outbreaks and implementing measures to minimize the health, social, and economic consequences of such an outbreak. These measures may include, but are not limited to, MCM dispensing, laboratory services, implementation of quarantine and isolation measures, human decontamination, and public messaging.

The primary role of state governments is to supplement and facilitate local efforts before, during, and after disasters. The state provides direct and routine assistance, including public health, medical, and human services, to its local jurisdictions.

## Healthcare Coalitions

Straddling the divide between the local public sector and private healthcare systems are healthcare coalitions. As originally defined, healthcare coalitions are a group of individual healthcare organizations in a specified geographic area that agree to work together to maximize surge capacity and capability during medical and public health emergencies by facilitating information sharing, mutual aid, and response coordination. To meet these goals, healthcare coalitions must be, by default, capable of response and recovery operations.<sup>43</sup>

During a biological incident, all three response objectives are particularly relevant. As an example, response coordination of typically independent private sector organizations can promote consistency in the evaluation and treatment of suspect cases; lack of a consistent approach results not only in inadequate care but also in the potential loss of public confidence in the entire system.

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<sup>43</sup> For detail on healthcare coalitions, see <http://www.phe.gov/preparedness/planning/mscc/documents/mscctier2jan2010.pdf>, accessed Dec. 1, 2016.

## Private Sector

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The private sector public health and medical service organizations and infrastructure provide local response capabilities during a biological incident. Hospitals, nursing homes, and community clinics and doctors; nurses; pharmacists; and trained, certified, or other specialists in public health are all representatives of the public health and medical service infrastructure at the private sector level. Their services, equipment, and advanced technologies assist with the delivery of local biological incident response and recovery capabilities. Non-government medical or disaster relief organizations, including animal care and health professionals (veterinarians, etc.), as well as culture- and faith-based organizations, can also bolster and assist local response capabilities.

## Appendix 3: Intelligence and Surveillance

This appendix summarizes the elements of information, including those related to risk and operational impacts that decision makers must have to accomplish the mission.

### Information, Surveillance, and Sources

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In public health, the term surveillance encompasses all data required to effectively establish an epidemiologic profile of an incident.

Biological incidents possess significant differences to other incidents in relation to the information characteristics required and their sources. For example—

- **Information may take time to establish:** In both intentional and naturally occurring biological incidents, information related to the size and scope of the impacts can take significant periods of time to establish. Parameters such as behavior of a specific pathogen or size of exposed populations are difficult to ascertain initially, and yet immediate decisions are required given the intelligence at a particular time. This requires flexibility to change courses of action during the incident and messaging that reflects the context in which initial decisions were previously made.
- **Information may require lengthy periods of data collection:** Collection of epidemiological data is critical to mount an effective response, which may require significant amounts of time.
- **Information regarding pathogens may change significantly during the incident:** Knowledge about a pathogen, such as its ability to spread or countermeasures that are effective, can change significantly during the incident, requiring major changes in courses of action. This can be a result of new knowledge gained or changes in the actual behavior of the pathogen (e.g., acquired resistance to a countermeasure).
- **Comprehensive surveillance data collection relies substantially on the private sector for source data and public health for collection and analysis:** Biological incident data collection relies substantially on reporting (often from private sector laboratories and clinicians) reported to state, local, territorial, and tribal (SLTT) public health officials who verify case identification and conduct contact tracing and epidemiologic investigation, all of which requires a mix of clinical, laboratory, and epidemiologic data.
- **Information from international partners is critical:** International organizations or foreign governments may have the best and/or most timely information about a developing biological incident. As a result, aligning and maintaining effective and efficient communications with international partners is an essential part of information collection.

### Initial Incident Identification

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Biological incident recognition can occur in a continuum or variety of manners with either significant or no warning (e.g., overseas origin). The intelligence or information necessary to

permit recognition can come from multiple sources and can come in multiple forms, including, in many instances, initial information that requires deliberative verification adding time to recognition.

The Federal Government provides support for external communications through the activation of Emergency Support Function (ESF) #15: External Affairs. However, unique communication resources do exist, specific to biological incidents or incidents that pose a threat to public health.

**Table 7: National-Level Incident-Specific Communications Resources**

Information Sharing Process	Description
BioWatch National Conference Call	Occurs within 2 hours of the BioWatch Actionable Result (BAR) declaration and after the local jurisdictional BioWatch Advisory Committee (BAC) call. It begins with a summary of laboratory testing data and a summary of the current local situation by the BAC chair and other local public health, law enforcement, and emergency management representatives to provide situational awareness of follow-on activities and potential requests for assistance from other federal agencies (DHS, CDC, FBI, EPA, or the SNS) and a decision regarding the next conference call time.
Clinician Outreach and Communication Activity (COCA)	Provides timely, accurate, and credible information to clinicians related to emergency preparedness and response and emerging public health threats. COCA fosters partnerships with national clinician organizations to strengthen information-sharing networks before, during, and after a public health emergency.
National Security Council (NSC) Process	Coordination can occur for a biological incident through the process outlined in Presidential Policy Directive–1. The NSC is the President’s principal means for coordinating the implementation of national security policy. The Principals Committee is the senior interagency forum for national security policy issues. The Deputies Committee is responsible for day-to-day crisis management. Interagency Policy Committees manage the development and implementation of policy.
Health Alert Network (HAN)	CDC’s primary method of sharing public health information with public information officers, federal and SLTT-area public health practitioners, clinicians, and public health laboratories. There are jurisdictional HAN programs from 50 states and the District of Columbia and 8 territories, as well as Chicago, Los Angeles, and New York City metropolitan areas.
HHS Public Affairs Conference Line (PACL)	Provides a conference line to allow telephone connectivity for public affairs staff supporting ESF #8. This conference line provides HHS public affairs personnel to work from dispersed sites during the crisis yet be able to receive guidance or direction or to provide information to those needing it.
National Incident Coordination Conference Line (NICCL)	While DHS traditionally leads the NICCL for transmission and exchange of critical and timely incident information among federal authorities, HHS, when needed, can coordinate communications information related to the public health and medical aspects of a response, particularly in a public health specific emergency such as a pandemic disease.
National Public Health Information Coalition (NPHIC)	Leverages a network of state and local public health communicators to exchange information and increase the likelihood of consistent messaging and communication activities between federal and SLTT-area governments regarding the emergency and its impact on health.
National Biosurveillance Integration System (NBIS) Protocol	Mechanism to bring federal NBIS partners together on a short-notice teleconference to share information on a potentially significant biological incident. It can be initiated at the request of any NBIS partner and is an example of a unique capability of the NBIC that helps enable national biosurveillance integration. The Protocol is activated when a situation meets one or more of the threshold criteria and is requested by a NBIS agency.
National Biosurveillance Integration Center	NBIC produces a daily Monitoring List that is distributed to over 1,700 federal, state, and local government stakeholders, as well as congressional staff members, and is intended to inform agencies of high priority, new, and ongoing events that NBIC is currently tracking.

<b>Information Sharing Process</b>	<b>Description</b>
(NBIC) Products and Services	NBIC also produces Biosurveillance Event Reports to provide an in-depth assessment of key developments, unusual characteristics, and risks associated with a high-priority biological event. The Biosurveillance Event Reports, updated as appropriate as the situation evolves, are distributed to a similar audience as the Monitoring List in addition to being made available through various secure government portals. Spot Reports are a third product and are designed to provide one-time, rapid communication of a high-priority event but offer no subsequent updates. Both the Biosurveillance Event Reports and Spot Reports are produced as needed rather than on a regular production schedule.
Epidemiologic Data	Sources of information may include clinical, epidemiologic, and laboratory data from different sources such as providers/private sector, local, state, and federal public health entities.
Epidemic Information Exchange (EpiX)	Epi-X is a web-based communications solution for public health professionals. Through Epi-X, CDC officials, state and local health departments, poison control centers, and other public health professionals can access and share preliminary health surveillance information—quickly and securely. Users can also be actively notified of breaking health events as they occur. Key features of Epi-X include unparalleled scientific and editorial support, controlled user access, digital credentials and authentication, rapid outbreak reporting, and peer-to-peer consultation.

Once verified, a critical United States Government (USG) action is disseminated across the relevant federal, SLTT, and private sector partners so that information is appropriately shared. Examples are included in the following table.

**Table 8: Identification of a Biological Incident**

<b>Source of Information</b>	<b>Examples of Initial Information Received</b>	<b>Verification Processes</b>	<b>Methods of Information Sharing</b>
Individual practitioner or healthcare facility laboratory	<ul style="list-style-type: none"> <li>Suspected sentinel case reported through local public health</li> <li>Confirmed sentinel case reported through local public health</li> </ul>	<ul style="list-style-type: none"> <li>Private sector, LRN, or CDC laboratory confirmation may be required</li> </ul>	HAN, NPIC, COCA
Individual facility, local or state health department surveillance systems	<ul style="list-style-type: none"> <li>Influx of patients with similar symptoms indicating potential new disease pathogen</li> </ul>	<ul style="list-style-type: none"> <li>Private sector, LRN, or CDC laboratory confirmation may be required</li> <li>Epidemiologic investigation to confirm patterns of similarity</li> </ul>	HAN, NPIC, COCA
Identification of novel or atypical pathogen in federal, SLTT, or private sector laboratory	<ul style="list-style-type: none"> <li>Individual not originally suspected but “surprise” diagnosis received through secondary testing</li> </ul>	<ul style="list-style-type: none"> <li>Private sector, LRN, or CDC laboratory confirmation may be required</li> </ul>	HAN, NPIC, COCA, NPHIC, PACL, NBIS Protocol
Novel emerging or reemerging infection reported by international	<ul style="list-style-type: none"> <li>New pathogen or pathogen of concern evolving in a situation</li> </ul>	<ul style="list-style-type: none"> <li>Multiple international partners as well as international</li> </ul>	HAN, NPIC, COCA, NPHIC,

<b>Source of Information</b>	<b>Examples of Initial Information Received</b>	<b>Verification Processes</b>	<b>Methods of Information Sharing</b>
partners or USG stakeholders operating in a foreign country under international health regulations from overseas source	in which spread to United States is possible	assistance provided by USG	PACL, NBIS protocol, IHR
Zoonotic outbreak identified by private sector, SLTT, or federal providers or laboratories	<ul style="list-style-type: none"> <li>Zoonotic pathogen identified in an animal population with potential for causing concerning human disease</li> </ul>	<ul style="list-style-type: none"> <li>USDA, CDC, SLTT, NAHLN, or private sector laboratory confirmation all possible</li> </ul>	HAN, NPIC, COCA, NPHIC, PACL, NBIS Protocol
Law enforcement intelligence	<ul style="list-style-type: none"> <li>Credible threat of deployment of pathogen of concern</li> </ul>	<ul style="list-style-type: none"> <li>Law enforcement investigations paired with public health expertise</li> </ul>	LES Bulletin, NSC Process, NICCL
Public media	<ul style="list-style-type: none"> <li>Announced release of pathogen of concern</li> </ul>	<ul style="list-style-type: none"> <li>Multiple entities/processes at various levels potentially involved</li> </ul>	NSC/DC Process, NICCL, follow on HAN, NPIC, COCA, NPHIC, PACL
BioWatch or other environmental sampling	<ul style="list-style-type: none"> <li>Pathogen of concern detected in environment leading to a BioWatch Actionable Result or BAR</li> </ul>	<ul style="list-style-type: none"> <li>BioWatch has internal verification processes and may conduct additional sampling</li> <li>If another environmental sample, may require USG support to SLTT sample to verify</li> </ul>	BioWatch National Conference Call, NSC Process, NICCL, follow on HAN, NPIC, COCA, NPHIC, PACL, NBIS Protocol

A critical initial consideration regarding any identified pathogen is whether or not it is contagious. Contagious diseases capable of person-to-person spread or spread between people and animals significantly alter the approach to response at all levels. In addition, there are various methods of spread, and degrees of infectivity, viability, and virulence which may not be known initially. Risk communication will be contingent upon some of these most basic attributes of the pathogen and any intelligence or information related to these parameters will be a priority.

Other initial critical elements of information may not be available in a comprehensive fashion but should serve as an early focus on information efforts:

- **Intentional incident:** Some incidents may at first glance appear natural but could in fact be intentional. It is government policy to consider all biological incidents as intentional until proven otherwise.
- **Area and size of population impacted:** Though it is rare that this will be known during initial epidemiologic investigations, initial estimates can at times be developed. An

important parameter often overlooked during novel pathogen outbreaks is that the denominator of exposed patients is rarely known, which can skew mortality and morbidity rates, making a pathogen appear more virulent than is real.

- **Populations at risk:** Early epidemiologic information can provide insight to particular populations at risk (hence requiring information, countermeasures, etc.). For examples, extremes of age, individuals in particular vocations, or individuals with particular travel histories can all be early indicators of risk.
- **Available treatment/prophylaxis:** Establishing early indication of available treatment/prophylaxis, or lack thereof, is critical in shaping not only response actions but also messaging.
- **Non-pharmaceutical intervention (NPI) effectiveness:** Establishing early recommendations regarding NPI's, including personal protective equipment can be important but must be shaped in the context of what is initially known about the pathogen and the fact that it may change as more knowledge becomes available.

Ongoing situational assessment, as mentioned above, will have a heavy reliance on data from the private sector and SLTT entities. The summary and analysis of this data is essential for tailoring the USG response. In addition, the USG can apply resources not always available at SLTT levels of response such as comprehensive geographic information systems mapping.

The goal of collecting epidemiologic, clinical, laboratory, and environmental data is to help drive the appropriate response to a biological incident. Although not complete, below is a list of some public health data points that could help drive decision making in response to a biological incident.

- Numbers of confirmed cases
- Numbers of suspected cases
- Numbers of exposed cases
- Morbidity and mortality rates
- Geographic locations of cases
- Zoonotic potential and properties (e.g., affected species, etc.)
- Environmental sampling
- Changes to assumed characteristics of agent (e.g., enhanced resistance, change in spread)
- Public health recommendations (updated as additional information is collected)
- Public health authority actions implemented (and effectiveness in limiting spread versus social disruptions/costs)
- Deployment of resources
- Resource limitations (medical equipment, personnel, pharmaceuticals, vaccines)
  - At SLTT level
  - At federal level (for self-protection/continuity of operations plan)
- Areas of environmental contamination
- Infrastructure and economic impacts
  - Primary: caused by disease itself
  - Secondary: caused by implementation of public health actions

The USG also has a significant role in conducting surveillance and supporting SLTT surveillance efforts. Examples of the numerous surveillance systems and information sources that help to create a common operating picture during a biological incident are listed in **Figure 8**.

The Integrated Consortium of Laboratory Networks (ICLN) shown in **Figure 9** provides for a federally coordinated and interoperable system of laboratory networks that provide timely, credible, and interpretable data in support of surveillance, early detection, and effective consequence management for acts of terrorism and other major incidents requiring laboratory response capabilities. The ICLN is a partnership between nine federal agencies: Department of Defense (DoD), Department of Agriculture, Department of Energy, Department of Health and Human Services, Department of Homeland Security, Department of Interior, Department of Justice, Department of State, and Environmental Protection Agency. The ICLN includes the following networks: DoD Laboratory Network (DLN), Environmental Response Laboratory Network (ERLN), Food Emergency Response Network (FERN), Laboratory Response Network (LRN), National Animal Health Laboratory Network (NAHLN), National Plant Diagnostic Network (NPDN), and the Veterinary Laboratory Investigation and Response Network.

