



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

*May 2023*



Homeland  
Security

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## Handling Instructions

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## 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., state, local, tribal, territorial [SLTT] as well as insular area governments; non-governmental organizations [NGOs]; voluntary agencies; and the private sector) engaged in their own planning efforts will find this document useful in enhancing their understanding of how the BIA is implemented and how to best integrate their planning efforts with those outlined in this annex.

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

## Rescission Notice

Publication of this BIA rescinds the following documents: *2008 BIA to the National Response Framework* and the 2017 BIA to the Response FIOP.

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## Annex Overview

This *Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plan (FIOP)* replaces the *2017 BIA to the Response FIOP*. The BIA serves as the federal organizing framework for responding to and recovering from a range of biological threats and incidents. The BIA also serves as a reference for state, local, tribal, and territorial (SLTT) authorities and private sector organizations to conduct adaptive planning that is consistent with hazard and risk analysis for specific biological threats in their communities. This BIA is designed to be scalable, flexible, and adaptable for a wide range of biological incidents, regardless of cause, size, location, or complexity.

In this annex, a biological threat/incident refers to a situation in which an agent of biological origins results in a significant national incident. Most actions necessary to address biological incidents occur at the SLTT levels and in the private sector. Although the federal government has a prominent supporting role and some primary responsibilities (e.g., border control), most legal authorities occur at the SLTT levels as well. The Department of Health and Human Services (HHS), in consultation with other relevant agencies, determines if interagency support is or will be required. Biological incidents can involve a microbiological organism (e.g., virus, bacterium, fungus, protozoan, etc.) or biologically derived protein or toxin (e.g., ricin, prions, etc.) that can affect human health, food and agriculture. (See the *Food and Agriculture Incident Annex [FAIA]* for additional details.) For investigations concerning suspected or known intentional biological incidents involving biologically derived toxins, see Attachment 1: Branch 1 Plan: Intentional Biological Incidents.

Response to a biological incident should be well coordinated across the federal government and, when appropriate, must be integrated with the law enforcement, intelligence community, and/or counterterrorism responses. Coordination across the consequence management, law enforcement, and counterterrorism communities helps to ensure integrated and risk-informed decision making.

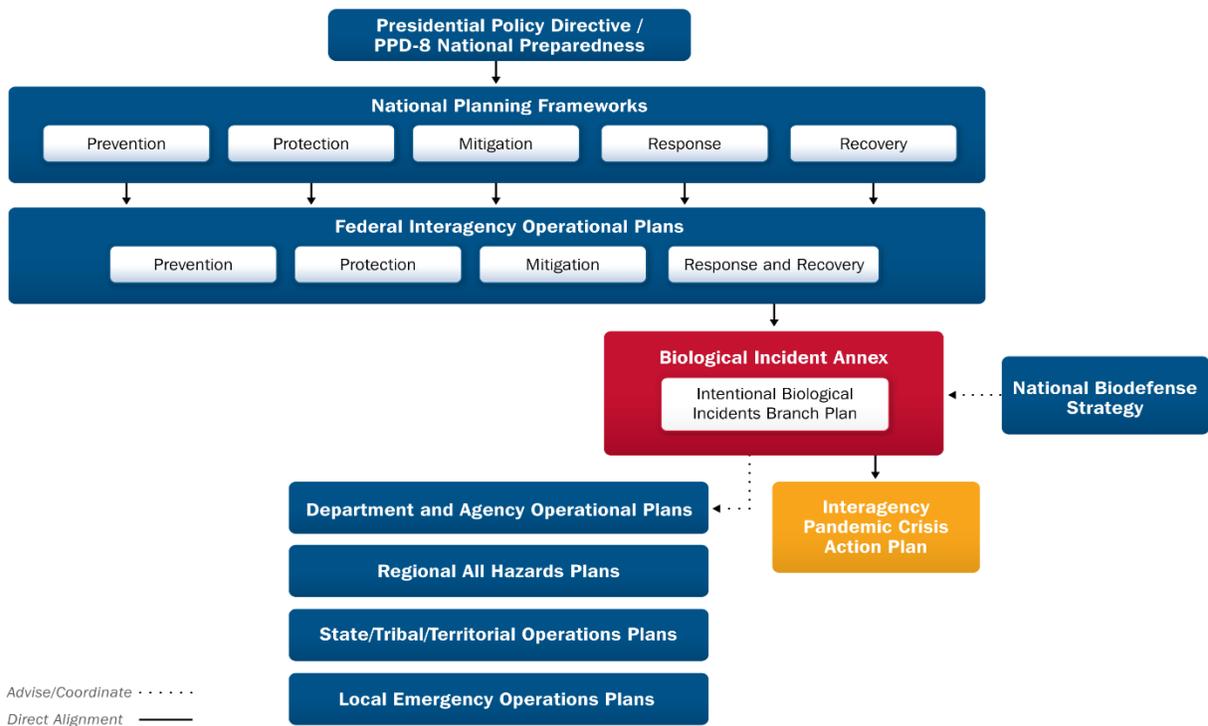
Although the BIA provides guidance for the whole community, it focuses intentionally on the requirements of those involved in delivering core capabilities at the federal level. The BIA does not alter or impede the ability of any SLTT authority or federal agency<sup>1</sup> to execute its authorities or to meet and carry out its roles and responsibilities under applicable laws, executive orders (EOs), regulations, or policy directives and memoranda. The BIA does, however, emphasize the importance of unified coordination, collaboration, and information sharing across the federal government to both support the designated lead federal agency (LFA) and to execute policies, response plans, and Executive Branch directives in the event of a biological incident not managed pursuant to the Robert T. Stafford Disaster Relief and

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<sup>1</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 over, or provide support to, the response to and recovery from a biological incident.

Emergency Assistance Act (Stafford Act) or managed pursuant to a Stafford Act Emergency Declaration.

The BIA is composed of a base annex and a branch plan for intentional biological incidents (Attachment 1: Branch 1 Plan: Intentional Biological Incidents), both of which are noted in Figure 1. The base document is applicable to most biological threats and incidents, whereas the Branch 1 Plan focuses on suspected or known intentional attacks affecting the United States or U.S. territories. The Branch 1 Plan, which covers intentional biological incidents, details the importance of establishing operational coordination among the Prevention, Response, and Recovery Mission Areas.<sup>2</sup> The BIA is supplemental to, and not duplicative of, the FIOF and other subordinate plans.



**Figure 1: Department and Agency Operational Plans**

The BIA is an annex to the Response and Recovery FIOF. The FIOF provide details regarding agency roles, responsibilities, and critical tasks and identify resourcing and sourcing requirements for the delivery of core capabilities. The BIA uses the same concepts of operations for delivering response and recovery core capabilities but highlights the unique attributes of a biological incident. The BIA also includes references to intentional threats and incidents, including acts of terrorism. This annex supersedes the previous *2017 BIA to the Response FIOF*. Actions described in this annex may take place with or without a Public

<sup>2</sup> Planners should also anticipate the execution of additional plans of the law enforcement community and, when appropriate, the counterterrorism community during the response phase to biological threats or incidents. These plans also contain descriptions of the roles and responsibilities of federal and SLTT agencies.

Health Emergency (PHE) declaration by the Secretary of HHS or a Presidential Stafford Act declaration.

The term “response” within this annex refers to those activities and capabilities within the Response and Recovery Mission Areas, commonly identified as “consequence management” activities and capabilities, that are exclusive of any law enforcement, counterterrorism, or criminal investigation activities and capabilities otherwise described within the Prevention Mission Area.