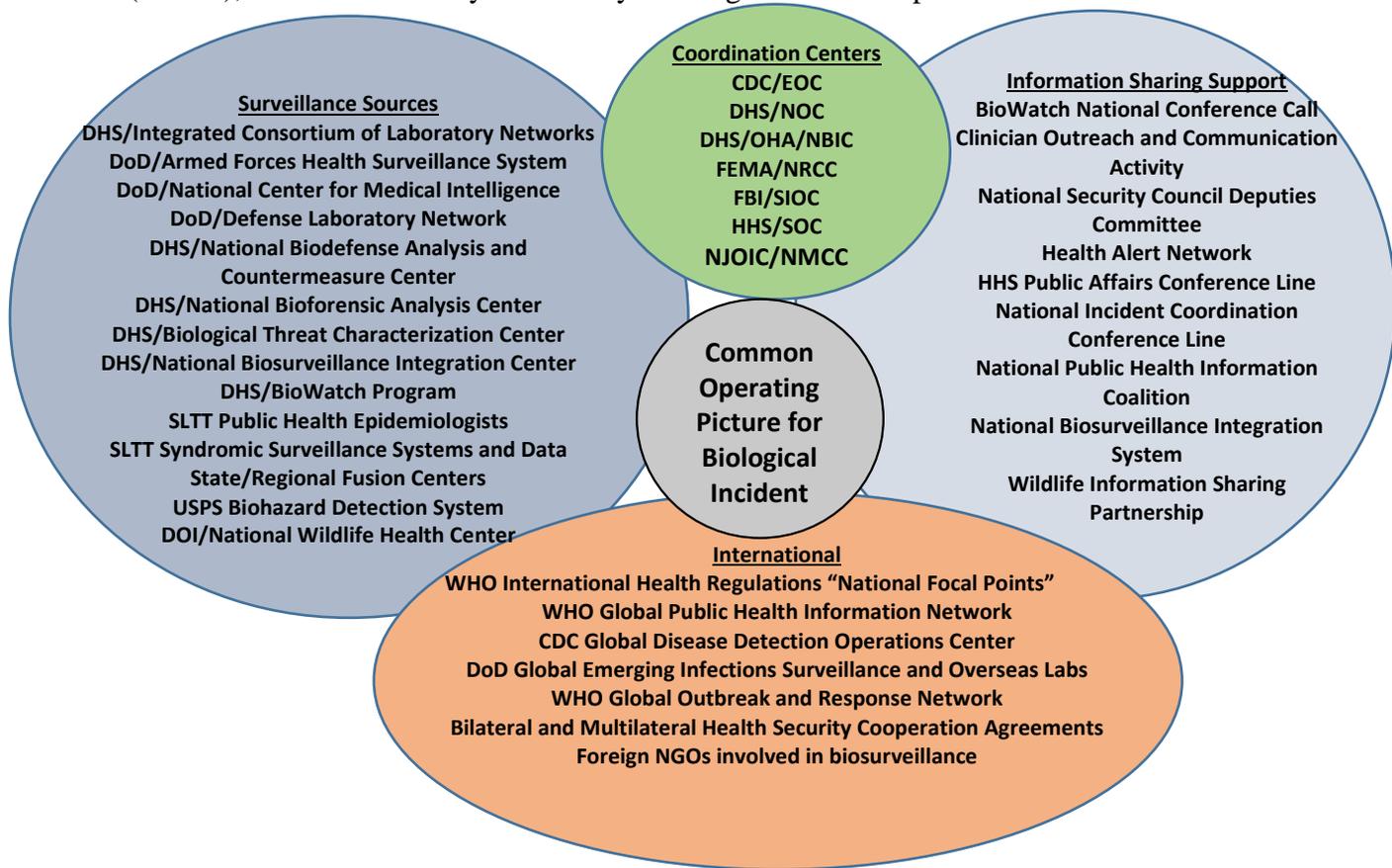


Figure 5: Surveillance and Information Sources

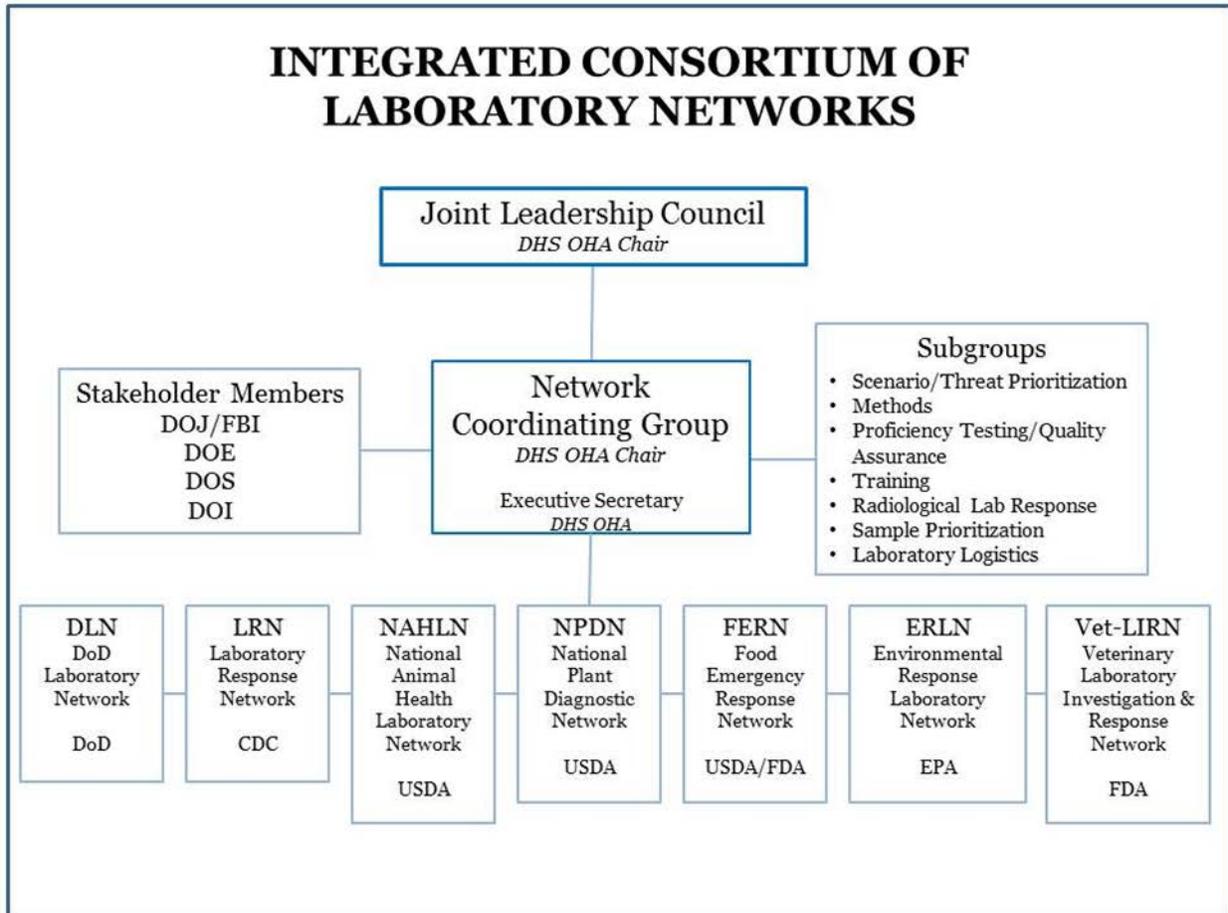


Figure 6: Description of Laboratory Networks

Table 9: Description of Laboratory Networks

Lab Network	Description
LRN	The LRN and its partners maintains an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies.
ERLN	Provides consistent analytical capabilities, capacities, and quality data in a systematic, coordinated response. ERLN integrates capabilities of existing public sector laboratories with accredited private sector labs to support environmental responses. EPA's ERLN is solely dedicated to the testing of environmental samples.
NAHLN	Nationally coordinated network and partnership of federal, state, and university-associated animal health laboratories. NAHLN laboratories provide animal health diagnostic testing, methods research and development, and expertise for education and extension to detect biological threats to the nation's animal agriculture, thus protecting animal health, public health, and the nation's food supply.
NPDN	Provides a cohesive, distributed system to quickly detect and identify pests and pathogens of concern. NPDN laboratories immediately report their findings to appropriate responders and decision makers. To accomplish this mission, the NPDN

<b>Lab Network</b>	<b>Description</b>
	has invested in diagnostic laboratory infrastructure and training, developed an extensive network of first detectors through education and outreach, and enhanced communication among public agencies and stakeholders responsible for responding to and mitigating new outbreaks.
FERN	Integrates the nation’s food-testing laboratories at the federal and SLTT levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. The FERN structure is organized to ensure federal and state inter-agency participation and cooperation in the formation, development, and operation of the network.
DLN	A DoD forum that allows DoD laboratories, programs, and activities with analytic or response capabilities to coordinate execution, develop consensus, and make recommendations governing the detection; identification, characterization, and diagnosis; and reporting of chemical, biological, radiological, and nuclear (CBRN) agents; infectious diseases; and other all-hazards agents of military or national significance in support of the DoD’s global and homeland defense missions.

## Appendix 4: Support and Coordination Elements

To facilitate federal interagency coordination and information sharing during a biological incident, several support and operational coordination elements are utilized. These elements, combined with the assets, resources, and teams identified in **Appendix 6**, represent unique or critical federal biological capabilities that support federal, state, and local response and recovery operations.

### Interagency Modeling and Atmospheric Assessment Center

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The Interagency Modeling and Atmospheric Assessment Center (IMAAC) is an interagency coordination element responsible for production, coordination, and dissemination of federal atmospheric dispersion modeling and hazard predictions for an airborne hazardous material release. The IMAAC provides the single federal consensus on atmospheric predictions of hazardous material concentration to all levels of the incident command and national response organizations. This capability is achieved through a partnership of the Department of Homeland Security (DHS), Department of Defense (DoD), Department of Health and Human Services (HHS), and Department of Commerce (through the National Oceanic and Atmospheric Administration), the Environmental Protection Agency (EPA), Department of Energy (DOE)/National Nuclear Security Administration (NNSA), and the Nuclear Regulatory Commission. Through plume modeling analysis, IMAAC provides emergency responders with predictions of hazards associated with atmospheric releases to aid in the decision-making process to protect the public and the environment.

DHS/Federal Emergency Management Agency (FEMA) is the federal agency responsible for the IMAAC program. The Defense Threat Reduction Agency, in cooperation with DHS/FEMA, runs the IMAAC Technical Operations Hub and is responsible for coordinating and disseminating chemical, biological, radiological, nuclear, and high-yield explosives (CBRNE) modeling products.

### Environmental Clearance Committee

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The Environmental Clearance Committee (ECC) is an optional independent group of experts that conducts a comprehensive review of the overall remediation process to make recommendations on whether clearance goals have been met. Members of the ECC are typically representatives from the local, county, and/or state public health agencies; the facility or property owner; local government; and subject matter experts from the Federal Government. The decision that clearance goals have been met will be made through unified command, with input from the

Centers for Disease Control and EPA. The final decision on clearance is usually made by the lead local health agency.<sup>44</sup>

## **Domestic Emergency Support Team**

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The Domestic Emergency Support Team (DEST) is a specialized, rapidly deployable interagency team that augments the Federal Bureau of Investigation (FBI) Joint Operations Center (JOC). As part of its mission, the DEST supports the FBI On-Scene Commander and other officials to integrate and prioritize consequence management decisions within the operational space of the Prevention Mission. The Team supports the FBI On-Scene Commander through a JOC Weapons of Mass Destruction Desk and maintains connectivity with the JOC Consequence Management Group and the Consequence Management Coordination Unit (CMCU). The DEST also provides the FBI On-Scene Commander with expert advice and guidance to shape Prevention operations in order to save lives and protect property. Team composition includes a ready roster from FEMA, FBI, DoD, HHS-Assistant Secretary for Preparedness and Response, DOE, EPA, and others as may be appropriate. Based upon the threat and requirements, the FBI determines the composition of the DEST and maintains operational control throughout its activation predicated upon an interagency developed proposed composition. The FEMA Administrator is responsible for policies and planning governing the Team and for facilitating approval for its deployment.

## **Weapons of Mass Destruction Strategic Group**

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When facing weapons of mass destruction (WMD) terrorist threats, the FBI-led Weapons of Mass Destruction Strategic Group (WMDSG) crisis action team is activated within the Strategic Information and Operations Center. It supports information exchange and deconfliction of counterterrorism activities to resolve imminent WMD terrorist threats while simultaneously coordinating with the nationwide effort to save lives and protect property. The WMDSG, through its collection of interagency representatives, facilitates the application of real-time investigative information, intelligence, and technical analysis to WMD counterterrorism (WMD-CT) law enforcement operations; facilitates the identification and acquisition of interagency assets that could support WMD-CT law enforcement operations; and enhances WMD-CT investigative information/intelligence sharing and synchronization of law enforcement operations with counterterrorism-related public health, homeland protection, and consequence management activities. The WMDSG, with its collaborative environment and through the dissemination of WMD Threat Profile products, contributes to the promotion of risk-informed operations and decision making at all levels of the counterterrorism response, including federal and state, local, territorial, and tribal law enforcement, public health, border security, and international partners. The WMDSG connects with the FBI field division(s) and appropriate local/regional partners through the JOC(s).

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<sup>44</sup> Federally owned and operated facilities are managed primarily by the unified command, to include CDC and EPA

## **Consequence Management Coordination Unit**

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FEMA staffs and manages the CMCU, which is the principal advisory unit for consequence management considerations within the WMDSG and provides strategic recommended and integrated courses of action in light of ongoing and evolving counterterrorism operations. The CMCU links operational coordination and information sharing to DHS and sector-specific agencies' response and protection activities. The CMCU is supported by federal technical capabilities provided through DOE/NNSA, HHS, DoD, and DHS. The CMCU responsibilities include—

- Coordination of the identification of potential risks for impacted populations.
- Identification of potential preparatory actions to reduce those risks to life and property by lessening the impact of the event.
- Positioning the response community to be able to respond should the event occur.

## Appendix 5: Incorporation of Public Health Functional Elements within Incident Management for a Biological Incident Response

Biological incident response is most commonly managed by public health authorities at the state local, tribal, and territorial (SLTT) levels, with additional support from other entities as required (e.g., assistance from other disciplines, mutual aid, and U.S. Government support). Response to unusual biological incidents that are widespread, rapidly expanding, involve significant morbidity and mortality, and/or have deliberate causation can be complex. Effective and timely management requires expansion of functional capabilities within incident management and multi-agency coordination systems such as those at multiple SLTT levels, Joint Field Offices, or federal department operations centers. The activities at each incident management level and location can vary significantly and cross multiple organizations, including the private sector. Informed decision making requires data acquisition from varied and disparate sources, with rapid processing from data to information to understanding the current situation and, more importantly, to projecting the evolving situation so that effective actions can be initiated and coordinated across the incident.

Various incident management entities have adopted models for management of biological incidents based on the Incident Command System (ICS), which is designated by the National Incident Management System (NIMS) for all domestic response emergency operations. A standard organizational chart utilized in ICS is presented in **Figure 10**. ICS provides a consistent methodology and organizational construct for management of complex response systems. It is meant to be flexible and scalable to adapt to the response parameters, as encountered.

Few of the currently published models, however, clearly demonstrate how the model system will manage the wide range of complexities during a large-scale, rapidly evolving, high-impact biological incident. This appendix outlines one published model of how the incident command structure construct could be applied at the incident management level or adapted for multiagency coordination. It is not intended to be proscriptive but rather to be illustrative in outlining potentially all necessary functions that would require coordination in an exceedingly complex biological incident. This model may be helpful to federal responders supporting SLTT operations. Consistent with ICS principles, the model is designed to be scalable and flexible and applicable at both the Incident Management Team and Multiagency Coordination Center levels, with not all functions being required; different organizational groups or task forces may be required depending on each incident and the progression through incident response (i.e., based on need, positions may be staffed and demobilized at various points throughout an incident). The model is summarized below and reproduced with permission. More details may be found at the web link in the reference note.<sup>45</sup>

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<sup>45</sup> Barbera J.A., Macintyre A.G. Medical and Health Incident Management (MaHIM) System: A Comprehensive Functional System Description for Mass Casualty Medical and Health Incident Management. Institute for Crisis, Disaster, and Risk Management, The George Washington University. Washington, D.C., October 2002. Supported by a grant from the Alfred P. Sloan Foundation.

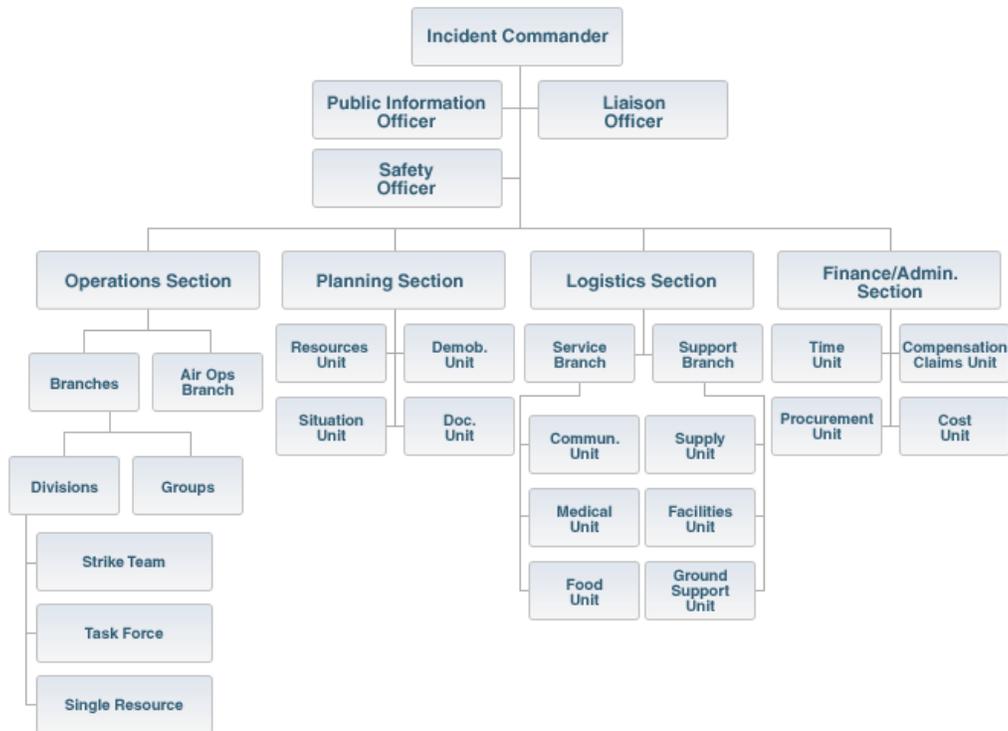


Figure 7: ICS Organizational Chart

## Medical and Health Incident Management<sup>46</sup>

In developing the Medical and Health Incident Management (MaHIM) model, investigators first identified and examined medical and public health response to a range of mass casualty incidents. They identified recurring issues that challenge effective coordination of the disparate entities working in the response effort. An engineered decomposition of each response was conducted to understand and describe the critical tasks needed to successfully manage complex, widespread incidents such as a rapidly evolving widespread bioterrorism attack. Using ICS principles, the functions necessary for emergency response and early recovery were then organized into the MaHIM model. In addition to a functional construct, the MaHIM system includes an action planning process to effectively operate under the time urgency, uncertainty, and high-commitment decision-making context of a major emergency situation. Though intended to be an all-hazards model, MaHIM is particularly suited to complex biological incident response.

Important elements described in the model include a concept of operations as to how the system is mobilized, functions during response, and is then demobilized as the incident winds down. For

<sup>46</sup> The complete [Medical and Health Incident Management \(MaHIM\) System: A Comprehensive ICS Response Organization for Mass Casualty and Mass Effect Incidents](#) can be found on the George Washington University web site.

the purposes of this annex, only the functional breakdown of incident activities is presented, to inform the reader of the potential complex set of actions involved in biological incident response. Furthermore, only the core functions of “Management,” “Operations,” “Logistics,” and “Planning” are described here. “Finance/Administration” and the processes that facilitate the interaction of these functions are further described in the reference document Medical and Health: “Management.”

As noted above, biological incident response at the incident management level will most commonly involve management by the relevant public health authority. The authors of the model chose “management” as opposed to “command” to describe this set of activities due to the nature of the multiple organizations participating in the model system (some from other disciplines, others from the private sector). The “Management” function is responsible for all strategic biological incident response issues utilizing a management by objective approach, based on the prospective establishment of incident and operational period objectives, which are constantly evaluated and revised throughout incident action planning operations. For some biological responses, “Management” could be unified in nature, using the ICS unified command principles, but relevant public health authorities usually function as the lead agency. An example of unified command including federal departments with an SLTT agency as the lead agency is the widely praised 9-11 response to the Pentagon attack. Arlington County, Virginia's Fire and Rescue Department was lead, with the Federal Bureau of Investigation, Department of Defense, and Federal Emergency Management Agency also participating in management level decision-making.

## **Medical and Health: “Operations Section”**

The “Operations Section” encompasses all activities that are necessary to directly achieve the strategic goals and objectives as established by “Management.” As **Figure 8** below demonstrates, this can span a wide variety of capabilities that address medical and health delivery of care, resource staging, disease containment, and other required operations. As an example, the “Incident Epidemiological Profiling” Group is comprised of all activities designed to identify, track, and understand an incident from a health perspective and provide the foundation to project forward for the purpose of decision making. This Group's activities include tracking of individual suspected and confirmed patients, diagnostic data from a wide range of sources (including law enforcement and other non-medical laboratories), animal surveillance, and environmental assessments. Importantly, all data is collected and reported up to a single node, designed for timely processing from data to actionable information for informed decision making and action implementation by senior incident managers and involved agencies.



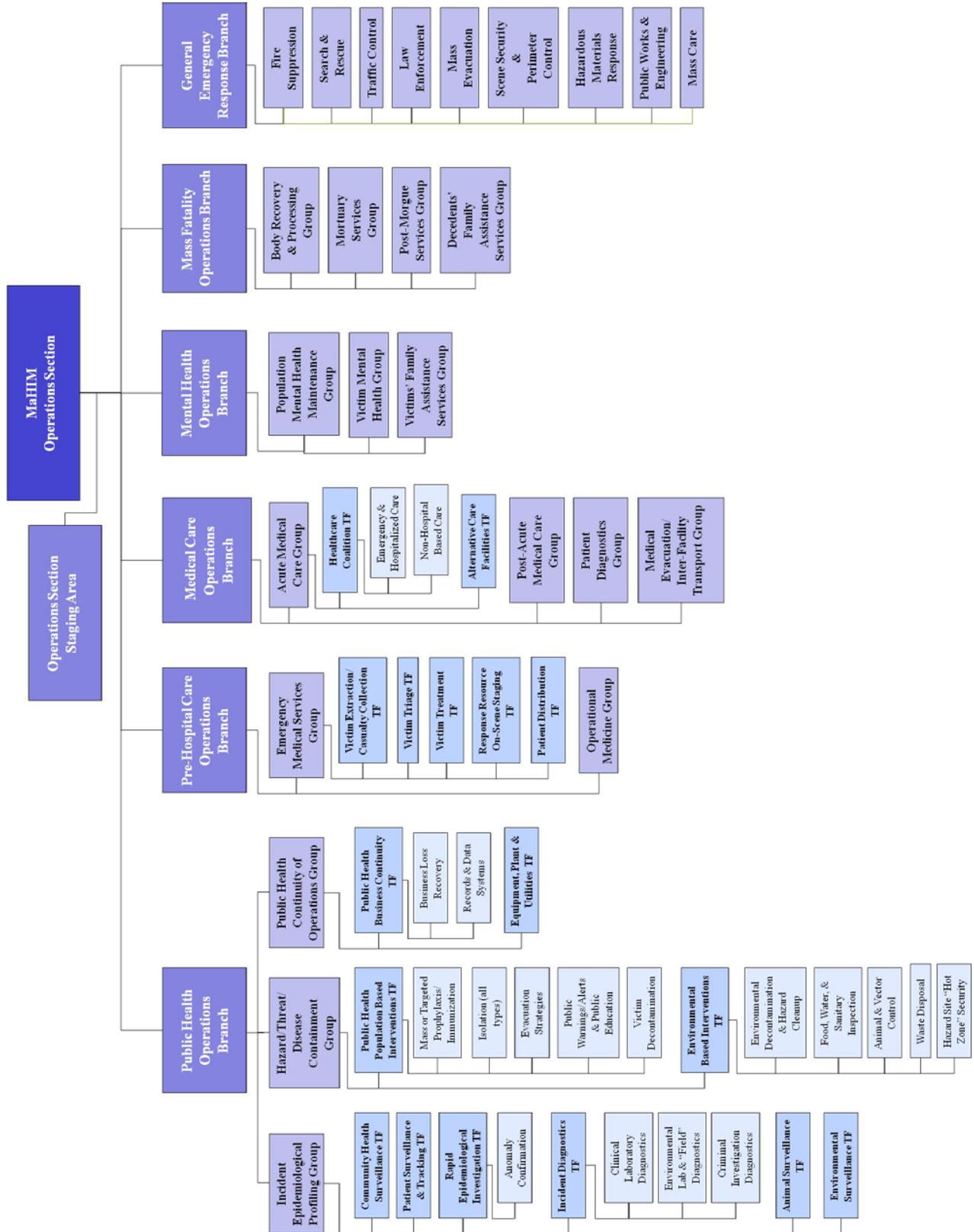


Figure 8: Operations Section Span of Capabilities

A key element in biological disease response is disease containment, designed to protect the unaffected population from exposure to factors that cause additional illness, death, and spread of illness or injury. This is especially important with contagious disease agents. A sub-function was specifically developed for this complex task and inclusively titled “hazard/threat/disease containment.” For biological incidents, containment likely requires resources from a variety of organizations collectively coordinated to conduct both population and environmentally based interventions. Another frequently overlooked capability is one that addresses mass fatalities, which may need to be bolstered with a Mass Fatality Operations Group designated to manage resources in support of the medical examiner, coroner facilities, acute healthcare organizations and family assistance services that may otherwise be overwhelmed.

Animal care needs resulting from owners and caretakers of animals in households and congregate animal facilities (including zoos, wildlife rehabilitators, breeders, and others) being incapacitated as a result of the biological incident must be considered to ensure humane care and mitigate cascading effects in the incident.

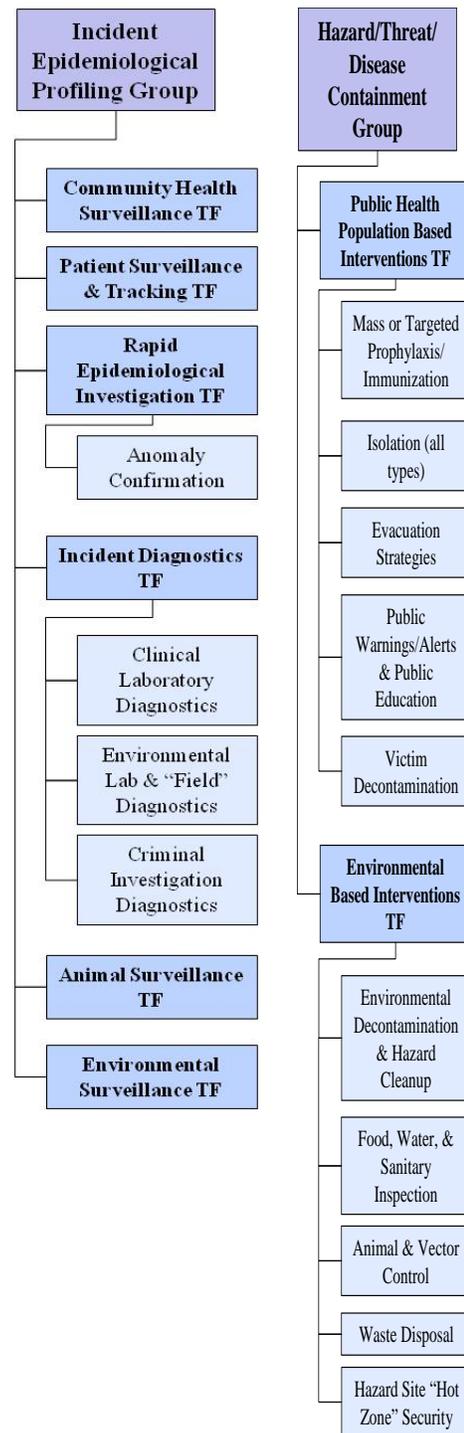


Figure 9: Public Health Operations Subgroups

## Medical and Health: “Planning Section”

The responsibilities of the MaHIM planning section, as described, in the revised version after the publication of NIMS in 2004, extend the usual functions of the ICS Planning Section to address the complexities of public health and medical incidents.

Recognizing the complexity of planning during large-scale biological and other unusual health incidents, a Planning Development and Assessment Unit was described. A critical activity for this unit is contingency planning: dedicated efforts to examine potential sudden changes or surges in secondary impacts and resource demands, followed by the development of initial plans to address these situations. Application of some of these planning principles at the SLTT level could come via contributions from the emergency management community, which is often practiced in adhering to a planning cycle during each operational period, providing a continuous, disciplined method for determining leadership direction, defining incident objectives, establishing organizational constructs, analyzing courses of action, and assigning and tracking the execution of tasks to meet approved objectives.

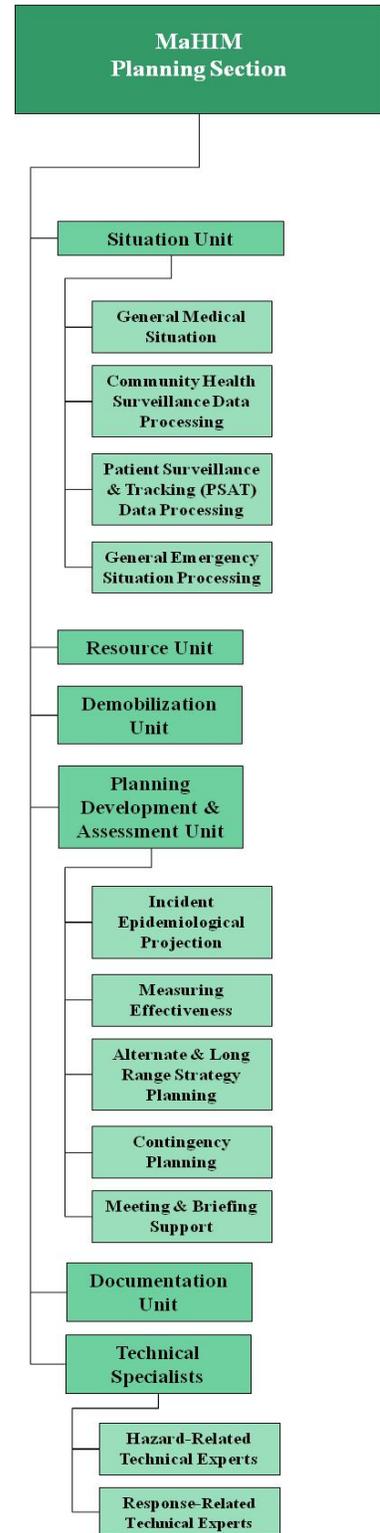


Figure 10: Planning Section

## Medical and Health: “Logistics Section”

The Logistics Section is charged with identifying and acquiring capabilities and other activities to support MaHIM System operations. This section may be expanded to address the acquisition and transportation of personal protective equipment, consumable medical supplies, medical countermeasures, and medical equipment. Medical personnel utilized in any response may require credentialing beyond usual registration, badging, and in-briefing.

These functions may exist at multiple levels within SLTT, regions or, potentially, even at the national level. Readers are encouraged to review the model for potential application as appropriate.

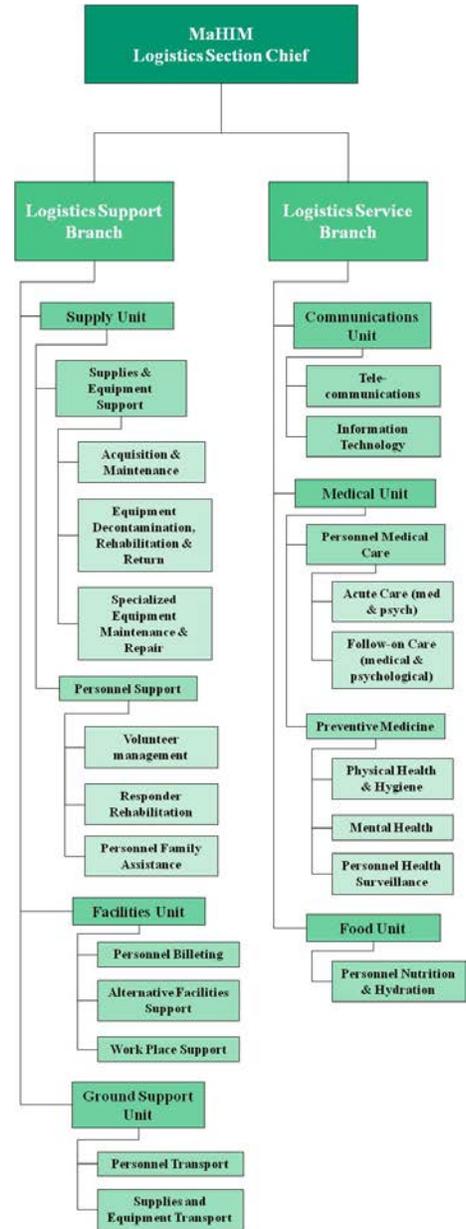


Figure 11: Logistics Section

## Appendix 6: Federal Response Capability Inventory – Biological-Specific Assets, Resources, and Teams

This appendix lists the resources that may be utilized in a biological incident; it is not meant to assign responsibility to any one agency or organization.