The term “consequence management” is used to describe Response and Recovery Mission Area activities that protect public health and safety, restore government services, and provide emergency relief to governments, businesses, and individuals affected by the consequences of an incident. For the purposes of this annex, these activities include but are not limited to securing the incident site, assessing the dispersal of biological material, enhancing first responder capabilities, ensuring the availability of decontamination and site remediation resources, providing biological medical triage capabilities, increasing population resilience and recovery capabilities, and providing public health guidance on and rapid development and deployment of medical countermeasures (MCMs).

The term “crisis management” is used to describe Prevention Mission Area activities that include but are not limited to activities for an operational law enforcement and counterterrorism response, including criminal investigative activities and other activities and capabilities that are more fully described in the Branch 1 Plan (Intentional Biological Incident) of this BIA. Consequence management and crisis management planners should recognize that some consequence management and crisis management activities may overlap during biological threats and incidents (e.g., securing the incident site or collecting evidence in hazardous environments).

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# SITUATION

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Public health emergencies can occur anywhere within the United States, sometimes impacting multiple geographic regions simultaneously. Greater movement of people, animals, plants, and goods across international borders increases the risk of exposure to health threats originating outside of the United States. Widespread and improper use of antibiotic, anti-viral, antifungal, and anti-parasitic medications and other medical countermeasures (MCMs) are accelerating the emergence of drug-resistant pathogens. While public health emergencies regularly require a coordinated response, this annex addresses biological pathogens<sup>3</sup> that pose a significant impact to the country, have the potential to overwhelm SLTT resources, and can lead to incidents for which HHS, as the lead federal agency (LFA)<sup>4</sup> for all public health and medical responses, deems that interagency support is or will be required.

Planning and preparedness for a biological incident requires consideration of features particularly characteristic of that type of incident, such as the infectious nature of the agent (communicable or non-communicable), availability and efficacy of MCMs, use of non-pharmaceutical interventions (NPIs), potential establishment of non-human reservoirs, or potential for environmental contamination.

A communicable disease is defined as an infectious disease that is transmissible by contact with infected individuals or their bodily discharges or fluids (such as respiratory droplets, blood, or semen), contact with contaminated surfaces or objects (fomites), ingestion of contaminated food or water, or direct or indirect contact with disease vectors (such as mosquitoes, fleas, or mice). Examples include cholera, hepatitis, influenza, malaria, measles, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)—the causative agent of Coronavirus disease 2019 [COVID-19], and hemorrhagic fever viruses such as Ebola virus, human immunodeficiency virus (HIV), and tuberculosis. Less common examples include pneumonic plague.

Note: Zoonotic disease (also known as zoonosis) occurs when a disease can be transmitted between animals and humans. Some communicable diseases of concern to the agricultural industry are zoonotic in nature (e.g., highly pathogenic avian influenza [HPAI]) and are only covered here when posing a risk to human life. Animal and agricultural risks are covered in the FAIA. A priority in communicable disease investigation and mitigation is determining the source of the disease to limit its further spread and to develop prevention and mitigation

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<sup>3</sup> Pathogen is the term used for this document; toxins are addressed in the Biotoxins Addendum.

<sup>4</sup> As set forth in greater detail below, this annex provides that HHS acts as the LFA for the public health and medical response during biological incidents. For suspected intentional biological threats and incidents, the Department of Justice (DOJ), acting through the Federal Bureau of Investigation (FBI), is the LFA for the operational law enforcement response to such threats and incidents. (See Attachment 1: Branch 1 Plan: Intentional Biological Incidents.)

measures.<sup>5</sup> Examples of non-communicable diseases that require an interagency response include inhalational/aerosolized anthrax and tularemia.

Some biotoxins are not covered in the base annex regardless of their biological origin, such as botulinum toxin, ricin, abrin, aflatoxin, and trichothecene mycotoxins. The Branch 1 Plan addresses intentional acts involving biotoxins. (Additional information is provided in Attachment 2: Biologically Derived Toxins Addendum to the BIA.)

It should be anticipated that the roles and responsibilities of the public health and medical community and the emergency management community will intersect. The timeframe in which to provide initial health and medical response support and the large number and variety of response partners require advanced planning as well as close coordination during a biological threat or incident for all communities to conduct operations successfully. Moreover, while the goal is to protect human health and safety, planning and preparedness for an intentional biological incident adds complexities that require enhanced planning and preparedness coordination among the consequence management and crisis management communities (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

Depending on the circumstance of the biological incident, response and recovery activities may be complex and challenging for the whole community. Many pathogens, including those that are novel and are difficult to detect and/or treat can spread across the globe quickly, posing threats to national security that require federal intervention and coordination. Moreover, each type of pathogen poses unique response and recovery challenges that the U.S. may be forced to confront. Climate change, disasters, or other incidents can change disease patterns, increasing the risk of a biological incident. Genetic shifts may alter the characteristics (e.g., virulence and transmissibility) of common pathogens, potentially resulting in increased morbidity and/or mortality.

Managing large-scale public health emergencies and coordinating the response and recovery related to those incidents increasingly requires simultaneous domestic and international actions that are often interconnected. Recent experiences, including the global spread of the COVID-19 (2020) virus, the H1N1 (2009) influenza virus, the emergence of Middle East respiratory syndrome coronavirus (MERS-CoV), the outbreak of Ebola virus disease in West Africa, Zika virus disease, H7N9 influenza virus, and a range of natural disasters with associated public health consequences (e.g., the Haiti earthquake) have shown that public health and medical emergencies in one part of the world can quickly develop into international health security crises that pose a risk to populations everywhere.

The list below provides examples of several biological incidents that have occurred since 2009 and required significant federal support.

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<sup>5</sup> Note: Some communicable diseases of concern to the agricultural industry that are zoonotic in nature may be covered in this document as well as the FAIA. This annex may use call-out boxes or using other methods to highlight the information.

- 2009 H1N1 Influenza Pandemic:** A novel influenza strain began spreading in 2009. Few young people had any existing immunity to the virus, but nearly one-third of people over 60 years old had antibodies against this virus, likely from exposure to an older H1N1 virus earlier in their lives. Since the 2009 H1N1 pandemic, the H1N1pdm09 virus has circulated seasonally in the U.S., causing significant illnesses, hospitalizations, and deaths. From April 12, 2009, to April 10, 2010, there were approximately 60.8 million cases, 274,304 hospitalizations, and 12,469 deaths in the U.S. due to the H1N1pdm09 virus.<sup>6</sup> A nationwide Public Health Emergency was declared by the HHS Secretary. HHS/Centers for Disease Control and Prevention (CDC) led the federal government response for the 2009 H1N1 influenza pandemic.
- West Africa Ebola Virus Epidemic (2014–2016):** Ebola virus was first described in 1976 near the Ebola River in what is now the Democratic Republic of the Congo. Since then, the virus has emerged periodically by infecting people in several African countries. Ebola virus disease is rare but severe and often deadly. The largest Ebola epidemic occurred in 2014 and resulted in over 28,610 cases and 11,308 deaths worldwide. In September 2014, a man flew from Liberia to Dallas, Texas, and became ill with Ebola after his arrival; he died in a Dallas hospital. Two nurses who cared for him became infected with Ebola, were hospitalized, and recovered. A fourth U.S. case was confirmed in a healthcare worker (HCW) who returned from West Africa to New York City in October 2014, was hospitalized there, and recovered. Additionally, seven persons with Ebola symptoms were transported by charter aircraft from West Africa to U.S. hospitals; six of these patients recovered. This epidemic highlighted the possibility of a localized outbreak threatening global populations. Even though the cases were limited in the U.S., HHS provided a large amount of direct and technical support. HHS worked alongside the United States Agency for International Development (USAID) to support impacted countries and prevent the spread of disease within Africa and to the U.S.
- Zika Virus Outbreaks (2016–2019):** Zika is a virus that can be transmitted through mosquito bites, from a pregnant woman to her fetus, through sex, and very likely through blood transfusion. Symptoms of Zika usually do not require hospitalization and very rarely is it deadly. Prior to 2014, very few travel-associated cases of Zika virus disease were identified in the U.S. In 2015 and 2016, large outbreaks of Zika virus occurred in the Americas, resulting in an increase in travel-associated cases in the continental U.S. (CONUS), widespread transmission in Puerto Rico and the U.S. Virgin Islands, and limited local transmission in Florida and Texas. When spread during pregnancy, the virus can cause microcephaly and other severe brain defects to the fetus and is linked to other serious issues, such as miscarriage, stillbirth, and other birth defects. Due to its potential effect on pregnant women and children born to pregnant women with Zika, a Public Health Emergency for Puerto Rico and

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<sup>6</sup> [2009 H1N1 Pandemic \(H1N1pdm09 virus\) | Pandemic Influenza \(Flu\) | HHS/CDC](#)

nationally was declared by the HHS Secretary. A regional Unified Coordination Group (UCG) was created to support the federal response in Puerto Rico.

- **COVID-19 Pandemic (2020–ongoing):** SARS-CoV2 is a novel respiratory virus that quickly spread globally. The virus has caused a wide range of severity among individuals, from asymptomatic infections to severe cases requiring hospitalization and mechanical support, and even death. As of May 15, 2022, 82,301,126 cases and 997,083 deaths in the United States were reported to HHS/CDC.<sup>7</sup> A nationwide Public Health Emergency was declared by the HHS Secretary. Additionally, this pandemic event was the first biological incident to receive a nationwide Stafford Act declaration. During the initial stages of the federal response, a UCG was formed to manage federal support to SLTT partners across the country.

Both state and non-state actors have expressed interest in the acquisition and intentional use of biological pathogens and toxins as weapons. Advances in technology and scientific knowledge can decrease the barrier of entry for the use of such weapons and therefore also greatly affect and change the threat landscape. It is the policy of the United States that, until otherwise determined,<sup>8</sup> any potential terrorist incident involving the suspected use of a weapon of mass destruction, to include a biological incident, is to be treated as an actual terrorist incident. (See Attachment 1: Branch 1 Plan: Intentional Biological Incidents.)

Biological threats and incidents may be complicated by incomplete information, particularly the uncertainty in detection and recognition that an incident is occurring. It is critical to establish initial incident parameters, although they may not be readily discernable, including:

- Potential for human-to-human transmission
- Virulence of the pathogen
- Enhanced drug resistance
- Engineered pathogens with special properties (e.g., immune escape)

Biological threats or incidents present numerous challenges that may diminish the ability of response entities to respond to the emergency. These include the following:

- They may pose a direct threat to first responders and receivers as well as their respective families.
- Pre-hospital services, healthcare, and public health systems, which are often taxed during day-to-day operations, can be overwhelmed.
- Lack of available specific MCMs (e.g., monoclonal antibodies or approved antiviral drugs) relegate treatment to general supportive care.

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<sup>7</sup> Current information available at [CDC COVID Data Tracker: Home](#).

<sup>8</sup> The Attorney General of the United States, acting through the Director of the FBI, determines whether a particular situation is to be treated as an actual terrorist incident.

- As a rule, most healthcare in the U.S. is provided in the private sector. The federal government does not have sufficient resources to replace this private sector capability.
- Response and recovery from a biological incident may span months or even years, therefore seamless, ongoing federal coordination is vital.

A biological threat or incident may generate fear/anxiety in affected communities, either due to the nature of the agent/incident itself or the propagation of misinformation, disinformation, or malinformation. In accordance with applicable policy, public health and other authorities should address any fear/anxiety or other public concerns that may arise from and combat misinformation, disinformation, or malinformation. In addition, the following measures should be implemented:

- Ensure early coordinated, consistent, and unified public messaging that provides credible, clear, timely, and actionable information that is accessible and culturally and linguistically appropriate for all affected populations. Public messaging should adhere to the principles of risk communications, even in areas unaffected by the incident, and include information regarding the threat, hazard, or incident, as well as the actions being taken and the assistance that is available, including addressing behavioral health impacts that may be significant in impacted populations.
- In some situations, citizens that have not actually been exposed may seek medical assistance, thereby unnecessarily burdening the capacity of medical facilities to treat those that have been wounded or are ill. Timely and effective public messaging and medical triage reduces such impacts. Significant mental health impacts (e.g., depression, anxiety, post-traumatic stress disorder) could overwhelm existing behavioral health counseling professionals and facilities and call for less-traditional methods of delivering psychological support.

This annex was written with the intent to cover a wide range of scenarios, leveraging the commonalities between them. Furthermore, not all infectious diseases cause a biological incident of the size and complexity to require the activation of a national level UCG. However, a set of core capabilities, if well executed, go far to mitigate the effects of a biological threat or incident. Additionally, preparing for, responding to, and recovering from an intentional biological threat or incident spans the Prevention, Response, and Recovery Mission Areas, further complicating the execution of the activities described in this annex.

## Purpose

The BIA provides hazard-specific supplemental information to the Response and Recovery FIOP. Federal interagency partners can respond in a lead role or in support of SLTT governments to save lives; reduce disease; protect property, critical infrastructure, the workforce, and the environment; ensure economic stability; and meet basic human needs when there is a threat of or an actual biological incident.

This BIA addresses pertinent core capabilities of LFAs, including the unique aspects of biological incidents that are not addressed in the Response and Recovery FIOP. The BIA acknowledges the potential differences in operational phase structures between federal agencies but urges the importance of alignment of federal coordination and collaborative mechanisms to achieve an early and effective response. The complex nature of biological incident response and recovery efforts among federal agencies requires effective communications, coordination, and collaboration. Intergovernmental collaboration could begin slowly and increase steadily, depending on how the incident spreads or occurs. Finally, the BIA aims to serve as a reference point for SLTT authorities and private sector organizations to conduct adaptive planning efforts, based on their hazard and risk analyses, for specific biological pathogens that are a threat to their communities and public health.

This BIA:

- 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 FIOP that is specific and unique to federal biological incident response and recovery processes, assets, resources, and teams.
- Acknowledges differences in operational phase structures between departments and agencies (D/A) and aligns coordination to foster effective communications, coordination, and collaboration between the federal government, SLTT governments, and private sector organizations.
- Details the mechanisms and structures for information sharing and coordination with the Prevention Mission and consequence management involving suspected intentional biological threats and incidents (e.g., FBI-led Weapons of Mass Destruction Strategic Group [WMDSG]).
- Serves as a reference point for SLTT authorities and private sector organizations to conduct adaptive planning efforts, based on their hazard and risk analyses, for specific biological pathogens that are a threat to their communities and public health.

The Branch 1 Plan (Intentional Biological Incidents) included in this BIA also describes operational coordination and information-sharing mechanisms within the Prevention Mission when biological threats and incidents are suspected to be or are intentional, including when federal crimes of terrorism involving biological pathogens are suspected. For example, for certain types of biological threats and incidents, the FBI-led WMDSG may be activated.