Organization	Resource Name	Description
USDA	Animal and Plant Health Inspection Service (APHIS)	Provides technical assistance and assists in coordinating with nonprofit and private organizations and government departments or agencies to support the rescue, care, shelter, and essential needs of owners and their household pets and service and assistance animals. Depending on the incident type, APHIS will coordinate with HHS, EPA, USACE, and/or FEMA to provide technical advice regarding disposal of animal carcasses.
USDA	Disaster Supplemental Nutrition Assistance Program (D-SNAP)	Through the D-SNAP, Food and Nutrition Services is able to quickly offer short-term food assistance benefits to families suffering in the wake of a disaster. Through D-SNAP, affected households use a simplified application. D-SNAP benefits are issued to eligible applicants within 72 hours, speeding assistance to disaster survivors and reducing the administrative burden on state agencies operating in post-disaster conditions.
USDA	National Animal Health Laboratory Network (NAHLN)	NAHLN laboratories perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for foreign animal diseases, protecting human health by decreasing the risk of zoonotic diseases (those that can affect animals and humans).
USDA	National Veterinary Stockpile	When a veterinary response is required, assets may be requested from the National Veterinary Stockpile, which is managed by USDA APHIS as a resource to address foreign animal disease in livestock and poultry.
DHS	BioWatch	BioWatch system consists of units that collect air samples in more than 30 cities and a network of local, state, and federal laboratories that analyze samples on a daily basis with a goal of providing warning of possible biological attacks within 12 to 36 hours of an agent's release. BioWatch has conducted 37 laboratory and 20 field audits to date. For more than 10 years, BioWatch has operated 24 hours a day, 365 days a year.
DHS	Domestic Communication Strategy	The Domestic Communication Strategy is a guidebook that provides options for public information strategies, complementing existing federal plans and strategic guidance documents, which may be employed in a domestic terrorist attack or a credible threat to the homeland.
DHS	Integrated Consortium of Laboratory Networks (ICLN)	ICLN provides for a federally coordinated and interoperable system of laboratory networks that provide timely, credible, and interpretable data in support of surveillance, early detection and effective consequence management for acts of terrorism and other major incidents requiring laboratory response capabilities. The ICLN is a partnership between nine federal agencies: Department of Defense (DoD), Department of Agriculture, Department of Energy, Department of Health and Human Services, Department of Homeland Security, Department of Interior, Department of Justice, Department of State, and Environmental Protection Agency. The ICLN includes the following networks: DoD Laboratory Network, Environmental Response Laboratory Network, Food Emergency Response Network, Laboratory Response Network, National Animal Health Laboratory Network, National Plant Diagnostic

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
		Network, and the Veterinary Laboratory Investigation and Response Network.
DHS	National Bioforensic Analysis Center (NBFAC)	Conducts bioforensic analysis of evidence from a biocrime or terrorist attack to attain a “biological fingerprint” to help investigators identify perpetrators and determine the origin and method of attack. NBFAC is designated by Presidential Directive to be the lead federal facility to conduct and facilitate the technical forensic analysis and interpretation of materials recovered following a biological attack in support of the appropriate lead agency.
DHS	National Biological Threat Characterization Center	Conducts studies and laboratory experiments to fill in information gaps to better understand current and future biological threats, to assess vulnerabilities and conduct risk assessments, and to determine potential impacts to guide the development of countermeasures such as detectors, drugs, vaccines, and decontamination technologies.
DHS	National Biosurveillance Integration System (NBIC)	The mission of NBIC is to enhance the capability of the Federal Government to— <ul style="list-style-type: none"> <li>• Rapidly identify, characterize, localize, and track a biological incident of national concern.</li> <li>• Integrate and analyze data relating to human health, animal, plant, food, water, and environmental domains.</li> <li>• Disseminate alerts and pertinent information.</li> <li>• Oversee development and operation of the National Biosurveillance Integration System interagency community.</li> </ul>
DHS	Surge Capacity Force	DHS Surge Capacity Force is organized into four tiers, for the purpose of prioritizing and providing for an informed selection of deployable human assets: <ul style="list-style-type: none"> <li>• Tier 1 – is comprised of FEMA Reservists with FEMA credentials.</li> <li>• Tier 2 – is comprised of FEMA Permanent Full-Time Employees with FEMA credentials.</li> <li>• Tier 3 – Is comprised of DHS full-time federal employees.</li> <li>• Tier 4 – Is comprised of full-time or part-time federal employees from other federal departments and agencies.</li> </ul>
DHS (CBP Laboratories and Scientific Services)	Weapons of Mass Destruction Response Teams	Provides level “A” hazardous material technical response capabilities.
DHS (NPPD)	Sector Specific Agency – HHS has area of responsibility for Healthcare and Public Health	The Sector Outreach and Programs Division builds stakeholder capacity and enhances critical infrastructure security and resilience through voluntary partnerships that provide key tools, resources, and partnerships. The division operates the council and stakeholder engagement mechanisms for the critical infrastructure security and resilience community. The division also serves as the sector-specific agency for 6 of the 16 critical infrastructure sectors and collaborates with the other 10.
DHS (NPPD/Federal Protective Service)	Hazardous Response Program	This program includes initial investigations of suspicious or threatening chemical, biological, radiological, nuclear, and explosive (CBRNE) incidents; conduction of CBRNE threat assessments; confirmations of unauthorized presence of CBRNE agents and materials; and the conduction of emergency operations. The Hazardous Response Program also provides evacuation support during CBRNE incidents, CBRNE mutual aid response through agreement and training assistance. The program is compliant with Occupational Safety and Health Administration and National Fire Protection Association guidance and regulations.

Organization	Resource Name	Description
DHS (FEMA)	Consequence Management Coordination Unit (CMCU)	In response to notification of a terrorist threat or actual incident, FEMA will activate the CMCU in support of FBI-led crisis management operations at the Weapons of Mass Destruction Strategic Group (WMDSG). Within the WMDSG, the FEMA staffs and manages the CMCU. This unit is also supported by federal technical capabilities provided through the DOE/NNSA, HHS, DoD, and DHS. As the principal advisory unit for consequence management considerations within the WMDSG, the CMCU provides recommended courses of action in light of ongoing and evolving operations. The CMCU provides a link between FBI-led crisis response and FEMA-coordinated consequence management response operations.
DHS (FEMA), DOJ (FBI), DoD, HHS, EPA	Domestic Emergency Support Team (DEST)	A rapidly deployable, interagency team responsible for providing expert advice and support to the FBI Special Agent in Charge concerning the Federal Government's capabilities in resolving a terrorist threat or incident.
DHS (FEMA)	National Ambulance Contract	The National Ambulance Contract is not to be used to transport contagious patients.
DHS (FEMA)	National – Incident Management Assistance Team (N-IMAT)	N-IMATs are trained on CBRN-related scenarios and will be FEMA's lead in the field to coordinate and integrate inter-jurisdictional response in support of the affected state(s) or U.S. territory(s). N-IMATs provide initial situational awareness for federal decision makers and support the initial establishment of a unified command. IMATs provide for multi-disciplinary needs of emergency management and may include members from the inter-agency community.
DHS (FEMA)	Interagency Modeling and Atmospheric Assessment Center (IMAAC)	The IMAAC provides a single point for the coordination and dissemination of federal atmospheric dispersion modeling and hazard prediction products that represent the federal position during actual or potential incidents involving hazardous material releases. Through plume modeling and analysis, the IMAAC provides emergency responders and decision makers with predictions of hazards associated with atmospheric releases to aid in protecting the public and the environment.
DHS (USCG)	Marine Security Response Teams (MSRT)	MSRTs constitute the Coast Guard's Counterterrorism Advanced Interdiction Force, capable of executing higher risk law enforcement missions against opposed/hostile maritime threats including all CBRN threats. The MSRT is a quick response, ready assault force to conduct Short Notice Maritime Response operations. The MSRT is capable of interdicting, boarding, verifying CBRN and explosive threats, and when required, engaging in offensive operations against hostile threats.
DHS (USCG)	National Strike Force (NSF)	The NSF supports On-Scene Coordinators, Lead Agency Incident Commanders, Operational Commanders, and Combatant Commanders with technical experts, specialized response equipment, and incident management skills to mitigate the effects of hazardous substance releases; oil discharges; and CBRN. The NSF includes the National Strike Force Coordination Center; Atlantic, Gulf, and Pacific Strike Teams, Incident Management Assist Team, and Public Information Assist Team.
DOC (NOAA)	Air Resources Laboratory (ARL)	The ARL focuses its dispersion research on the development and improvement of sophisticated dispersion models and other tools for air quality and emergency response applications. This includes volcanic eruptions, forest fires, nuclear accidents, and homeland security incidents. ARL also designs and evaluates high resolution observing networks, develops instrumentation, and conducts tracer field studies to improve the accuracy of atmospheric transport and dispersion predictions.

Organization	Resource Name	Description
DoD	Military Aeromedical Evacuation (AE)	<p>Patient movement by the DoD requires a request from a state or a federal department and the activation of the patient movement and definitive care components of the National Disaster Medical System (NDMS). Patient movement regulated by the Global Patient Movement Requirements Center (GPMRC) is conducted on fixed wing aircraft from an Aerial Port of Embarkation to an Aerial Port of Debarkation</p> <p>The AE Patient Movement functions are coordinated by the Global Patient Movement Requirements Center (GPMRC), a unit of the U.S. Transportation Command, at Scott Air Force Base, Illinois. The GPMRC will collect casualty information from the states and determine patients' clearance for flight. DoD then matches the patients' needs with the aircraft, medical crew on board, and a destination facility (also known as "patient regulation").</p> <p>States may move patients using civilian or National Guard assets to hospitals within the state (presumably based on a state emergency plan) without the involvement of GPMRC.</p> <p>Movement of patients with highly contagious diseases on DoD aircraft requires approval from the Secretary of Defense</p>
DoD	Chemical, Biological, Radiological, and Nuclear (CBRN) Response Enterprise	<p>The CBRN Response Enterprise is composed of both Active Component (Title 10) Federal, and Reserve Component (Title 10) (Reserve Component Title 10 could include federalized National Guard forces) elements with the mission of providing focused lifesaving capabilities with increased responsiveness for Defense Support of Civil Authorities. National Guard CBRN Response Enterprise elements include WMD Civil Support Teams, CBRN Enhanced Response Force Packages, and Homeland Response Forces. National Guard forces that have not been ordered into a Title 10 status are under state Governor, not Secretary of Defense, command and control. The Defense CBRN Response Force, and two Command and Control CBRN response elements are composed of active duty, National Guard, and Reserve forces allocated to USNORTHCOM to respond in a Title 10 status.</p>
DoD	Defense Intelligence Agency/National Center for Medical Intelligence (NCMI)	<p>The National Center for Medical Intelligence provides intelligence assessments of foreign health threats, including pandemic warning, to prevent strategic surprise across the broad threat spectrum.</p>
DoD	DoD Laboratory Network (DLN)	<p>DLN provides capability which allows DoD laboratories, programs, and activities with analytic or response capabilities to coordinate execution, develop consensus, and make recommendations governing the detection; identification, characterization, and diagnosis; and reporting of chemical, biological, radiological, and nuclear (CBRN) agents; infectious diseases; and other all-hazards agents of military or national significance in support of the DoD's global and homeland defense missions.</p>
DHS (USCG)	Marine Security Response Teams (MSRT)	<p>MSRTs constitute the Coast Guard's Counterterrorism Advanced Interdiction Force capable of executing higher risk law enforcement missions against opposed/hostile maritime threats including all CBRN threats. The MSRT is a quick response, ready assault force to conduct Short Notice Maritime Response operations. The MSRT is capable of interdicting, boarding, verifying CBRN and explosive threats, and when required, engaging in offensive operations against hostile threats.</p>
DOI/USGS	U.S. Geological Survey (USGS) Environmental Health	<p>The USGS Environmental Health Mission Area has the capability to develop models and tools for identifying, monitoring and assessing emerging environmental health threats and pathways for human and animal exposure. These activities build upon USGS's expertise in the hydrologic, atmospheric, geologic, and ecologic processes that affect the transport and fate of agents in the environment.</p>

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
DOI/USGS	The USGS Western Fisheries Research Center (WFRC)	WFRC conducts research and diagnostics on high consequence disease of wild fish species, including diseases that can spill over into and result in economic impacts to US aquaculture. WFRC serves as an Office of International Enforcement Reference Laboratory that provides international expertise on infectious hematopoietic necrosis (a viral disease) and bacterial kidney disease of fish.
DOI/FWS	The U.S. Fish and Wildlife Service (FWS) Wildlife Health Office	The FWS Wildlife Health Office conducts critical work in wildlife health and disease surveillance, response, and management. The Wildlife Health office comprises a network of wildlife health experts located across the country supporting refuges, wetland management districts, and other service programs by (1) providing technical advice about wildlife disease issues, (2) providing guidance on adapting management strategies to prevent wildlife diseases, (3) identifying health surveillance needs, (4) conducting research projects to determine best practices in disease prevention, (5) providing veterinary services for field activities, and (6) supporting emergency response efforts.
DOI/USGS	The USGS National Wildlife Health Center	The National Wildlife Health Center is the DOI lead for animal health emergencies under ESF #11 and serves as the point of contact for any zoonotic diseases involving wildlife. The Center can assist in responding to a highly contagious/zoonotic diseases, biohazard event, or other emergency involving wildlife by providing: wildlife emergency response teams; risk assessment, mapping tools, and epidemiological modelling; general and targeted surveillance for wildlife-associated zoonotic diseases; assistance in the identification of known, new, and emerging/resurging zoonotic diseases; the services of Biosafety Level 3 laboratories for the diagnosis of high-consequence and zoonotic diseases and other biohazard analyses; assistance with the prevention, control, and eradication of any highly contagious/zoonotic disease involving wildlife; and carcass disposal facilities, as appropriate. The Center also has expertise in risk communication.
DOI/NPS	National Park Service (NPS) Wildlife Health Branch and Office of Public Health	The NPS Wildlife Health Branch provides professional veterinary consultation and technical assistance to aid parks in conserving wildlife, identifying and responding to zoonotic diseases in wildlife populations, and working closely with the NPS Office of Public Health and state and local health departments in zoonotic disease prevention and response. The NPS Office of Public Health is staffed by public health service officers including physicians, veterinarians, environmental health service officers and engineers that oversee food, drinking water, and wastewater safety in parks as well as assisting in zoonotic and vector-borne disease surveillance and responses in parks.
DOJ (FBI)	Hazardous Evidence Response Teams	These teams are FBI field teams trained, equipped, and authorized to collect CBRNE evidence in hazardous environments.
DOJ (FBI)	Weapons of Mass Destruction Strategic Group (WMDSG)	The WMDSG is an FBI-led interagency coordination mechanism to successfully resolve imminent WMD terrorist threats or incidents, to include biological threats or incidents, while simultaneously coordinating its information with the nationwide effort to save lives and protect property.
DOJ/FBI	Critical Incident Response Group (CIRG)	Provides expertise in crisis management, hostage rescue, surveillance and aviation, hazardous devices mitigation, crisis negotiations, behavioral analysis, strategic information dissemination, and tactical operations.

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
DOJ/FBI	Hazardous Evidence Analysis Team (HEAT)	Composed of forensic examiners and crime scene specialists trained to perform cyber and traditional forensic analyses CBRN material in containment facilities.
DOJ/FBI	FBI Laboratory	Coordination of CBRN evidence collection during a deliberate event; analysis of evidence for CBRN materials; and research, development and validation of methodologies used for CBRN forensic investigations.
EPA	CBRN Consequence Management Advisory Team	This team is the lead EPA special team for provision of scientific and technical support for all phases of environmental response to a CBRN incident, including health and safety, site characterization, environmental sampling and analysis, environmental monitoring, building, structure, and outdoor decontamination, waste treatment environmental cleanup, and clearance; manages the EPA's Airborne Spectral Photometric Environmental Collection Technology fixed-wing aircraft, which provides chemical/radiological data and deploys and operates mobile and fixed chemical and biological laboratories.
EPA,	Environmental Response Laboratory Network (ERLN)	ERLN provides capability to perform routine and emergency analysis of environmental samples. ERLN is integrated into the ICLN organization.
EPA	Environmental Response Team	This team provides scientific and technical expertise for response to traditional chemicals and hazardous materials, including health and safety, environmental sampling, air monitoring, toxicology, risk assessment, waste treatment, contaminated water/scientific divers, and site decontamination and cleanup and provides field-analytical and real-time air monitoring for chemicals with the EPA mobile laboratories known as Trace Atmospheric Gas Analyzers.
EPA	National Criminal Enforcement Response Team	This team provides technical, safety, hazardous evidence collection, and other forensic support to law enforcement in the instance of a WMD terrorist attack or environmental catastrophe.
EPA	National Response Team (NRT)	NRT is a national-level multi-agency coordination entity comprised of 15 federal agencies that provides technical assistance and resource and policy support to the federal On-Scene Coordinator during NCP and ESF #10 responses to oil and hazardous materials.
EPA, DHS (USCG)	Regional Response Team (RRT)	RRTs are co-chaired by the EPA and USCG. A regional-level multi-agency coordination entity comprised of 15 federal agencies, state, and tribal representatives that provide technical assistance and resource support to the federal On-Scene Coordinator during NCP and ESF #10 responses to oil and hazardous materials.
EPA, DHS (USCG)	On-Scene Coordinators (OSC)	OSCs coordinate the on-scene, tactical response to oil and hazardous substances incidents. Actions include assessment of the extent and nature of environmental contamination; assessment of environmental cleanup options; and implementation of environmental cleanup, including decontaminating buildings and structures and management of wastes. The EPA generally provides the federal OSC for incidents in inland areas, while the USCG provides the federal OSC for incidents in coastal areas.
HHS	Administration for Children and Families (ACF)	ACF promotes the self-sufficiency of individuals, families, and populations with access and functional needs prior to, during, and after disasters; Human Services Technical Assistance assets are utilized in the field to provide these services.
HHS	Aerial Ports of Embarkation	HHS National Disaster Medical System Teams provide critical care health care provider augmentation to federal transporters at aerial ports of embarkation to manage patients prior to flight.