## Scope

The BIA applies to the federal response to biological threats and incidents, regardless of whether they are naturally occurring, accidental, or intentional acts that pose a significant

human health hazard to the United States, as measured by injury, death, or damage to property, critical infrastructure, the environment, or the economy. It incorporates national capabilities and requirements that are fully executable anywhere in the United States or U.S. territory areas, including those originating abroad that have the potential to spread among the U.S. population.

The BIA 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 authorities.

The BIA maps to the Response and Recovery FIOP and addresses the following:

- Identifies top-level, decision-making processes.
- Spans response through recovery actions.
- Supports international aspects of biological threats or incidents as they relate to domestic preparedness and response.
- Addresses the human-animal interface as it pertains to a biological incident.

The BIA does not address the following:

- International response operations.
- Diseases in livestock, poultry, and other animal-specific and plant-borne biological hazards that pose a limited threat to human populations.
- Biotoxins (e.g., ricin, saxitoxin, mycotoxins):
  - For criminal-related investigations concerning intentional incidents involving biologically derived toxins (e.g., ricin, saxitoxin, mycotoxins), see Attachment 1: Branch 1 Plan: Intentional Biological Incidents.
  - For consequence management responses to such incidents, see Attachment 2: Response to Biologically Derived Toxins Addendum.

## Facts, Planning 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 FIOP. Additional facts, assumptions, and considerations that pertain to the specifics of an intentional incident are delineated in Attachment 1 of this BIA (Branch 1 Plan: Intentional Biological Incidents).

### Facts

- SLTT governmental public health agencies have primary responsibility and authority for the public health response to biological incidents within their jurisdictions and can independently implement public health actions. Because of this, these actions may

differ from those of surrounding jurisdictions or those proposed by the federal government.

- The HHS Secretary is authorized to take measures to prevent the entry and spread of communicable disease from foreign countries into the U.S. and between states. The authority for carrying out these functions daily has been delegated to HHS/CDC.<sup>9</sup>
- Under the International Health Regulations (IHR) of 2005, the United States is obligated to report to the World Health Organization (WHO) any potential Public Health Emergency of International Concern (PHEIC). This is done through the U.S. IHR National Focal Point (NFP) at HHS. In addition, the U.S. provides information to the United Nations on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal patterns of spread, in accordance with its obligations under the Biological Weapons Convention.<sup>10</sup>
- If the pathogen has an animal or plant reservoir, infection control measures for humans may include an available MCM and isolation. To control the pathogen in animal or plant species, biosecurity measures, quarantine, and/or depopulation, disposal, and decontamination may be necessary.
- Many illnesses have similar initial symptoms and may be undiagnosed or improperly diagnosed until the disease and time progress or there is laboratory confirmation of the biological agent.
- NPIs are measures that limit the spread of a pathogen and can be applied at the individual level or community level.
- MCMs have been identified and stockpiled to reduce the health impacts of specifically identified biological threats. Others may need to be developed at the time of the incident and could require significant investment of resources.
- Biological contaminants are likely to redistribute in the environment following an intentional release. Response and remediation strategies should anticipate, monitor, and adapt to these changes.

## Planning Assumptions

In the absence of facts, planning assumptions represent information presumed to be true and are necessary 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.

- Public health epidemiological investigations are used to identify causative agents, sources of exposure, and populations at risk and may be conducted concurrent to or jointly (Criminal-Epidemiological) with law enforcement to determine the source of

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<sup>9</sup> Section 361 of the Public Health Service Act (42 U.S.C. § 264) and 42 Code of Federal Regulations (CFR) 70 and 71.

<sup>10</sup> In the instance of a criminal investigation/act or suspected threat of terrorism, FBI shall be consulted before releasing potentially sensitive law enforcement information.

the outbreak for suspected intentional incidents. (See Branch 1 Plan: Intentional Biological Incidents.)

- Full information about biological threats may not be immediately available and may take hours (e.g., pathogen identification), days (e.g., exposure areas, affected populations), or months (e.g., attack and secondary attack rates, lethality, susceptibility to countermeasures). Situational awareness of the type of agent may be limited and decisions need to be made without complete information.
- The cause of a biological incident (e.g., naturally occurring, intentional, or accidental) may not be readily apparent and all possibilities are considered in the response.
- Responders and first receivers may be disproportionately impacted depending on the agent and the nature of the incident.
- Members of other segments of the workforce whose duties must be performed in person, including but not limited to those that work in critical infrastructure, are also at risk of being impacted.
- Any potentially intentional biological threat or incident, including but not limited to a suspected act of terrorism, requires a joint Crim-Epi investigation. DOJ/FBI establishes a Joint Operations Center (JOC) to manage and 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. (See Attachment 1: Branch 1 Plan: Intentional Biological Incidents.)
- A contagious disease incident may include waves of secondary and tertiary infections within the original outbreak region and beyond. Disease transmission may vary depending on the source of the agent and how it is transmitted, which may present challenges in planning for these incidents in a linear, phased fashion.
- The first detected cases of an incident may not be in the location of the initial release or exposure.
- Planning for an incident of undetermined origin or an intentional biological threat or incident adds additional complexities.
- NPIs such as social distancing, quarantine, travel restrictions, and 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.
- The size, scope, and/or complexity of a biological incident may overwhelm existing SLTT capabilities and resources, causing significant strain on the whole community.
- Individual practitioners, healthcare organizations, healthcare coalitions, and non-governmental organizations (NGOs) are all an integral part of the public health response.

- For pathogens with no pre-established MCMs, development and production would occur as quickly as possible but may take months to years to fully and safely deliver to affected populations.
- The impacts of a biological incident can cascade nationally, even for a localized incident. Recovery of impacted populations and environments may take many years.
- The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) signed into law in March 2020 provides a potential legislative precedent for future economic assistance and other recovery activities.
- The HHS Secretary may issue a PHE declaration for a biological threat or incident response.
- Depending on the circumstances for a biologic incident that exceeds affected SLTT government capabilities and whether Stafford Act assistance is necessary to protect public health and safety, the Governor may request and the President may authorize a Stafford Act declaration.

## Critical Considerations

The following critical considerations are supplemental to those outlined in the Response and Recovery FIOF:

- A biological threat or incident suspected or known to be intentional requires close coordination between the public health and law enforcement communities, and potentially the counterterrorism community. Public health, emergency management, law enforcement, and counterterrorism stakeholders require close collaboration on the ground at the incident level all the way through national multi-agency coordination centers, such as the FBI-led WMDSG (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).
- When warranted by the complexity of the situation, in order to fully address potential cascading impacts from a widespread biological incident and ensure unity of effort across the federal response, the President, or their designee, retains broad discretion to select an appropriate LFA to coordinate across multiple lines of effort to ensure unity of effort for the overall federal response.
- A biological threat or incident also requires a coordinated response among SLTT governments, NGOs, the private sector, and international partners. The private sector has a major role in recovery, both from the standpoint of owning equipment that might need to be used for response activities to owning assets (e.g., transport vehicles, landfills, incinerators, autoclaves) that are key to the response.
- Interdependent decisions that involve mission areas and execution of tasks within Lines of Effort (LOEs) are coordinated to avoid unintended consequences. These decisions include but are not limited to pre-positioning of MCMs, security of points of entry or enhanced screening, public messaging, and operations to resolve the threat.

- During a response where federal or SLTT authorities conflict or intersect, critical legal and policy decisions are required and may be elevated to higher levels of government for resolution (such as movement restrictions, civil order). Planning should consider the fact that different states have different authorities.
- The public will require consistent, unified, and coordinated public messaging that is credible and provides clear, timely, and actionable information. This public messaging must be accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities). In addition, this information should be provided in relevant languages other than English in order to reach individuals who are limited English proficient. Finally, this public information should adhere to the principles of risk communications, even in areas unaffected by the incident. This includes information regarding the threat, hazard, or incident, as well as the actions being taken and assistance that is available.
- In situations involving a biological threat or incident suspected or known to be intentional, the President directs the Secretary of DHS and the Attorney General to coordinate in the execution of key responsibilities that provide public information and warning messaging to the nation regarding terrorist threats and attacks. (See Attachment 1: Branch 1 Plan: Intentional Biological Incidents.)<sup>11</sup>
- Public messaging and verbiage must communicate that the response effort is non-stop and constantly evolving, and all public messaging must comply with Rehabilitation Act Section 508 accessibility requirements and be written in easy-to-understand language for the public.
- The U.S. engages in several international partnerships on preparedness and response for biological incidents.<sup>12</sup> International partners may request information or assistance from the United States, or the U.S. may request information or assistance from international partners. For foreign requests for assistance,<sup>13</sup> the U.S. may also need to assist foreign governments (as requested) to contain the spread of a biological incident to the United States by controlling it at its source.
- Each department and agency considers specific requests for their resources. Politically sensitive requests or requests for scarce resources may be elevated to the National Security Council (NSC) through the National Security Memorandum-2 (NSM-

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<sup>11</sup> Whenever there is a biological threat or incident suspected or known to be intentional, the *Terrorism Incident Law Enforcement and Investigation Annex*, or successor annex, as well as other applicable national policies, including Presidential policy directives and memoranda, should be consulted to identify any necessary coordination mechanism.

<sup>12</sup> The United States is part of key multi-lateral 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 (CBRN) threats and the pandemic influenza. On a regional level, U.S. health security efforts include the *North American Plan for Animal and Pandemic Influenza* and the health security aspects of the U.S./Canada Beyond the Border Initiative. Internationally, the United States supports the Global Health Security Agenda and is a State Party to the Biological Weapons Convention.

<sup>13</sup> Policy Framework for Responding to International Requests for Public Health Emergency Medical Countermeasures from the U.S. Department of Health and Human Services.

2) process or its successor. HHS has a series of Frameworks<sup>14</sup> that can be used to address requests for public health and medical resources.

- Foreign offers of assistance are made to the federal government and are managed in accordance with the International Assistance System Concept of Operations facilitated by the Department of State (DOS).
- The President may direct a change in Continuity of Government Condition (COGCON) level, and departments and agencies may activate plans depending on the pathogen's impact to the continued performance of essential functions. Prioritization of capabilities is necessary to balance competing missions, maximize efficiency, and ensure continuity of National Essential Functions (NEFs).
- Departments and agencies are responsible for maintaining and implementing workforce protective actions. Consistency with guidance for the private sector and public should be established as well.
- There is the potential for pathogens to be resistant to MCMs and there are no available MCMs against novel biological pathogens, limiting the availability of prophylaxis and treatment options.
- There is limited, if any, immunity in the population to most novel emerging infections.
- Available but limited MCMs may fall short of required demand due to a variety of factors (e.g., geographical variance in the severity of the outbreak, logistical issues, disruption to pharmaceutical production, other supply chain considerations). MCMs may be exhausted. Further complications may arise from existing drug shortages, as mentioned in Executive Order (EO) 13588, Reducing Prescription Drug Shortages (Oct. 31, 2011).
- SLTT entities may lack the ability to immediately provide MCMs 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.
- Both federal and SLTT authorities must consider public safety and security during implementation of response and recovery measures (e.g., security at MCM dispensing areas and at healthcare and public health critical infrastructure) and other secondary or tertiary public safety factors (e.g., civil disobedience or other disruptions to the enforcement of certain mandates).
- Unapproved MCMs or unapproved uses of approved MCMs may need to be made available using appropriate regulatory mechanisms (e.g., Emergency Use Authorization [EUA]).

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<sup>14</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 U.S. Government interagency group that analyzes international requests for public health and medical personnel and develops recommendations for U.S. action.

- Contact tracing, as an essential public health tool, can be complicated by changing case definitions, willingness of individuals to comply with the process, and the intensity of resources required. At certain burdens of disease, community mitigation measures become more efficient in decreasing spread of disease (but are more restrictive for populations).
- Management of large quantities of hazardous waste can prove challenging and further drain resources, as the pathogen type can have an impact on hazardous waste processing and disposal. (See Appendix U for further waste management considerations.)
- Responders and essential personnel 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 resources may be strained by both naturally occurring and intentional incidents. For the former, regular processing mechanisms are likely to be overwhelmed due to large numbers of human remains, which may be 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.
- Public concern for exposure, with or without demonstration of illness, may amplify the demand for medical and health resources. Additional behavioral health impacts should be anticipated. For example, there may be a negative perception of individuals, families, communities, ethnic/racial groups, or even certain professions that may become associated with the pathogen.
- Appropriate procedures may be necessary to prevent entry of disease into certain geographic areas. These may include health screening, quarantine (for the exposed), and isolation (for the infected). For persons entering the country from foreign countries, many of these authorities reside at the federal level; however, the mechanisms (health, safety, law enforcement) to implement them often reside at SLTT levels.<sup>15</sup>
- A select few biological 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, closing affected areas to individuals and businesses.
- Animals may present complexities in managing a biological incident. Aside from zoonotic potential, other possible complexities include insufficient qualified personnel to care for exposed or infected animals and owners' behavior, impacting

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<sup>15</sup> If U.S. citizens exposed abroad require transportation to a healthcare facility in the United States; emergency repatriation will be coordinated between DOS and HHS.

decisions on disposition of the animals (both for private pets as well as animals industrially produced).

- 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.
- Local, national, and global markets may be affected by hazard impacts. The resultant socio-economic and commercial implications (e.g., supply chain) may challenge response and recovery actions.
- 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, the response to public health incidents should minimize impacts on travel and trade.
- Specific resources may be limited, and allocation algorithms may be required. These may occur at various levels of government and require coordination, in addition to attention to equity and fairness. See the “Health Equity” section on the following page for additional details.
- U.S. mission personnel and/or U.S. citizens in countries that are experiencing a biological incident may be directed to evacuate to the United States. Extensive planning for how these evacuees would be tested and, pending risk assessment, quarantined, either in the U.S. or in a foreign country safe haven, would be required while preparing for community transmission in the United States.
- The healthcare workforce (HCW) can be stressed for numerous reasons related to supply and demand. The federal ability to source this larger private sector capacity is limited. The potential for the availability of HCWs during a biological incident may drive the use of contracts to fill shortages.
- A biological response can be disrupted by additional disaster responses and overtaxed responders.
- Because some information about the threat agent may be classified, key decision makers need to ensure that they have sufficient security clearances and a need to know and work with security managers to provide an unclassified tear line for first responders.

## Health Equity

Established patterns of public health emergencies tend to disproportionately impact communities that experience health disparities and inequities. Therefore thorough, systematic attention should be given to health equity considerations in all coordination activities and LOEs in every information-sharing process and during every Operational Phase.

In addition to descriptive population health data, health equity considerations should include consideration of how social policies, structures, conditions, and characteristics defining specific places may create differences in exposure risks, social vulnerability, and resilience among diverse populations in emergencies.

Rapidly assess the clustering of communicable and non-communicable or chronic diseases and the chronic strains and stressors within populations that have historically experienced social, economic, or political disadvantages and how exposure to the emergency might exacerbate poor health outcomes. For example, consider how differences in these variables may be linked to disproportionate impact and burden, to variations in the effectiveness and unintended consequences of mitigation strategies, and to disparities in incident-related outcomes, losses, or long-term effects.