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
HHS	Assistant Secretary for Preparedness and Response (ASPR)	ASPR leads the nation and its communities preparing for, responding to, and recovering from the adverse health effects of public health emergencies and disasters. ASPR focuses on preparedness, planning, response, and recovery; provides federal support, including medical professionals through ASPR's National Disaster Medical System, to augment state and local capabilities during an emergency or disaster; and leads the federal Health and Social Services RSF of the NDRF to assist locally led recovery efforts in the restoration of the public health, health care and social services networks of impacted communities.
HHS	Assistant Secretary for Public Affairs (ASPA)	The HHS ASPA assumes the lead in media response for public health, coordinated with and through the Joint Information Center. HHS ASPA coordinates the overall HHS Public Affairs planning, development, and implementation of emergency incident communications strategies and activities for the department.
HHS (ASPR)	At-Risk, Behavioral Health and Community Resilience	Provides subject matter expertise, education, and coordination to internal and external partners to ensure that the functional needs of at-risk individuals and behavioral health issues are integrated in the public health and medical emergency preparedness, response, and recovery activities of the nation to facilitate and promote community resilience and national health security.
HHS	Biomedical Advanced Research and Development Authority (BARDA)	BARDA, within the ASPR Office of HHS, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies.
HHS	Crisis Counseling Assistance and Training Program	This is a state grant program administered by HHS/Substance Abuse and Mental Health Services Administration and funded by the FEMA.
HHS	Disaster Medical Assistance Team (DMAT)	A DMAT is a group of professional and para-professional medical personnel (supported by a cadre of logistical and administrative staff) designed to provide medical care during a disaster or other incident. DMATs are designed to be a rapid-response element to supplement local medical care until other federal or contract resources can be mobilized, or the situation is resolved.
HHS	Disaster Mortuary Operational Response Team (DMORT)	DMORTs are intermittent federal employees, each with a particular field of expertise, who are activated in the case of a disaster. The DMORTs are directed by ASPR/OEM/NDMS. Teams are composed of funeral directors, medical examiners, coroners, pathologists, forensic anthropologists, medical records technicians and transcribers, finger print specialists, forensic odontologists, dental assistants, x-ray technicians, mental health specialists, computer professionals, administrative support staff, and security and investigative personnel.
HHS	Disaster Mortuary Operational Response Team-Weapons of Mass Destruction (DMORT-WMD)	The DMORT-WMD team is composed of intermittent federal employees from across the nation. The primary focus of DMORT-WMD is decontamination of bodies when death results from exposure to chemicals or radiation. DMORT-WMD is developing resources to respond to a mass disaster resulting from biological agents. However, this team might have difficulty in responding to such an incident if the deaths occur in multiple locations.
HHS	Disaster Portable Morgue Unit (DPMU)	DPMUs are staged at locations on the East and West coasts for immediate deployment in support of DMORT operations. The DPMU is a depository of equipment and supplies for deployment to a disaster site. It contains a complete morgue with designated workstations for each processing element and prepackaged equipment and supplies.

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
HHS	Emergency Management Group (EMG)	The EMG is a scalable team that is utilized every day at some operational level of intensity. Its organization is designed to be flexible and can expand as needed. The EMG is the established structure through which information and potential threats are received and decisions, including the deployment of an Incident Response Coordination Team, are made. The EMG operates within the principles of the Incident Command System and National Incident Management System. The EMG effectively operates 24/7 but can reach its full capacity with associated liaisons within four hours.
HHS	Federal Medical Station	Federal Medical Stations (FMSs) are modular and rapidly deployable, providing a platform for the care of displaced persons who have non-acute health-related needs that cannot be met in a shelter for the general population during an incident.
HHS	Incident Response Coordination Team (IRCT)	The IRCT and the IRCT-Forward act as the HHS agent's on scene at emergency sites under the direction of the EMG. The IRCT directs and coordinates the activities of all HHS personnel deployed to the emergency site and assists state, local, tribal and other federal/government agencies as applicable.
HHS	Joint Patient Assessment and Tracking System Strike Team	This is a two-person strike team that will be deployed to aerial ports of embarkment, patient reception areas/casualty collection points, and destination locations to track patients through the system.
HHS	National Disaster Medical System (NDMS)	ASPR OEM NDMS provides deployable medical response teams to augment the nation's medical response capability and support SLTT authorities through three major missions: (1) provide emergency medical care support, (2) transport patients from the affected area to medical care locations remote from the affected areas, and (3) provide definitive medical care at NDMS civilian member hospitals.
HHS	National Electronic Disease Surveillance System	This system facilitates electronically transferring public health surveillance data from the healthcare system to public health departments. It is a conduit for exchanging information that supports the National Notifiable Disaster Surveillance System.
HHS	National Institutes of Health (NIH)	NIH is made up of 27 different components called institutes and centers. Each has its own specific research agenda. All but three of these components receive their funding directly from Congress and administer their own budgets.
HHS	National Public Health Information Coalition	HHS will leverage a network of state and local health public health communicators to exchange information and increase the likelihood of consistent messaging and communication activities between federal and state or local governments regarding the emergency and its impact on health.
HHS	National Veterinary Response Team	This is a cadre of individuals within the NDMS who have professional expertise in areas of veterinary medicine, public health, and research. It is the primary federal resource for the treatment of injured or ill animals affected by disasters.
HHS	Regional Emergency Coordinators	ASPR's primary representatives throughout the country at the regional level; coordinates preparedness and response activities for public health and medical emergencies.
HHS	Secretary's Operations Center (SOC)	The SOC operates 24/7/365. The mission of the SOC is to serve as the focal point for synthesis of critical public health and medical information on behalf of the U.S. Government.

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
HHS (And Private Sector)	Certified Bio-Containment Units for Highly Infectious Diseases (Category A)	These include Emory University, Atlanta, GA; Nebraska Medical Center, Omaha, NE; National Institutes of Health, Bethesda, MD; St. Patrick Hospital, Missoula, MT.
HHS (CDC)	CDC Emergency Operations Center (CDC-EOC)	The CDC EOC coordinates the deployment of CDC staff and the procurement and management of all equipment and supplies that CDC responders may need during their deployment. When activated for a response, the CDC EOC can accommodate up to 230 personnel per 8-hour shift to handle situations ranging from local interests to worldwide incidents.
HHS (CDC)	Epidemic Information Exchange (Epi-X)	CDC's secure, web-based communications network that serves as a powerful communications exchange between CDC, state and local health departments, poison control centers, and other public health professionals. The system provides rapid reporting, immediate notification, editorial support, and coordination of health investigations for public health professionals.
HHS (CDC)	Epidemic Intelligence Service (EIS) Officers	EIS officers work in many health departments in the United States or at the CDC through the CDC's Center of Surveillance, Epidemiology, and Laboratory Services and are dispatched to investigate possible epidemics, due to both natural and artificial causes, including <i>Bacillus anthracis</i> hantavirus West Nile virus, and the Ebola virus.
HHS (CDC)	Health Alert Network	CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, and local public health practitioners; clinicians; and public health laboratories.
HHS (CDC)	National Institute for Occupational Safety and Health (NIOSH)	NIOSH is the U.S. federal agency that conducts research and makes recommendations to prevent worker injury and illness. NIOSH can deploy a multidiscipline team to provide guidance and technical assistance on responder and worker safety and health.
HHS (CDC)	Laboratory Response Network (LRN)	The LRN and its partners maintains an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies.
HHS (CDC)	National Notifiable Disease Surveillance System (NNDSS)	NNDSS is a nationwide collaboration that enables all levels of public health—local, state, territorial, federal, and international—to share notifiable disease-related health information. Public health uses this information to monitor, control, and prevent the occurrence and spread of state-reportable and nationally notifiable infectious and noninfectious diseases and conditions. NNDSS is a multifaceted program that includes the surveillance system for collection, analysis, and sharing of health data. It also includes policies, laws, electronic messaging standards, people, partners, information systems, processes, and resources at the local, state, territorial, and national levels.
HHS (CDC)	Public Health Information Network	CDC's national initiative to increase the capacity of public health agencies to electronically exchange data and information across organizations and jurisdictions (e.g., clinical care to public health, public health to public health and public health to other federal agencies). To do so, the Network promotes the use of standards and defines functional and technical requirements for public health information exchange.
HHS (CDC/Agency for Toxic Substances and Disease Registry)	Rapid Response Registry Team	This survey instrument gives local and state entities a tool to register responders and other persons exposed to chemical, biological, or nuclear agents from a disaster. The survey instrument is a two-page form that can be distributed on paper or electronically. It can be

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
		implemented quickly to collect information rapidly to identify and locate victims and people displaced or affected by a disaster.
HHS (CDC)	Strategic National Stockpile (SNS) Push Packages	A SNS Push Packages is a cache of pharmaceuticals and medical supplies designed to provide rapid delivery of a broad array of assets for an undefined public health threat in the initial hours of an event. This cache is packed in cargo containers that can be delivered anywhere in the United States within 12 hours of the federal decision to deploy.
HHS (CDC)	Strategic National Stockpile; Managed Inventory (MI)	If the incident requires additional pharmaceuticals and/or medical supplies, follow-on MI supplies will be shipped to arrive within 24 to 36 hours. If the agent is well defined, Vendor Managed Inventory (VMI) can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent(s). In this case, the VMI could act as the first option for immediate response from the SNS program.
HHS (FDA)	Regulated Products/Commodity Response Teams	Provides assistance to state and local health authorities or in the absence of state and local health investigators, assumes primary responsibility for evaluation and recovery of food service establishments and pharmacies.
HHS (FDA)	Medical Countermeasures Initiative (MCMi) Office of Counterterrorism and Emerging Threats (OCET)	This office coordinates FDA's medical countermeasures development, availability, preparedness, and response." with "This office leads an FDA-wide initiative to coordinate medical countermeasure development, preparedness and response. FDA ensures that medical countermeasures (MCMs)—including drugs, vaccines and diagnostic tests—to counter CBRN and emerging disease threats are safe, effective, and secure. This includes coordinating research, setting deployment and use strategies, and facilitating access to MCMs
HHS (USPHS)	Applied Public Health Team (APHT)	APHT provides resources and assistance to local health authorities throughout the United States. Currently five APHTs, each of which is a work force comprising 47 USPHS-trained Commissioned Corps officer responders. Yet each APHT is scalable and capable of providing only those resources needed. Each APHT is also responsive; as a Tier 2 team the APHT can deploy within 36 hours of activation.
HHS (USPHS)	Capital Area Provider	Providers who respond only in the National Capital Region – mass gatherings on the Mall; e.g., doctors, mid-levels, nurses.
HHS (USPHS)	Mental Health Team	The mental health team can respond nationwide; provides assessment, screening, and training for behavioral health issues; psychologists, psychiatrists, licensed clinical social workers.
HHS (USPHS)	National Incident Support Team (NIST)	The NIST consists of 72 USPHS-trained Commissioned Corps officer responders. Each NIST is scalable, and is capable of providing only those resources needed. NIST is a Tier 1 team and can deploy within 12 hours of activation.
HHS (USPHS)	Rapid Deployment Force (RDF)	There are currently five RDFs, each of which is a workforce comprising 105+ trained USPHS Commissioned Corps officer responders. Yet each RDF is scalable, and is capable of providing only those resources needed. The RDF is also responsive; as a Tier 1 team the RDF can deploy within 12 hours of activation.
HHS (USPHS)	Regional Incident Support Team (RIST)	RISTs provide rapid assessments and initial incident coordination resources and assistance to state, tribal, and local health authorities within defined regions of the United States. There are currently eleven RISTs, each of which is aligned with one of the HHS regions (including the National Capital Region).

<b>Organization</b>	<b>Resource Name</b>	<b>Description</b>
HHS (USPHS)	Service Access Teams	Service Access Teams provide assistance to health care facilities and other entities where federally medically evacuated patients have been sent.
HHS (USPHS)	Tier 1 – USPHS-Commissioned Corps Response Groups	Tier 1 teams (RDFs, NISTs, and RISTs) have implicit concurrence on the part of their respective agencies for deployability within 12 hours.
HHS (USPHS)	Tier 2 – USPHS-Commissioned Corps Response Groups	Tier 2 officers are also formally rostered on response teams (APHTs, Mental Health Teams, Capital Area Provider Teams, and Services Access Teams) and maintain implicit agency concurrence for deployability within 36 hours.
HHS (USPHS)	Tier 3 – USPHS-Commissioned Corps Response Groups	Tier 3 officers are not rostered on specific teams and do not maintain implicit agency concurrence but are on call once within every five-month period—their activation requires agency concurrence at the time of deployment.
GSA	Public Building Services	GSA provides facility space as requested
United States Postal Inspection Service	United States Postal Inspection Service	Conducts biological surveillance for pathogens shipped through the mail.
Department of Veteran's Affairs (VA)	Federal Coordinating Centers	Federal Coordinating Centers are DoD or VA centers whose personnel recruit non-federal hospitals within approximately a 50-mile radius of the airport or military airfield where NDMS hospital inpatients from affected states will likely arrive and be triaged, received, and transported to NDMS partner hospitals for inpatient medical care
Department of Veteran's Affairs (VA)	Disaster Emergency Medical Personnel System	Veterans Health Administration's main deployment program for clinical and non-clinical staff to an emergency or disaster. This program may be used for an internal VA mission as well as supporting a mission after a Presidential Disaster Declaration under the NRF ESF #8 (Public Health and Medical Services).

## Appendix 7: Training to Support Biological Response and Incidents

Misperceptions and a lack of knowledge about biological incidents and their effects can create confusion and mistrust within the general public, with emergency responders, and even among officials who have a responsibility to provide for an effective response to a biological incident.

This appendix provides training resources available through both public and governmental web sites that can promote a better understanding of biological hazards that could commonly result from the type of biological incidents covered in this document. All of this training could be useful in preparation for operations to respond to and recover from these incidents either in a real-world scenario or through preparedness exercises.

Below is a list of web sites that provides training opportunities related to biological emergency preparedness. This is not an all-inclusive list but a starting point on available training.

- [CDC | Bioterrorism Training and Education](#)
- Center for Domestic Preparedness (CDP) [Bold Steps in Preparedness Training for Biological Attacks](#)
- [Johns Hopkins Center for Public Health Preparedness Training](#)
- FBI Bioterrorism Training and Education (For more information on training opportunities and resources please contact the FBI's WMD Directorate's Biological Countermeasures Unit at [BiologicalCounterMeasuresUnit\\_BCU@ic.fbi.gov](mailto:BiologicalCounterMeasuresUnit_BCU@ic.fbi.gov))
- [S3: Science, Safety, and Security](#)

## Appendix 8: Logistics

This annex identifies any unique features of incident support as they pertain to the Logistics Section of the Unified Coordination Staff or the Resource Support Sections of the Regional Response Coordination Staff or the National Response Coordination Staff. The annex specifies logistics support that is essential to accomplishing the mission, including location of pre-designated staging areas and points of distribution, as well as detailed information concerning sourcing for required assets, etc.

### Situation

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The Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response (ASPR)/Office of Emergency Management (OEM) Logistics provides coordinated federal assistance to supplement state, local, tribal, and territorial (SLTT) resources in response to a public health or medical disaster and potential or actual incidents requiring a coordinated federal response and/or during a developing potential health and medical emergency.

### Mission

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The Logistics mission is to provide supplemental assistance of health/medical/veterinary equipment and supplies to support medical logistics where HHS has the lead and oversight of this responsibility during a developing potential health and medical emergency or a coordinated federal response.

### Execution

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The execution of logistics for biological incidents is carried out in accordance with the resources, policies, and procedures outlined in the following references:

- Annex D: Public and Private Services and Resources of the Response Federal Interagency Operational Plan (FIOP)
- Annex D, Tab 1: Pre-Scripted Mission Assignments of the Response FIOP
- Appendix 1 to Annex D: Critical Transportation of the Response FIOP
- Appendix 1 to Annex D, Tab 1: Resource and Team Cache of the Response FIOP
- National Response Framework Emergency Support Function (ESF) Annexes
  - ESF #1: Transportation
  - ESF #7: Logistics

HHS's ASPR/OEM Logistics is responsible for researching, coordinating, selecting, and managing facility locations that store ASPR medical supplies and equipment to support incidents.

Applicable Core Capabilities are—

- Public and Private Services Resources
- Critical Transportation

## **Concept of Support**

ASPR/OEM's national cache storage, maintenance, and management system makes recommendations for cache storage locations based on public health and medical operational plans and includes requirements for mobilization; deployment; employment; sustainment; and redeployment of personnel, equipment, and supplies.

## **National-level Supply Chain Management**

At the national (strategic) level, the focus and priority of supply chain management is to ensure adequate resources are acquired and to maintain constant visibility of one or more Incident Response Coordination Team (IRCT) operational area resources to include resources available from strategic partners. The Emergency Management Group (EMG) Logistics staff (EMGLOG) must effectively and efficiently establish strategic partnerships with federal entities, commercial vendors, and distributors and create communication channels for critical information such as logistics and infrastructure capabilities at the strategic and operational levels.

EMGLOG maintains situational awareness of ASPR/OEM Logistics capabilities and requirements by hosting routine logistics conference calls and further coordinates with EMG Critical Infrastructure Key Resources (CIKR) to identify any potential supply chain pressures so any potential issues are identified in advance, and the appropriate mitigation actions can be implemented. EMG CIKRs will have the primary responsibility for monitoring the overall status of the healthcare and public health supply chain during a response.

## **Regional-level Supply Chain Management**

At the regional (operational) level, the focus and priority of supply chain management is to monitor the operational area's resources (internal and external) and establish re-supply priorities, capabilities, and methods to meet requirements at the tactical level. Acting as a conduit of information, HHS regional authorities communicate these requirements and priorities to the EMGLOG. The regional authorities, coordinated through the IRCT and effectively liaising with the tactical or SLTT-level Federal Emergency Management Agency Joint Field Office representatives for operations maintain visibility of capabilities and logistics resources. The IRCT coordinates all procurement and contracting activities in advance with EMGLOG to ensure headquarters' contract services are accurate.