Each decision, activity, product, or process should be assessed regarding how equity is affected. Every effort should be made to find options that reduce inequities. Moreover, an inclusive, structurally competent workforce equipped to assess and address the needs of increasingly diverse populations should be meaningfully engaged and leveraged in key leadership positions.

Participation of the community throughout the preparedness, response, and recovery cycle is crucial both to identifying and addressing health disparities and for achieving health equity. Community groups and members are the subject matter experts (SMEs) when it comes to identifying their own needs prior to an emergency, advocating for governmental assistance and interventions during a response, and helping to prioritize recovery activities in their communities.

Preparations for, rapid responses to, and recovery efforts centering on health equity following biological incidents can be facilitated by deploying a Chief Health Equity Officer.

## MISSION

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### Mission Statement

The mission of the federal government during a biological incident is to save lives; reduce human suffering; control the spread of disease; protect property and the environment; restore critical infrastructure; reestablish an economic and social base; and support community efforts to overcome the physical, emotional, and environmental impacts of the biological incident. If the biological threat or incident is intentional, the mission of the federal government includes conducting investigations to determine attribution, conducting operations, and using all available tools to hold perpetrators accountable. This federal mission is contingent upon coordination with and the success of the whole community response.

## Desired End State

The desired end state of federal response and recovery operations to a biological incident is achieved when the following have occurred:

- Adequate federal support has been provided to SLTT governments to mitigate the effects of the biological incident and further federal government support is no longer required.
- Community Lifelines are stabilized, federal operations to achieve recovery outcomes are complete, and support to SLTT governments can be managed using steady-state programs.
- SLTT governments and private sector entities can meet the needs of their communities through existing resources and processes.
- 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.
- Exposed populations are fully identified and have received appropriate MCMs 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—accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities) and individuals who are limited English proficient—to protect against or recover from the biological incident.
- Pathogen transmission has stabilized and is showing continuous deceleration 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 to include successful decontamination and further risk to human health, which has been verified to be mitigated.
- Persistent disease threats to humans from animals or any other sources have been addressed and threats from reservoirs are mitigated.
- The needs of all members of the community (e.g., older adults, children, people with disabilities, people who are limited English proficient, people with low literacy, and

people with chronic medical conditions, among others) have been addressed with implementation of sustainable activities.

- Appropriate care is identified and provided for dependents (e.g., elderly, children) without caretakers due to the incident.
- Appropriate care is identified and provided for pets or animals without owners/caretakers due to the incident.
- For intentional biological threats and incidents, perpetrators have been identified, and the biological agent has been identified, characterized, and linked to the perpetrators.

## Primary Authorities and Relevant Declarations

### Primary Authorities

There are numerous federal authorities applicable to biological threats and incidents, and a detailed but non-exhaustive list is contained in Appendix V, Authorities and Other References. This annex **does not** alter or impede the ability of any federal department or agency to exercise their authorities or to perform their responsibilities under the law. This annex does establish parameters and methods for interagency 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 the response to 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*, DOS has the lead foreign policy role in supporting federal government agencies and managing the international aspects of a domestic incident. As noted in Table 1, HHS is the LFA for all public health and medical activities described in the base annex and the Branch 1 Plan, and the FBI is the LFA for all operational law enforcement response activities described in the base annex and the Branch 1 Plan.

Although Table 1 lists lead federal authorities, other federal departments and agencies have significant roles in each incident type (see the “Roles and Responsibilities of Federal Agencies with Primary Authority for Response to a Biological Incident” section of Appendix A). Due to these potential complexities, it is the responsibility of the lead agency to establish interagency coordination mechanisms as soon as possible during an incident. For some incidents (e.g., naturally occurring, or intentional, both domestic and international) there may be two lead agencies for different mission areas (crisis versus consequence management) and coordination between these agencies is required.

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

Authority	Incident Type/Location	Lead Agency*
Response and Recovery (Consequence Management for Human Disease)	Naturally occurring/domestic	<ul style="list-style-type: none"> <li>• HHS (Public Health Response)</li> </ul>
Response and Recovery (Consequence Management for Human Disease)	Intentional/domestic	<ul style="list-style-type: none"> <li>• DOJ/FBI (Criminal Investigation)</li> <li>• HHS (Public Health Response)</li> </ul>
Response and Recovery (Consequence Management for Human Disease)	Naturally occurring/international with potential domestic impact	<ul style="list-style-type: none"> <li>• DOS</li> <li>• HHS<sup>16</sup> (Public Health Response)</li> </ul>
Response and Recovery (Consequence Management for Human Disease)	Intentional/international with potential domestic impact	<ul style="list-style-type: none"> <li>• DOJ/FBI (Criminal Investigation)</li> <li>• HHS (Public Health Response)</li> <li>• DOS</li> </ul>
Response and Recovery (Consequence Management for Human Disease)	Naturally occurring/domestic with potential significant impacts to food and agriculture response <ul style="list-style-type: none"> <li>• For details, refer to the <i>Food and Agricultural Incident Annex</i> [FAIA].</li> </ul>	<ul style="list-style-type: none"> <li>• HHS (Public Health Response)</li> <li>• USDA</li> <li>• Department of the Interior (DOI)</li> </ul>
Response and Recovery (Consequence Management for Human Disease)	Stafford Act Declaration (Disaster or Emergency) for naturally occurring domestic or intentional domestic	<ul style="list-style-type: none"> <li>• HHS (Public Health Response)</li> <li>• DHS/FEMA</li> </ul>
Prevention (Crisis Management)	Domestic or foreign origin	<ul style="list-style-type: none"> <li>• FBI (Criminal Investigation)</li> <li>• DOS</li> </ul>

\* Note: Outside of a Stafford Act declaration, DHS/FEMA may also 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 authorities 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. Management of bioterrorism waste might be federally regulated under Department of Transportation (DOT) Hazardous Materials Regulations. Therefore, coordination between SLTT officials and their federal partners for waste management decisions is critical.

<sup>16</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. DOS coordinates diplomatic engagement and communications with foreign governments and leads humanitarian assistance efforts as needed.

## Major Declarations of Relevance

In a biological incident, the following declarations may be issued and may influence the response and recovery to an incident. SLTT jurisdictions can issue their own public health emergency declarations at their discretion. These are associated with varying degrees of public health authority. As sovereign nations, tribes have the authority to declare states of emergency on tribal lands through their constitutions, legal codes, or the inherent authorities of their governing councils.

### *HHS Declaration of a Public Health Emergency (PHE)*

Section 319 of the Public Health Service Act (PHSA) authorizes the Secretary of HHS to determine that a 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 authorizes 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 Public Health Emergency Fund (PHEF) to respond. The Secretary has broad authorities to respond to a public health emergency, regardless of whether a formal PHE is declared. Furthermore, a PHE declaration allows the Secretary, upon request by a state/territorial governor or tribal organization, to authorize the temporary reassignment of health department or agency personnel funded in whole or in part through programs authorized under the PHSA to aid in the public health response to a federally declared public health emergency.