## **SLTT-level Supply Chain Management**

At the SLTT (tactical) level, the focus and priority of supply chain management is to fulfill requirements to the public health and medical service provider. Accomplishing this critical task requires logistics personnel to be highly skilled in forecasting re-supply requirements or burn rate of medical supplies and equipment. SLTT-level logistics personnel submit re-supply requests to the IRCT.

## Appendix 9: Outstanding Policy Issues

This appendix presents some important areas requiring additional attention and of which stakeholders should be aware. Attempts to address said gaps early will likely mitigate the potential impact in terms of lives lost and resource mismanagement.

### Mass Care and Human Services

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- Identify and meet community healthcare, behavioral health, and social services needs that are no longer met by existing infrastructure resources.
  - Federal assistance to local entities working to establish mass care services and support impacts on social services is limited. Furthermore, distinctive requirements for emergency assistance will arise during a biological incident due to the unique characteristics of a disease outbreak. Existing resources for the impacted population's physical and emotional well-being are likely to be exceeded rapidly. The Unified Coordination Group (UCG) may consider additional support through Substance Abuse and Medical Health Services Administration Disaster Technical Assistance Center; subject matter expert support to the Emergency Management Group (EMG) from the Assistant Secretary for Preparedness and Response Technical Resource Guide; or expansion of Emergency Support Function (ESF) support by EMG/Federal Resource Coordinator/UCG.
- Augment mass care capabilities to reduce the burden on healthcare facilities (access, functional, and basic care needs).
  - Federal and state, local, tribal, and territorial (SLTT) agencies responsible for public health, social services, and emergency assistance services will need to coordinate efforts closely with private sector and outside organizations to meet the large-scale demands of a biological incident. In addition to a surge in care for impacted populations, there is also a comparable requirement for services to homebound and other at-risk populations as caregivers are lost or otherwise impacted by the incident. Increasing aid for individuals with disabilities or those with access and functional needs could potentially be addressed through collaboration with the Commissioned Corps of the US Public Health Service, service access teams, and Individual Assistance-Technical Assistance Contracts; delivery services; or nongovernmental organizations (NGO) and Voluntary Organizations Active in Disaster (VOAD) such as the Red Cross or Salvation Army. ESFs #6, #7, and #8 should be followed for guidance on coordinated meals, home healthcare, medical countermeasures (MCM), and other assistance.
  - Animal care, treatment, sheltering, and placement are managed according to SLTT jurisdictional plans and supported by ESFs #6, #8, and #11 as well as national NGOs.
  - Support resources are required (at shelters or non-congregate settings) to meet the needs of unaccompanied children, seniors, and other at-risk populations (including animals) who rely on caregivers.

## Augment Essential Services and Facilitate Long-Term Recovery

- Classify critical infrastructure, responders, and other personnel and populations for prioritized receipt of personal protective equipment (PPE) and MCM.
  - There are many different ways to prioritize receipt of PPE and MCM; however, having a method for classifying the critical infrastructure, responders and other personnel and populations most at risk is imperative to minimizing the impact of an incident. In large-scale biological incidents, this presents a number of challenges based on the agent, the magnitude of the outbreak, and resource availability. Additional policy decisions will need to be made across agencies to develop protocols addressing prioritization of said resources. Currently, the UCG may link a matrix of the various types of biological threats to recommendations for prioritized PPE use and populations; utilize Health and Human Services (HHS)/Department of Labor (DOL) decision protocols to assess occupational risk and develop/update recommendations for protection of workforce; or defer to interagency coordination between HHS, Centers for Disease Control, and DOL to modify existing agency recommendations, or a combination of all three options is a possibility. In a UCG setting, the Federal Emergency Agency and HHS will coordinate and prioritize all resources. For specific resources allocation challenges the National Security Council can provide guidance to UCG.
- Coordinate and support continuity of operations tactics to maintain critical infrastructure capabilities.
  - Maintenance of critical infrastructure may be challenging during a biological incident for many reasons. Exposure or illness of personnel or responders is likely to cause cumulative downstream effects in critical operations. Such service interruptions could disrupt supply chains, security, and provision of basic resources to the general public. Methods to assure continued operational capabilities may include coordination among Sector-Specific Agencies (SSAs), Sector Coordinating Councils (SCCs), and Government Coordinating Councils; of assessments and support through related ESFs; and through a combination of ESFs, the National Incident Coordination Center, and SSAs/SCCs.
    - Identify, develop, and implement initial recovery measures for degraded critical infrastructure and essential services.
    - There are limited federal resources to augment specific personnel needs during a large biological incident; this shortage will be further impacted as staff becomes part of the impacted population. Recovery measures to facilitate salvage of critical infrastructure may be located in Recovery Federal Interagency Operational Plan Annex E: Infrastructure Systems Recovery Support Function Operation; otherwise, such measures may be developed or initiated via identification of levels 1 and 2 Critical Infrastructure Key Resources (CIKRs) in affected areas by Department of Homeland Security (DHS) Homeland Infrastructure Threat and Risk Analysis Center and Office of Cyber and Infrastructure Analysis,

implementation of CIKR and other support plans by HHS and SLTT coordination, or collaboration between SLTT and the Environmental Protection Agency to develop and implement plans.

## **Augment State and Local Public Health and Medical Resources**

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- Provision of support to public health and medical surge needs; conservation of public and private healthcare/pharmaceutical supply chains.
- There is limited capability in the interagency to provide support to public health and medical surge needs as well as protect and preserve public and private healthcare and pharmaceutical supply chains. There are challenges in developing specific federal support capabilities caused by differences in local plans and capabilities, a lack of quantified/uniform gaps for medical shortfalls, and the lack of uniform reporting of surge capabilities/needs. During an incident, both skilled and non-skilled labor forces may be called upon to assist as needed for additional support. The UCG may consider requesting the use of resources from the following assets and teams to support SLTT capability gaps: NGOs/VOAD and nonclinical volunteers, National Disaster Medical System teams, DHS Surge Capacity Force, federal clinical personnel, other ESF #6 and #8 resources, and Department of Defense personnel, if available. Maintaining or surging existing supply chains for medical (and veterinary) material including medications, supplies, and equipment could be accomplished using foreign aid or the Defense Production Act, but there could be delays in receiving the product. A work group could be formed to review policy implications (e.g., sending federal teams into potentially harmful environments) and resource shortages to meet objectives.

## **Federal Surge Personnel to Assist with MCM Dispensing**

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Since the issuance of Executive Order 13527, Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack (Dec. 30, 2009), the USG has made great strides in its preparedness planning for MCM dispensing. This planning has included joint local, state, and federal efforts, as well as a wide range of interagency and private sector engagement. Plans have focused on the identification of point-of-distribution (POD) locations, exact numbers for required doses and detailed timelines for resource movement and the logistics required to move the MCM. In each of the 10 largest U.S. cities that participate in the Urban Area Security Initiative, there now exist a detailed execution matrix, timeline, and resource inventory that include pre-identified personnel for MCM distribution. Through robust engagement from all partners and detailed analysis that informed these plans, exact numbers for required doses for each POD are now known. By far the greatest of the limitations in these plans is the ability to staff these PODs in time to disseminate the MCM within the window in which it will be effective. An option to resolve this challenge would be for federal workers to augment local capabilities regarding contacting, registering, and communicating across federal departments and agencies. Policy-level decision making may be needed during an incident to

waive Title V employment, workforce safety, and workforce duty assignment limitations in order to identify and deploy a surge of federal resources from within the affected metropolitan area to support local public health official POD operations.

## **Waste Management Planning Considerations**

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Recent experiences with handling of contaminated waste generated by patients with Ebola virus disease demonstrated that there was a gap in understanding how to safely inactivate or dispose of contaminated waste. The leadership for facilities and communities that may or will need to manage contaminated waste should ensure they have a pre-incident waste management plan to address the entire waste lifecycle—from creation to final disposition. The plan should detail how waste management tasks (waste classification, waste minimization, segregation, storage, etc.) will be accomplished, and it should provide facility- or community-specific procedures. Each plan should have input from appropriate state and local health and environmental departments, and it should primarily focus on the safety of the people who will handle or package—or otherwise risk contact with—contaminated materials. Plans should pre-identify whether waste will be inactivated on-site or transported to a final treatment and disposal site. DOT/PHMSA regulates movement of hazardous materials across all modes of transportation through the Hazardous Materials Regulations, which are designed to minimize the risks to life, property, and the environment during the transportation of hazardous materials. The HMR provide clear regulations for classification, packaging, and communication procedures that must be followed. DOT/PHMSA also has the authority to issue a special permit for transporting contaminated waste in a manner that deviates from conventional, established HMR methods (e.g., using alternate packaging).

## **Oversight and Maintenance of Federal Closed PODs**

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There is limited oversight and visibility of the presence and capacity of federal closed POD capabilities in metropolitan areas. Federal Executive Boards (FEBs) are interagency organizations comprised of the highest ranking local Federal officials in 28 metropolitan areas; FEB officers are elected annually and serve on a voluntary basis. OPM has oversight for the FEBs and can work with FEMA to assist with the awareness and interagency communications of federal PODs in FEB areas.

## Appendix 10: Human-Animal Interface

Many disease agents are a threat to both humans and animals, and some can be transmitted between animal species to humans and vice versa (zoonotic diseases). Examples include: *Yersinia pestis* (plague), *Bacillus anthracis* (anthrax), ebolavirus, Monkeypox, Nipah virus, and some influenza viruses. (Diseases primarily affecting livestock and poultry are addressed under the Food and Agriculture Incident Annex to the Federal Interagency Operational Plans.)

The Department of Health and Human Services; Department of Labor; U.S. Department of Agriculture; Department of the Interior; and other federal, state, local, tribal, and territorial agencies have authority and capabilities to take actions for these diseases in animal populations to protect human health as well as to limit their impact on animals. Response activities may include exposure assessment, surveillance, monitoring and disease mapping, medical countermeasures, and mitigation including quarantine, movement, disposition, depopulation, and appropriate carcass disposal.

The primary Emergency Support Function (ESF) support mechanism for animal issues during a biological incident is ESF #8, Public Health and Medical Services; however, ESF #11, Agriculture and Natural Resources provides critical support for animal issues following a biological incident. Specific response and recovery actions will vary depending on the biological agent. Multi-agency coordination and inclusion of agencies with animal authorities and capabilities are critical. At the federal level, there is an animal emergency management multi-agency working group that addresses animal issues in all phases of emergency management (called Federal Animal Emergency Management Working Group).

Issues unique to animals contribute to an effective federal response and recovery and include the following:

- Awareness of the role of animals as vectors and/or reservoirs of zoonoses and the need for human and animal surveillance and monitoring.
- Mapping capabilities to track disease spread for human health preparedness.
- Care of animals when mitigation of disease spread isolates owners and their pets (social distancing), including commodity distribution and care/husbandry support.
- Care and housing of animals (temporarily or permanently) when owners or facilities are unable to care for them (e.g., congregate housing, zoos, wildlife rehabilitators, research facilities, shelters, sanctuaries, farms, breeders, etc.) to prevent further negative outcomes.
- Animal movement restrictions as a result of biological incident using subject matter experts (veterinarians, animal behaviorists, biologists, ecologists).
- Response actions and decontamination for animals located in a contaminated area.
- Isolation, euthanasia, depopulation, and carcass management of infected animals to protect animal and human health.
- Captive and free-ranging wildlife with the potential to transmit or transport a biological agent present unique and potentially significant challenges for disease management (such as endangered species, conservation issues, animal migration, etc.).

- Potential risk of animals as vectors and reservoirs with novel or genetically modified zoonotic organism.
- Risk communication to animal industry (veterinarians, agriculture, zoos, wildlife rehabilitators, etc.) relating to animal exposure/infection in a biological incident.
- Risk communication to pet and service animal owners relating to animal exposure/infection in a biological incident.
- Risk communication to public health organizations, providers and the public regarding impacts of wildlife disease on human health

Capabilities to conduct a field response to wildlife health emergencies and enact disease control and management actions.

- BSL-3 laboratories to diagnose known or novel emerging diseases
- Design regional and national-scale wildlife disease surveillance
- Carcass disposal facilities
- Risk assessment, risk mapping, and epidemiological modelling.
- BSL-3+ facilities to conduct research on wildlife-associated zoonotic diseases

# Branch 1: Intentional Biological Incident

## Situation

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This branch plan will address the unique nature of intentional biological incidents.

## Purpose

This branch plan provides supplemental information to the Biological Incident Annex (BIA) Base Plan. Federal interagency partners can respond in a lead role or in support to state and local governments to save lives, protect property and the environment, and meet basic human needs when there is a threat of or an actual intentional attack involving biological agents.

## Scope

This branch plan applies to all federal responses to intentional biological incidents, regardless of size or complexity, unless otherwise noted. The main focus is on a covert incident where the need for immediate federal and state assistance is obvious, resource pre-positioning is not possible, and the exact nature of resource and asset requirements is not known.

## Facts, Planning Assumptions, and Critical Considerations

### Facts

The following facts pertain to intentional biological incidents:

- An intentional incident may result in a large number of casualties and the need for medical services can quickly overwhelm city or state resources.
- The complexity and potential consequences requires multi-agency coordination at all levels of the response.
- Federal law enforcement operations may or may not need to occur in contaminated environments.
- The response to a suspect or actual intentional biological incident requires integration and coordination of consequence management, critical infrastructure protection, and law enforcement/counterterrorism operations.
- Responders can effectively conduct operations safely if they understand the risk and have the appropriate personal protective equipment and resources available.

### Planning Assumptions

The following planning assumptions pertain to intentional biological incident and are supplemental to the assumptions listed in the base annex:

- **Incident Cause:** All biological incidents, as defined in the BIA, will be treated as an act of terrorism until determined otherwise.

- **Method of Incident Detection:** There are many methods for detecting a biological incident such as (1) provision of intelligence information, (2) criminal and epidemiologic investigations, (3) environmental monitoring (e.g., Department of Homeland Security [DHS] Office of Health Affairs BioWatch program), (4) electronic disease reporting, (5) syndromic surveillance by public health authorities (e.g., Centers for Disease Control [CDC] and state, local, tribal, and territorial [SLTT] health departments), and (6) animal/veterinary disease reporting. Depending upon the particular agent and associated symptoms, a delay could occur before public health and medical authorities detect a biological incident,
- **Responder Preparedness:** Federal agencies are responsible for ensuring the safety, health, and behavioral health of their own response and recovery workers (including contract workers), along with decision making and implementation of protective actions. Federal employers must be prepared before a biological incident by ensuring that their workers have received training about how to protect themselves when responding to such an incident; workers have and can properly use appropriate personal protective equipment; and medical monitoring, medical examination, and fit-testing programs are in place.
- **Response Timeline:** Federal assistance will be mobilized as rapidly as possible; however, there may be a significant delay for personnel to arrive on scene.
- **Federal, State, and Local Government Response Delays:**
  - Full information about the biological agent will not be immediately available and can take hours, days, or months to become known.
  - Availability and deployment will vary depending on asset status, political decisions, infrastructure availability, etc.
  - Adequate federal and state resources (personnel, equipment, commodities, and materiel) capable of safe and efficient operations will require several hours of activation, staging, and deployment prior to the commencement of tactical operations.
- **Exposed Population:** The incident will require a national effort to identify the potential victims and refer them for medical follow-up, as appropriate.
- **Contamination Control:** Depending on the agent, contamination may spread to uncontaminated areas from transit through the contaminated zones.
- **Law enforcement:** In all suspected intentional biological incidents, the Federal Bureau of Investigation (FBI) will lead and coordinate the law enforcement and criminal investigative response and related intelligence activities to resolve the threat, through the FBI Joint Operations Center (JOC). Operational coordination with the FBI On-Scene Commander is critical to risk-informed operations and decisions across the Response, Recovery, and Prevention Missions.

## Critical Considerations

- **Immediate Public Information:** There will be an immediate need to inform the public on the situation and what protective actions to take.<sup>47</sup>
- **Simultaneous Operational Mission Requirements:** Multiple interagency missions (e.g., Counterterrorism, Defense, Continuity, Response, and Recovery) will occur simultaneously.
- **Host State Resources:** Neighboring and host states may withhold emergency services resources to ensure that sufficient capability exists to secure their own jurisdictions.
- **Proactive Response:** Notification and full coordination with states occur, but the coordination process should not delay or impede the rapid mobilization and deployment of critical federal resources.
- **Reporting Requirements:** Terrorist threat-related information collected domestically, including suspicious activity reporting involving suspected federal crimes of terrorism, will be shared comprehensively and immediately with the FBI Joint Terrorism Task Forces so that threats can be investigated and resolved as soon as possible. This includes assessing the credibility of the threat and determining the appropriate prevention operation. In addition, response operations to save lives and protect property, including public health operations, will benefit from operational coordination and information sharing with the Prevention Mission. The Response Mission therefore will require timely threat reporting from the Prevention Mission to inform decisions or operations.
- **Incident Identification:** The first indicator of an intentional biological incident may be patients seeking treatment for an unexplained illness or resulting casualties. The ability of responders to identify and accurately report aspects of the incident (e.g., signs and symptoms exhibited by victims) and to report suspicious activity will be key for triggering a federal prevention operation.
- **Locations as Crime Scenes:** The location of a suspected or actual intentional biological incident will be treated as a federal crime scene. The preservation and collection of evidence is critical to determine the identity of culpable parties or information of additional planned attacks. Therefore, it is important to ensure that response and recovery personnel understand and recognize possible access restrictions to crime scenes. Further, the Response and Recovery Missions should collaborate with the Prevention Mission within the JOC to establish joint priorities to save lives, protect property, and conduct prevention activities.
- **Intentional Incidents:** A suspected or actual intentional biological incident could take many forms. Mission area planning should account for a full range of possible incident

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<sup>47</sup>The President of the United States has directed the Secretary of Homeland Security and the Attorney General to coordinate with each other to execute key responsibilities that provide public information and warning to the Nation regarding terrorist threats and attacks. Where there is an imminent terrorist threat or a suspected act of terrorism, consult the Terrorism Incident Law Enforcement and Investigation Annex and national policy, including applicable Presidential policy directives, to identify necessary coordination mechanisms.

scenarios. Incident scenarios may involve one or more, but are not limited to, the following characteristics:

- *Non-contagious biological agent*. Not all biological agents are transmissible between humans or from animals. In these circumstances, the cases of disease may be limited to those immediately exposed during the release; however, exposures could occur after the release if individuals are exposed to residual biological agent in the environment or through cross-contamination. It is important for this information to be conveyed with prevention as it may aid the investigation in the identification of culpable parties and prevent future attacks.
- *Contagious biological agent*. Some biological agents are contagious and may involve person-to-person transmission, resulting in the spread of disease beyond the initial geographic area of the attack. Subsequently the population affected by the attack may infect those beyond the initial area of attack; thus the area at risk may be nationwide or even go beyond international borders. It is critical that public health coordinate and share information relative to this type of scenario to stress the importance and urgency of containment and to stop ongoing or planned attacks.
- *Multiple areas*. The effect of a bioterror attack may be temporally and geographically dispersed within a city or within a state, with no readily determined or defined “incident site.” Close coordination with the Prevention Mission Area may provide critical information of possible pending or ongoing attacks that would drive response operations.
- *Multiple attacks*. In a multiple attack scenario, the Prevention and Response Missions may be operating concurrently and possible in different phases (see below) for different attacks/threats.
- *Indeterminate location(s)*. The location of a bioterrorism attack provides value to determining methods of operations utilized by culpable actors. This information may help law enforcement stop ongoing or future biological incidents. However, the location may not be immediately known. In these cases, public health should coordinate and share information with the FBI, who will be leading law enforcement, counterterrorism, and intelligence activities to identify possible location(s) associated with the attack. All biological incidents as defined by the BIA are evaluated to determine if there is a credible terrorist or criminal threat. However, an intentional release of a biological agent may be indistinguishable from a naturally occurring outbreak. Therefore, all intentional biological incidents will be treated as terrorist threats until determined otherwise. This will result in Response, Recovery, and Prevention.<sup>48</sup> Missions operating concurrently to save lives, protect property and resolve threats.

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<sup>48</sup>The Prevention Federal Interagency Operations Plan has additional information on the federal law enforcement investigative, intelligence, and operational response and describes existing structures intended to link with SLTT, federal, and insular-area government’s law enforcement operational structures and capabilities to resolve imminent threats and prevent terrorist attacks and follow-on attacks.

If a biological incident is to be treated as intentional, such as a suspected or actual act of terrorism or other federal crime, or if the cause of a biological incident is undetermined, the response requires integration of consequence management, critical infrastructure protection, and law enforcement/counterterrorism operations. In either case, public health and law enforcement may need to conduct joint criminal and epidemiological investigations to determine the cause. Numerous examples demonstrate the complexity of bioterrorism threats and need for integrated response operations.

To this end, the intent of this branch is to support the integration of Response and Recovery Missions (including consequence management and critical infrastructure protection operations) with the Prevention (imminent threats or attacks) Mission. This integration structures coordination and timely information sharing to inform operations and decisions across the mission areas to achieve unity of effort. Given the complexity of response across mission areas, unity of effort is critical to avoid unintended consequences of decisions that may have negative impacts across mission areas. This increases the likelihood of successfully saving lives, protecting property and resolving threats.

## **Mission**

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### **End State**

In addition to the criteria described in the base plan, achieving the desired end state of response and recovery operations to an intentional biological incident occurs when—

- State and local governments can meet the needs of citizens.
- Coordination with federal law enforcement has been achieved and maintained until the biological threat is resolved and attribution efforts are underway.

## **Execution**

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In response to an intentional biological incident, immediate priority must be given to addressing self-decontamination and shelter-in-place messaging to affected populations to save lives. Immediate removal of contaminated clothing, showering, and staying indoors will have the greatest impact on the health of affected populations in the first 24 hours. Immediate response actions must focus on—

- Incident characterization.
- Delivering self-decontamination messaging that addresses people, their animals, and the environment, as appropriate.
- Coordinating messaging with SLTT.

The steps leading to implementation of response and recovery efforts will differ between intentional and naturally occurring or inadvertent incidents.

## Recognition of an Intentional Biological Incident

The FBI and law enforcement are constantly vigilant for threats of terrorism, including bioterrorism incidents. The public health community and emergency management officials should work closely with law enforcement regarding positioning resources and appropriate capabilities in the emergence of an intentional biological incident. Threat information is provided through a variety of sources, including open source, private sector, SLTT partners, federal departments and agencies, the intelligence community, or foreign governments. Important informational or decisional points for each of the various phases of response, which may lead to a suspected or actual intentional incident are addressed below:

### Key Information Channels

- Report of a BioWatch Actionable Result (BAR) by the local BioWatch jurisdiction.
- Determination of a suspected or confirmed biological agent through the FBI's Threat Credibility Evaluation (TCE) process.
- Clinical recognition of signs and symptoms by healthcare providers and/or clinical laboratory diagnosis indicative of an intentional act.
- Disease surveillance activities suggest a suspicious pattern that may indicate an intentional act.

### Notification of an Intentional Biological Incident

Law enforcement personnel may be confronted with a number of situations involving the actual or threatened use of a biological agent as a weapon. These can range from non-credible threats (hoaxes), announcements or indications that a release of a biological agent has occurred (overt), or unannounced releases of a biological agent (covert). Notification of a potential incident requires response community personnel to open a number of communication channels

### Key Federal Decisions

- Hold a local/state jurisdictional call with key stakeholders on the confirmation of a BAR from a BioWatch detector.
- Initiate a federal information-sharing call within two hours of a BAR confirmation or as early as possible based upon other forms of intentional biological incident detection, as described previously.
- Hold a TCE led by the FBI. No other authority will be the lead to hold a TCE other than the FBI.
- Determine at the FBI Headquarters and/or FBI Field Offices the need to conduct a law enforcement investigation; possibly in conjunction with a public health epidemiological investigation as appropriate.
- Notify the World Health Organization via the U.S. International Health (IHR) Regulations National Focal Point, per our obligations under the IHR 2005, must occur within 24 hours of federal confirmation of an IHR reportable event and requires

coordination and communication between local and state level and the federal technical agency to compile reportable event information.<sup>49</sup>

- Once the threat of a potential intentional incident is received, the FBI will conduct a law enforcement investigation into the situation. All possible incidents are immediately evaluated to determine if they are weapons of mass destruction (WMD) and possibly linked to terrorism.

## **Conduct a Law Enforcement Investigation**

The occurrence of an intentional biological incident may result in an emergency that may overwhelm state and local capabilities and undoubtedly require a whole community approach. An intentional biological incident may cause mass casualties, displacement of people, and other obstacles to response. The Federal Emergency Management Agency (FEMA) will not wait for a disaster declaration before activating all Emergency Support Functions (ESFs) and positioning federal capabilities; however, federal asset engagement under HHS authorities and/or under the Stafford Act will be conducted in concert with and at the request of the state and local authorities that will retain leadership of response operations.

### *Key Federal Decisions*

- Determination at the FBI Headquarters and/or FBI Field Offices to conduct a counterterrorism response.
- Standup of the FBI Weapons of Mass Destruction Strategy Group (WMDSG).
- Make recommendations concerning possible deployment and composition of the Domestic Emergency Support Team (DEST), based on the standup of the FBI WMDSG.
- Determine the FEMA standup of the Consequence Management Coordination Unit (CMCU) to support the FBI's counterterrorism response to a suspected or actual intentional biological incident, based on the standup of the FBI WMDSG.
- Share information, when appropriate, with the CDC in order to determine potential public health and medical impacts to the U.S. population.

## **Transition from Counterterrorism Response to Consequence Management**

The completion of the response to a possible or actual intentional biological incident will be determined by the unique aspects and magnitude of each situation. The timeline required to neutralize the criminal element will vary greatly. The criminal investigative end state will transition the response efforts from counterterrorism activities into consequence management. The FBI, in conjunction with FEMA, will use ongoing critical information sources to provide situational awareness to facilitate the gradual stand down of several groups.

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<sup>49</sup> Coordination with the Attorney General should be performed before the release of information to the World Health Organization during a suspected or intentional bioterrorism event. Where there is an imminent terrorist threat or a suspected act of terrorism, consult the Terrorism Incident Law Enforcement and Investigation Annex and national policy, including applicable Presidential policy directives, to identify necessary coordination mechanisms.

### Key Federal Decisions

- Determine the stand down of the DEST.
- Determine the stand down of the FBI WMDSG.
- Determine the stand down of the FEMA CMCU to transition to long-term recovery operations.

The full range of a federal response is far more robust than described in this branch. It will include many factors requiring the involvement of a number of federal, SLTT, private, and nongovernmental entities, which may or may not be law enforcement, and will continue long after the end of the initial law enforcement/counterterrorism investigation.

## Support and Coordination Elements

To facilitate federal interagency coordination and information sharing during a biological incident, several support and operational coordination elements are utilized. These elements, combined with the assets, resources, and teams identified in **Appendix 6**, represent unique or critical federal biological capabilities that support federal, state, and local response and recovery operations.

### Domestic Emergency Support Team

The DEST is a specialized, rapidly deployable interagency team that augments the FBI's JOC. As part of its mission, the DEST supports the FBI On-Scene Commander and other officials to integrate and prioritize consequence management decisions within the operational space of the Prevention Mission. The Team supports the FBI On-Scene Commander through a JOC WMD desk and maintains connectivity with the JOC Consequence Management Group and the CMCU. The DEST also provides the FBI On-Scene Commander with expert advice and guidance to shape prevention operations in order to save lives and protect property. Team composition includes a ready roster from FEMA, FBI, Department of Defense (DoD), Health and Human Services (HHS) Office for the Assistant Secretary for Preparedness and Response, Department of Energy (DOE), Environmental Protection Agency, and others as may be appropriate. Based upon the threat and requirements, the FBI determines the composition of the DEST and maintains operational control throughout its activation predicated upon an interagency developed proposed composition. The FEMA Administrator is responsible for policies and planning governing the Team and for facilitating approval for its deployment.

### Weapons of Mass Destruction Strategic Group

When facing WMD terrorist threats, the FBI-led interagency WMDSG crisis action team is activated within the Strategic Information and Operations Center. It supports information exchange and deconfliction of counterterrorism activities to resolve imminent WMD terrorist threats while simultaneously coordinating with the nationwide effort to save lives and protect property. The WMDSG, through its collection of interagency representatives, facilitates the application of real time investigative information, intelligence, and technical analysis to WMD counterterrorism (WMD-CT) law enforcement operations; facilitates the identification and acquisition of interagency assets that could support WMD-CT law enforcement operations; and enhances WMD-CT investigative information/intelligence sharing and synchronization of law

enforcement operations with counterterrorism-related public health, homeland protection, and consequence management activities. The WMDSG, with its collaborative environment and through the dissemination of WMD Threat Profile products, contributes to the promotion of risk informed operations and decision making at all levels of the counterterrorism response, including federal and SLTT law enforcement, public health, border security, and international partners. The WMDSG connects with the FBI field division(s) and appropriate local/regional partners through the JOC(s).

### **Consequence Management Coordination Unit**

FEMA staffs and manages the CMCU, which is the principal advisory unit for consequence management considerations within the WMDSG and provides strategic recommended and integrated courses of action in light of ongoing and evolving counterterrorism operations. The CMCU links operational coordination and information sharing to DHS and sector-specific agencies' response and protection activities. The CMCU is supported by federal technical capabilities provided through DOE/National Nuclear Security Administration, HHS, DoD, and DHS. The CMCU responsibilities include—

- Coordination of the identification of potential risks for impacted populations.
- Identification of potential preparatory actions to reduce those risks to life and property by lessening the impact of the event.
- Positioning the response community to be able to respond should the event occur.

### **Operational Phases**

Operational phases for the response to and recovery from a biological incident vary based upon the size, scope, and complexity of the incident. The operational phases identified in the Response and Recovery Federal Interagency Operations Plans serve as the default posture for achieving BIA response and recovery objectives. The base annex provides an overview of this default posture. It is noted that for an intentional biological incident, Response, Recovery and Prevention Mission activities are interdependent and often concurrent. Decisions made and priorities set early in the response will have a cascading effect on the nature and speed of recovery and resolution of the threat. The phases detailed below are where certain actions during response and recovery to an intentional biological incident may diverge from actions detailed in the base Biological Incident Annex.

#### **Phase 1a (Normal Operations)**

Phase 1a activities include public preparedness messaging, educational opportunities, general response awareness, and training of emergency responders to recognize the signs and dangers associated with response to a biological incident.

The FBI and law enforcement are constantly vigilant for threats of terrorism, including biological incidents. The public health community and emergency management officials should work closely with law enforcement regarding positioning resources and appropriate capabilities in the case of an intentional biological incident.

## Phase 1b and 1c (Elevated Threat and Credible Threat)

Phase 1b and 1c activities involve employing preventive capabilities to detect the presence of biological agents. This does not include actions taken to respond to the consequences of the release of biological materials. Discovering and locating biological agents may be accomplished through active and passive surveillance and search procedures, which may include the use of systematic examinations and assessments or physical investigation and intelligence.

Suspect intentional biological incidents are immediately evaluated to determine whether the threat is credible law enforcement personnel may be confronted with a number of situations involving the actual or threatened use of biological material as a weapon. These can range from non-credible threats (hoaxes<sup>50</sup>), announcements or indications that a release of biological material has occurred (overt), or unannounced releases of a biological agent (covert). Threat information is provided through a variety of sources, including open source, private sector, SLTT partners, federal departments and agencies, the intelligence community, or foreign governments.

No single agency, department, or level of government can independently complete a threat picture of all terrorism and national security threats. With this in mind, terrorism threat intelligence and information sharing involves engagement across SLTT, federal, private sector, faith-based, and international partners to facilitate the collection, analysis, and sharing of suspicious activity reports to further support the identification and prevention of terrorist threats; enhance situational awareness of threats, alerts, and warnings; and develop and disseminate risk assessments and analysis of national intelligence to SLTT and private sector partners and across mission areas as appropriate. **Figure 12** is an example of an operational construct that could be used in phases 1b through 1c.

Phase 1c begins with the determination of a credible threat. After the threat has been deemed credible, the FBI will determine courses of action such as how to best collect and analyze the evidence, including, but not limited to, biological environmental samples. Led by the FBI, the interagency WMDSG provides a mechanism for information sharing support to strategic decision making and coordination of operations during a suspected or intentional biological incident requiring investigation into the incident's association with an actual or potential terrorist threat.

**Figure 12**, Phase 1b and 1c (Elevated Threat and Credible Threat) involve employing preventive capabilities to detect illicit biological materials and WMD at the point of manufacture, transportation, and use and to identify the nature of material through adjudication or resolution of the detection alarm. The Department of Justice (DOJ), through the FBI, is the lead agency during these two phases. HHS would serve as the Lead agency to advise and to support the crisis management activities of DOJ/FBI in medical and public health matters relevant to the biological materials and WMD. Phase 2, however, begins the implementation of the initial response whereby DOJ/FBI retain the lead in crisis management (e.g., identify the scope and nature of the threat and conducting ongoing investigative and intelligence activity), but HHS in a large-scale

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<sup>50</sup> If the threat is deemed non-credible, the FBI may initiate an investigation to identify and prosecute those responsible for creating the perception that there was a threat (i.e., a hoax).

biological incident may establish a unified coordination group (UCG) with federal departments/agencies with equities in the same core capabilities identified for naturally occurring/unintentional biological incidents. Delivery of public health and medical services and materials (e.g., Strategic National Stockpile) and the implementation of a Recovery Support Strategy for affected populations are the focus for consequence management.