### *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 EOs published in the Federal Register and transmitted to Congress. The significance of an NEA declaration involving a biological incident was realized in 2009 and 2020. During both the 2009 H1N1 influenza pandemic and the COVID-19 pandemic, a Presidential declaration of a national emergency was issued under the NEA. For COVID-19, the NEA declaration occurred on March 13, 2020, coupled with the prior PHE determination of the Secretary of HHS. In addition, a Stafford Act Declaration was issued. These declarations enabled the invocation of Social Security Act (SSA) Section 1135 waiver authorities. The authorities under section 1135 of the SSA allowed the HHS Secretary to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and Accountability Act Privacy Rule throughout the duration of the PHEs that were declared in response to the 2009 H1N1 influenza and COVID-19 pandemics.

### *Stafford Act Declaration*

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 occurs through the National Response Coordination Center (NRCC) or the Regional Response Coordination Center (RRCC) of affected jurisdictions under this Act's authorities. DHS/FEMA executes its Stafford Act authorities in providing both individual and public assistance as well as any appropriate mitigation efforts to impacted SLTT jurisdictions. The NRF and *National Disaster Recovery Framework* (NDRF), as well as the associated FIOP and this BIA, serve as guidance to provide appropriate federal assistance. Federal departments and agencies identified as relevant Emergency Support Functions (ESFs) activate their respective components and participate in the NRCC in accordance with the NRF, ensuring that all relevant information and resources are coordinated and collaborated among federal partners.

### *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 that 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 World Health Organization (WHO) of an event that potentially constitutes a PHEIC through their IHR NFPs; the Director-General of WHO determines whether an incident constitutes an actual PHEIC. In accordance with IHR, the U.S. would have 48 hours to assess and determine whether a potential PHEIC notification should be sent to WHO. If the severity or impact of a biological incident poses a significant threat (through international spread) or may require a coordinated international response to contain, the Director-General of WHO may declare the incident a PHEIC.

## EXECUTION

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### Operational Phases

The operational phases provide a sequencing structure for organizing response and recovery operations. Phases are not distinguished by date or time but rather by the nature of the activity performed (see Figure 2) and the achievement of a desired end state. Although the scope of this annex update includes Recovery, or Phase 3, biological incidents can be extremely prolonged and require increased emphasis on pre-incident activities and ongoing response activities. Therefore, the content below focuses on information and activities that take place during Phases 1 and 2.

The phases are used to describe how operations evolve over time and to promote unity of effort between federal and SLTT governments. Activities are focused on situational awareness, operational coordination, resource management, and program delivery and are

written broadly to allow for consideration of the unique geography, operational practices, and requirements pertaining to a biological incident.

The extent of recovery to a large-scale biological incident is dependent upon the specific size and complexity of the incident. For example, a global pandemic is not likely to impact physical structures, preventing homes and businesses from being disrupted (unless economic shutdowns are implemented at the SLTT level with the aim to curb human-to-human transmission). A large, area-wide biological aerosol release, particularly in an urban area, however, may likely require extensive recovery efforts due to remediation and waste management activities (to include workforce and decontamination procedures and testing to validate safe re-occupancy), which are well beyond the response efforts to immediately save lives.

Figure 2 outlines response and recovery operational phases, as applied specifically to a biological incident. Note that for widespread events, phasing may vary across locations and agencies based upon the situation, roles, and actions required. LFA pre-incident coordination with the NSC begins during phases 1b and 1c for High Consequence Emerging Infectious Disease Threats and Biological Incidents.

There are multiple ways in which a biological incident can unfold. Many departments and agencies can be involved in public health actions during steady state and even more may be involved as a biological pathogen is detected. Some activities may be occurring before this annex is applicable, and some departments or agencies may have initiated their own responses as part of their statutory authorities.

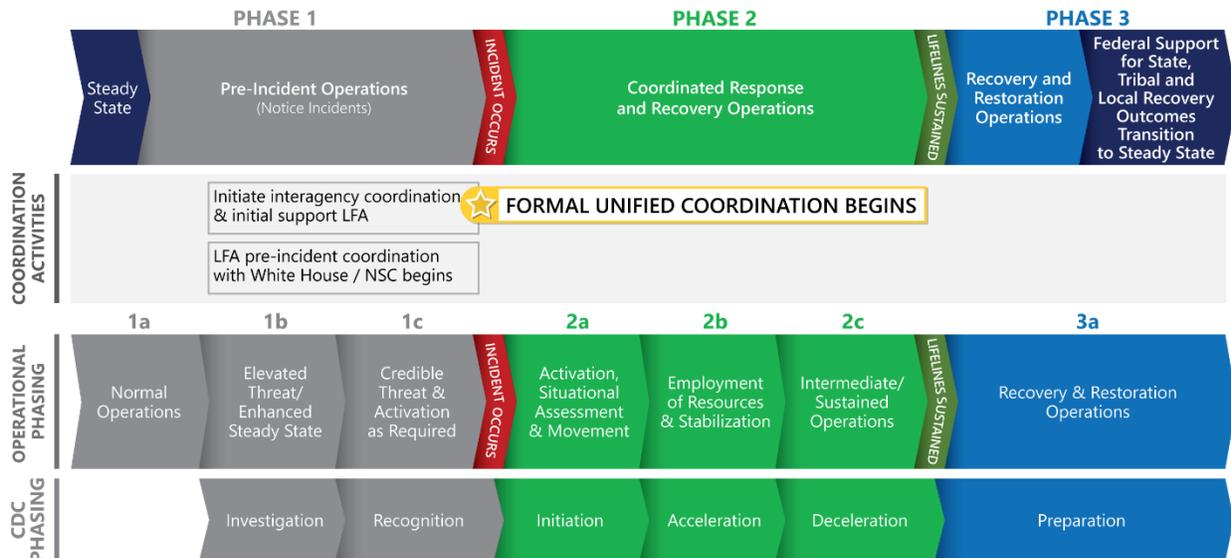


Figure 2: Operational Phases During a Biological Incident<sup>17</sup>

### Phase 1 (Pre-Incident)

This phase is characterized by pre-incident awareness, preparedness, protection, and mitigation activities. The federal government funds and conducts research and provides mitigation guidelines. Pre-incident activities also involve the development of response plans as well as the conducting of training and exercises for incident response. (See “Training” section of Appendix D for additional information.)

Preparatory activities may begin to occur. Phase 1 should entail, but is not limited to, the following activities:

- Enhance situational awareness through increased epidemiological studies at the federal and SLTT levels to gain a better understanding of the biological agent threat.
- Initiate coordinated public messaging with federal partners—accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities) and individuals who are limited English proficient—on public health measures to implement to reduce human exposure.
- The LFA should initiate inter-departmental coordination to address medical and public health impacts as well as to being to evaluate effectiveness and quantities of existing MCMs.

<sup>17</sup> Although not depicted in this figure, during intentional threats and incidents such as terrorism or other criminal acts, law enforcement prevention activities may occur during and continue through each phase of response, recovery and restoration operations.

- The LFA should evaluate the Strategic National Stockpile (SNS) in anticipation of SLTT resource requests (e.g., PPE) and actively engage with SLTT health departments in reviewing their MCM stockpiles and/or contingency plans for resources.
- The LFA should initiate early unified coordination with appropriate partners, starting with the ESF #8 (Public Health and Medical Services) coordinating agencies, to identify potential response capabilities required for current and near future operations if the biological incident increases in size and/or complexity.