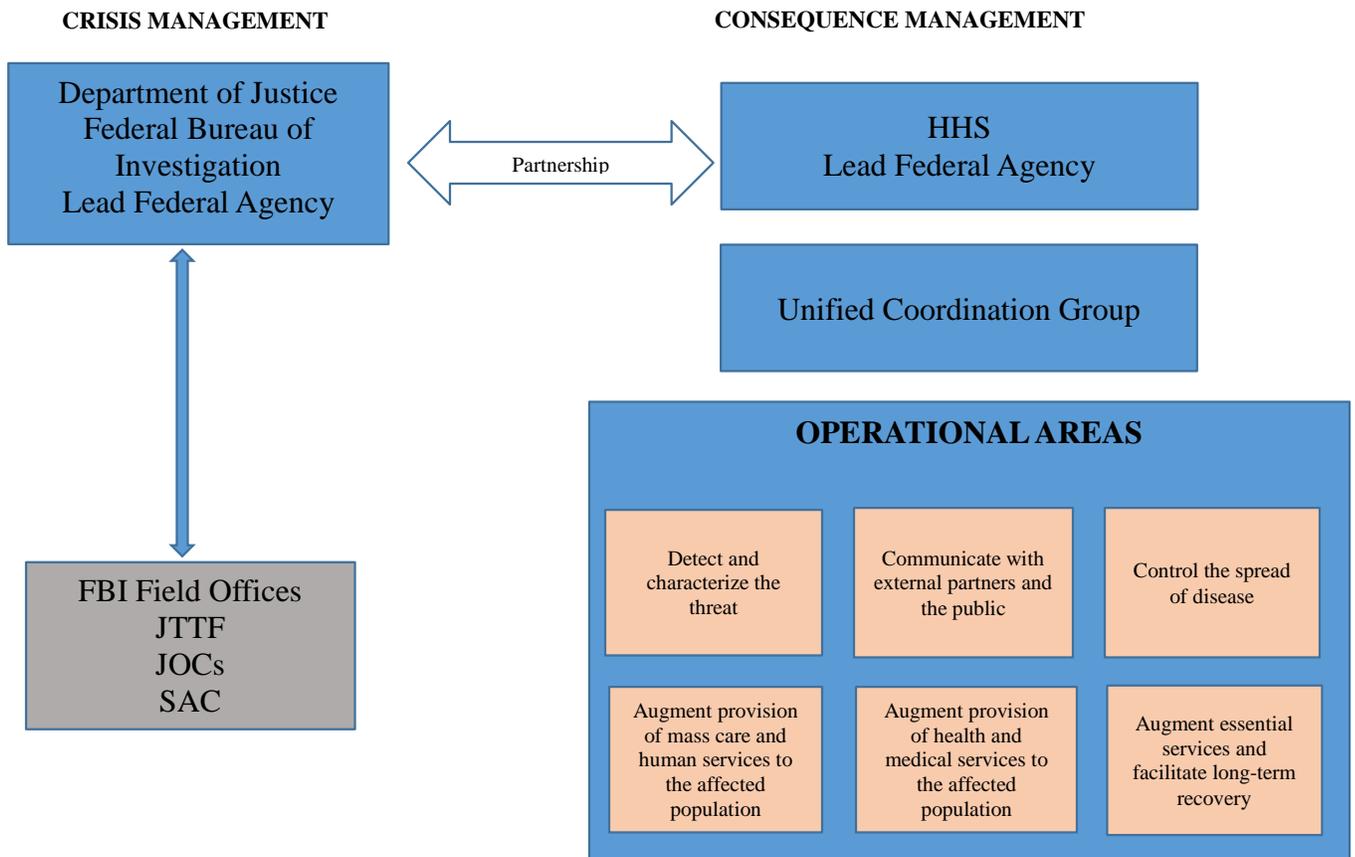


Figure 12: UCG Construct for Intentional Biological Incident

### Phase 2a (Immediate Response)

This phase begins with the implementation of initial response activities following the identification of a credible threat. This phase is dominated by efforts to provide accurate and credible information to affected individuals. In addition, law enforcement and counterterrorism operations are now actively underway.

The Prevention Mission will work to fully identify the scope and nature of the threat, such as previously unknown targets or attacks, threat network resources, and additional WMD devices. This will include conducting ongoing investigative and intelligence activities to further identify the threat, associated networks, sites, and WMD devices, etc. Steps may also be taken to verify or characterize the threat of materials or weapons that have already been located. Finally, the White House Director of Communications will coordinate risk communication strategies by implementing the Domestic Communications Strategy using primarily ESF #8 (Public Health and Medical) and ESF #15 (Public Information and Warning).

### **Phase 2b (Deployment)**

This phase begins with the implementation and deployment of federal response-related resources (personnel, personnel protective equipment, medical countermeasures) to supplement and support SLTT health authorities' activities and protect public health and safety.

### **Phase 2c (Sustained Response)**

As response operations transition to recovery, the law enforcement and counterterrorism response will likely continue (assuming the threat/s has not been fully neutralized), and the overall incident response begins to enter a sustained, long-term operation. Here, the delivery of Stafford Act programs (if there is a Stafford Act Declaration), the delivery of public health services and material (e.g., Strategic National Stockpile), and the completion of a Recovery Support Strategy have occurred. In addition, the provision of accessible interim housing/sheltering solutions (for those affected populations with contaminated biological agent/s) and the supporting reestablishment of businesses have occurred.

## Acronyms

Acronym	Term
ACF	Administration of Children and Families
AE	Aeromedical Evacuation
AFHSB	Armed Forces Health Surveillance Branch
APHIS	Animal and Plant Health Inspection Service
APHT	Applied Public Health Team
ARL	Air Resources Library
ASPA	Assistant Secretary for Public Affairs
ASPR	Assistant Secretary for Preparedness and Response
BAC	BioWatch Advisory Committee
BAR	BioWatch Actionable Result
BARDA	Biomedical Advanced Research and Development Authority
BIA	Biological Incident Annex
BINA	Biological Incident Notification and Assessment
CBP	Customs and Border Protection
CBRN	Chemical, Biological, Radiological, Nuclear
CBRNE	Chemical, Biological, Radiological, Nuclear, and High-Yield Explosives
CDC	Centers for Disease Control and Prevention
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CIKR	Critical Infrastructure Key Resource
CMCU	Consequence Management Coordination Unit
COCA	Clinician Outreach and Communication Activity
COG	Continuity of Government
COM	Chief of Mission
COOP	Continuity of Operations
DEST	Domestic Emergency Support Team
DHS	Department of Homeland Security
DLG	Disaster Leadership Group

<b>Acronym</b>	<b>Term</b>
DLN	Department of Defense Laboratory Network
DMAT	Disaster Med Assistance Team
DMORT	Disaster Mortuary Operational Response Team
DOC	Department of Commerce
DoD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
DOJ	Department of Justice
DOL	Department of Labor
DOS	Department of State
DOT	Department of Transportation
DPA	Defense Production Act
DPMU	Disaster Portable Morgue Unit
DRG	Domestic Resilience Group
D-SNAP	Disaster Supplemental Nutrition Assistance Program
ECC	Environmental Clearance Committee
EIS	Epidemic Intelligence Service
EMG	Emergency Management Group
EMGLOG	Emergency Management Group Logistics
EO	Executive Order
EOC	Emergency Operations Center
EPA	Environmental Protection Agency
EpiX	Epidemic Information Exchange
ERLN	Environmental Response Laboratory Network
ESF	Emergency Support Function
ETA	Employment Training Administration
EUA	Emergency Use Authorization
FAA	Federal Aviation Administration

<b>Acronym</b>	<b>Term</b>
FBI	Federal Bureau of Investigations
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
FERN	Food Emergency Response Network
FHCO	Federal Health Coordinating Officer
FIOP	Federal Interagency Operational Plan
FSIS	Food Safety and Inspection Service
FWS	U.S. Fish and Wildlife Service
GPMRC	Global Patient Movement Requirements Center
HAN	Health Alert Network
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HIPPS	Department of Health and Human Services International Policy Group for Personnel Sharing
HRSA	Health Resources and Services Administration
HSPD	Homeland Security Presidential Directive
ICLN	Integrated Consortium of Laboratory Networks
ICS	Incident Command System
IC/UC	Incident Command/Unified Command
IHR	International Health Regulations
HIS	Indian Health Service
IMAAC	Interagency Modeling and Atmospheric Assessment Center
IRCT	Incident Response Coordination Team
ISMPG	International Sharing of Medical Countermeasures Policy Group
JIC	Joint Information Center
JOC	Joint Operations Center
JTTF	Joint Terrorism Task Force
LRN	Laboratory Response Network

<b>Acronym</b>	<b>Term</b>
MaHIM	Medical and Health Incident Management
MCM	Medical Countermeasures
MCMi	Medical Countermeasures Initiative
MI	Managed Inventory
MSRT	Marine Security Response Team
NAHLN	National Animal Health Laboratory Network
NBFAC	National Bioforensic Analysis Center
NBIC	National Biosurveillance Integration Center
NBIS	National Biosurveillance Integration System
NCMI	National Center for Medical Intelligence
NDMS	National Disaster Medical System
NDRF	National Disaster Recovery Framework
NEA	National Emergencies Act
NGO	Nongovernmental organization
NICCL	National Incident Coordination Conference Line
NIH	National Institutes of Health
N-IMAT	National Incident Management Assistance Team
NIMS	National Incident Management System
NIOSH	National Institute for Occupational Safety and Health
NIST	National Incident Support Team
NNDSS	National Notifiable Disease Surveillance System
NNSA	National Nuclear Security Administration
NOAA	National Oceanic and Atmospheric Administration
NOC	National Operations Center
NPDN	National Plant Diagnostic Network
NPHIC	National Public Health Information Coalition
NHTSA	National Highway Traffic Safety Administration
NPI	Non-Pharmaceutical Intervention

<b>Acronym</b>	<b>Term</b>
NPPD	National Protection and Programs
NPS	National Park Service
NRCC	National Response Coordination Center
NRF	National Response Framework
NRT	National Response Team
NSC	National Security Council
NSF	National Strike Force
OCET	Office of Counterterrorism and Threats
OEM	Office of Emergency Management
OFDA	Office for Foreign Disaster Assistance
OHA	Office of Health Affairs
OPM	Office of Personnel Management
OPP	Office of Policy and Planning
OSC	On-Scene Coordinator
OSH Act	Occupational Safety and Health Act
OSHA	Occupational Safety and Health Administration
PACL	Public Affairs Conference Line
PAHPA	Pandemic and All-Hazards Preparedness Act
PAHPRA	Pandemic and All-Hazards Preparedness Reauthorization Act
PHE	Public health emergency
PHEF	Public Health Emergency Fund
PHEIC	Public health emergency of international concern
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHMSA	Pipeline and Hazardous Materials Administration
PHS	Public Health Service
PHSA	Public Health Service Act
PKRMRA	Post-Katrina Emergency Management Reform Act
POD	Point of Distribution

<b>Acronym</b>	<b>Term</b>
PPD	Presidential Policy Directive
PPE	Personal Protective Equipment
PREP	Public Readiness and Emergency Preparedness (Act)
RDF	Rapid Deployment Force
REC	Regional Emergency Coordinator
RIST	Regional Incident Response Team
RRT	Regional Response Team
RSF	Recovery Support Function
SAMHSA	Substance Abuse and Medical Health Services Administration
SCC	Sector Coordinating Council
SLTT	State, local, tribal, territorial
SNS	Strategic National Stockpile
SOC	Secretary's Operation Center
SSA	Sector-Specific Agency
TCE	Threat Credibility Evaluation
UCG	Unified Coordination Group
USACE	U.S. Army Corps of Engineers
USAID	U.S. Agency for International Development
USCG	U.S. Coast Guard
USDA	U.S. Department of Agriculture
USG	United States Government
USGS	U.S. Geological Survey
USPHS	U.S. Public Health Service
USNORTHCOM	U.S. Northern Command
VA	Department of Veterans Affairs
WFRC	Western Fisheries Research Center
VOAD	Voluntary Organizations Active in Disasters
WHO	World Health Organization

<b>Acronym</b>	<b>Term</b>
WMD	Weapons of Mass Destruction
WMD-CT	Weapons of Mass Destruction Counterterrorism
WMDSG	Weapons of Mass Destruction Strategic Group

## Glossary

**Aerosol:** Fine liquid or solid particles suspended in a gas; for example, fog or smoke.

**Animal:** Animals include household pets, service and assistance animals, working dogs, livestock, fish, wildlife, exotic animals, zoo animals, research animals, and animals housed in shelters, rescue organizations, breeding facilities, and sanctuaries.

**Bacteria:** Microscopic one-celled organisms present throughout the environment that require a microscope to be seen. While not all bacteria are harmful, some cause disease. Examples of bacterial disease include diphtheria, pertussis, and tetanus.

**Biological Actionable Result:** A polymerase chain reaction verified positive result from a BioWatch collector.

**BioWatch:** U.S. Federal Government program to detect the release of pathogens into the air as part of a terrorist attack on major U.S. cities.

**Category A Biologic Agent:** organisms/biological agents that pose the highest risk to national security and public health because they (1) can be easily disseminated or transmitted from person to person, (2) result in high mortality rates and have the potential for major public health impact, (3) might cause public panic and social disruption, and (4) require special action for public health preparedness.

**Category B Biologic Agent:** the second highest priority organisms/biological agents that (1) are moderately easy to disseminate, (2) result in moderate morbidity rates and low mortality rates, and (3) require specific enhancements for diagnostic capacity and enhanced disease surveillance.

**Category C Biologic Agent:** the third highest priority and include emerging pathogens that could be engineered for mass dissemination in the future because of (1) availability, (2) ease of production and dissemination, and (3) potential for high morbidity and mortality rates and major health impact.

**Causative Agent:** The biological pathogen that causes a disease such as a virus, parasite, fungus, or bacterium.

**Contaminated:** The presence of an infectious agent on a body surface, the environment, also on or in clothes, bedding, toys, surgical instruments or dressings, or other inanimate articles or substances including water, milk, and food.

**Decontamination:** The process of making any person, animal, object, or area safe by absorbing, destroying, neutralizing, making harmless, or removing the hazardous material.

**Detection:** The clinical or laboratory discovery of a biological pathogen.

**Disease:** Sickness, illness, or loss of health.

**Disease Surveillance:** An epidemiological practice by which the spread of disease is monitored in people, animals, in order to establish patterns of progression.

**Epidemiologist:** An investigator who studies the occurrence of disease or other health-related conditions, states, or events in specified populations; one who practices epidemiology; the control of disease is advised by the epidemiologist based on his/her investigation.

**Exposed:** Unprotected contact to an infectious agent, which may or may not develop disease.

**Exposure:** Contact with infectious agents (bacteria or viruses) in a manner that promotes transmission and increases the likelihood of disease.

**First Receiver:** Employees at a hospital engaged in decontamination and treatment of victims who have been contaminated by a hazardous substance(s) during an emergency incident. The incident occurs at a site other than the hospital. These employees are a subset of first responders.

**Infectious:** Capable of spreading disease; also known as communicable.

**Infectious agents:** Organisms capable of spreading disease (e.g., bacteria or viruses).

**Isolation:** Isolation involves physical separation of individuals with a contagious infectious illness from healthy individuals that have not been exposed to the biological agent. Isolation can be implemented at home or in a separate room in a healthcare setting depending on the specific nature of the biological incident.

**Medical Countermeasures (MCM):** Regulated pharmaceutical products and interventions used to combat the effects of chemical, biological, radiological, or nuclear incidents.

**Multi-Agency Coordination Centers (MACC):** A combination of facilities, equipment, personnel, procedures, and communications integrated into a common system with responsibility for coordinating and supporting domestic incident management activities.

**National Biosurveillance Integration Center (NBIC):** An entity within DHS, established to enhance the nation's capability to integrate biosurveillance efforts. The NBIC serves as the designated government entity to synthesize and analyze information collected from across the spectrum of biosurveillance organizations.

**Non-pharmaceutical interventions (NPI):** Item such as ventilators, devices, personal protective equipment such as face masks, gloves, and public health interventions (e.g., contact and transmission interventions, social distancing, and community shielding) to prevent and mitigate the health effects of biological agents, some of which may be FDA-regulated and some of which are not.

**Outbreak:** An increase in a disease in a certain geographic area, over a certain period of time, above an expected baseline (it may be one case for smallpox, for example, but for others there may be some baseline level of disease that needs to be exceeded to be considered an outbreak

**Pandemic:** An epidemic that has spread to human populations across a large geographic area.

**Parasite:** Any organism that lives in or on another organism without providing benefit in return.

**Pathogens:** Organisms (e.g., bacteria, viruses, parasites, and fungi) that cause disease in human beings.

**Public Health Emergency (PHE):** An incident, either natural or manmade, that creates a health risk to the public.

**Prion:** A small proteinaceous infectious disease-causing agent that is believed to be the smallest infectious particle. A prion is neither bacterial nor fungal nor viral and contains no genetic material.

**Quarantine:** Quarantine is the segregation of individuals, families, groups, and communities that have been exposed to a contagious disease but are not ill. These individuals are physically separated and their movement restricted within defined geographic areas. Quarantine may be done at home or in a restricted area depending on the specific nature of the biological incident.

**Vaccine:** A preparation of killed or weakened microorganism products used to artificially induce immunity against a disease.

**Virus:** A microscopic organism that multiplies within cells and causes disease such as chickenpox, measles, mumps, and rubella. Viruses are not affected by antibiotics, the drugs used to kill bacteria.

**Zoonotic Diseases:** Disease where a virulent pathogen may move from animal to human communities or vice versa.

**Zoonosis:** A disease communicable from animals to humans and vice versa under natural conditions.