## Phase 2 (Incident Occurs)

The transition from Phase 1c to Phase 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 2 focuses on an immediate, coordinated, and effective federal response to save lives and reduce casualties following the confirmation of an intentional or unintentional biological incident. The response phase includes three sub-phases—Phases 2a, 2b, and 2c—all of which support the synchronization of activities, priorities, resources, and decisions. Phase 2 also consists of response activities that help facilitate the transition to and support for the Recovery Mission Area. As Phase 2 progresses, the scope of recovery activities increases as the scope of response activities decreases. Phase 2 ends as critical lifesaving response resources are demobilized and recovery operations begin. Phase 2 should entail, but not be limited to, the following activities:

- Fully established, federal-level UCG, which may include either a non-Stafford arrangement (LFA and its ESF #8 coordinating agencies) or Stafford arrangement (DHS/FEMA partnership with the LFA and various designated ESFs and liaisons, depending upon the NRCC activation level deemed appropriate).
- Establishment under a non-Stafford incident of dedicated federal or federally leased spaces to support the HHS Secretary’s Operations Center (HHS SOC) as the central focus for coordination or, in a Stafford incident, establishment of the NRCC to facilitate coordination among federal agencies.
- Reporting schedule for Senior Leadership Briefs to inform the White NSC and federal partners on key response actions taken and situational awareness of the biological incident.
- Forecasting through coordinated disease modeling entities (federal and academic centers of excellence) to inform federal and SLTT entities of predicted new cases, hospitalizations, and anticipated fatalities to inform management of resource requests.
- Full implementation of LOEs described in the BIA.

## Concept of Operations

Biological incidents are primarily managed and monitored by public health agencies at SLTT levels of government. As incidents change in size, scope, and complexity, a higher level of

coordination among the public health, emergency management, law enforcement, and counterterrorism communities may be required in the form of supplemental and complementary support. The federal [Community Vaccination Centers \(CVC\) Playbook](#) used for the COVID-19 Pandemic is a useful resource that could be tailored for a given biological incident.

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 LFA for this support. For suspected intentional biological threats and incidents, DOJ, acting through the FBI, is the LFA for operational law enforcement response (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

### **Steady-State Operations**

Steady-state and elevated threat/enhanced steady-state operations encompass normal or pre-incident operations, including but not limited to planning, training, surveillance, and information gathering by multiple federal agencies and numerous SLTT entities. Some of the 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 regular ongoing activities. Multiple federal agencies are tasked with seeking out and reporting any abnormalities (e.g., environmental sampling) or unusual cases of concern as part of their daily work to prevent and detect biological threats.

Steady-state and elevated threat/enhanced steady-state operations involve several 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 B: Intelligence and Surveillance.

### **Biological Agent Detection**

Detection is defined as the 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. Table B-3 in Appendix B provides examples of some potential sources of initial information along with their associated 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.

Many of the examples cover complex sets of activities, and in some examples federal partners are either primarily responsible for or provide support to SLTT entities and the

private sector. As an example, air samplers are deployed throughout many metropolitan areas of the United States.

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 horizontal and vertical partners to detect and confirm the presence of a biological pathogen of concern. As these efforts expand across 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 Administration for Strategic Preparedness and Response (ASPR) is the lead for coordinating federal public health and medical preparedness and response and recovery to biological threats or incidents and other public health emergencies. HHS/ASPR also has responsibilities for providing departmental resources to assist federal and SLTT governmental requests for public health and medical assistance during biological incidents.

In large-scale biological incidents, which occur with little-to-no notice (e.g., intentional area-wide agent dispersion) and where an NEA and/or Stafford Act declaration is issued by the President, DHS/FEMA activates the NRCC, executes its Stafford Act authorities, and requires the LFAs described in Table 1 to co-lead with DHS/FEMA as part of the established UCG within the NRCC immediately.

#### ***Initial Parameters for Decision on Interagency Coordination***

Biological incidents requiring coordination among two or more federal departments/agencies trigger the establishment of an interagency task force headed by a White House coordinator. The Assistant Secretary for ASPR is responsible for determining, in consultation with other agencies as relevant, when interagency coordination related to a biological incident is necessary. Factors supporting such a decision could include the following:

- The lead agency has exhausted their organic resources or has insufficient domestic incident management capacity to meet incident demands, necessitating augmentation.
- The incident has the potential to increase in magnitude and complexity such that it requires substantial survivor mass care services and logistics architecture, public safety and security, and other elements outside of the abilities of HHS.

### ***Additional HHS/ASPR Parameters for Decision on Interagency Coordination on a Biological Incident***

Other than an NEA and/or Stafford Act declaration early in the biological incident response, if the need for interagency coordination is not immediately apparent, the Assistant Secretary for ASPR considers additional factors that may include 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 of and ability to deploy effective MCMs and NPIs
- Effectiveness of MCMs
- Immediate and short-term needs of local public health authorities and medical facilities
- Need for health risk communications 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
- Confirmed cases of human illness or unusual animal illness or deaths involving a select agent (see [Select Agents and Toxins List](#) on the Federal Select Agent Program website<sup>18</sup>)
- Potential or actual PHE declaration or emergency management declaration
- Report of a case of disease caused by a very uncommon biological agent or that presented in a very unusual manner (e.g., *Inhalational Bacillus anthracis*)
- Simultaneous occurrence of similar illness in non-contiguous areas or unusual geographic or seasonal distribution
- Actionable finding by National Biosurveillance Integration System (NBIS) (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents)
- BioWatch Actionable Result (BAR) received or declared by one or more SLTT jurisdictions (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents)

### **Notification**

There are numerous notification methodologies employed at the federal level that could play a role in a biological incident. Table 2 lists examples of information-sharing processes along with descriptions of when they are used. For the purposes of this annex, notification is most

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<sup>18</sup> <http://www.selectagents.gov/SelectAgentsandToxinsList.html>

appropriately used 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 Homeland Preparedness and Response (HPR) Interagency Policy Committee (IPC) and other entities (e.g., WHO), as appropriate and per statutory and policy requirements for notification. Initial biological incident notification includes all ESF #8 departments and agencies.

An activation notification to relevant interagency partners for a biological incident includes the following:

- 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 2: Examples of National-level Notification Modes<sup>19</sup>**

Information-Sharing Platform	Description
Health Alert Network (HAN)	HAN is HHS/CDC’s primary method of sharing public health information with public information officers and 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, eight territories, as well as the Chicago, Los Angeles, New York City, and Philadelphia metropolitan areas.
Epidemic Information Exchange (Epi-X)	Epi-X is a web-based communications solution for public health professionals. Through Epi-X, HHS/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 incidents 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, 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.
HHS Public Affairs Conference Line (PACL)	Provides a conference line to allow telephone connectivity for public affairs staff supporting ESF #8. This conference line enables HHS public affairs personnel to work from dispersed sites during the crisis yet be able to receive guidance and direction or to provide information to those needing it.

<sup>19</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 Platform	Description
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 can coordinate communications information related to the public health and medical aspects of a response when needed, 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 the State Incident Coordination Conference Line, respectively.
National Public Health Information Coalition (NPHIC)	Leverages a network of state and local public health communicators for the exchange of information, increasing the likelihood of consistent messaging and communications activities between federal and SLTT governments regarding the emergency and its impact on health.
Biological Incident Notification and Assessment (BINA) Protocol	The BINA Protocol provides a consistent means for NSC staff to convene agencies pursuant to the interagency policy process outlined in NSM-2 provides 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 coordinated action among agencies, as directed by the President.
BioWatch National Conference Call	Occurs within 2 hours of a 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, providing situational awareness of follow-on activities and potential requests for assistance from other federal agencies (e.g., DHS, HHS/CDC, DOJ/FBI, EPA, Department of Defense [DOD], USDA) and/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.

Initial notifications related to intentional biological threats and incidents, including those within the scope of National Security Presidential Memorandum 36, Guidelines for United States Government Interagency Response to Terrorist Threats or Incidents in the United States and Overseas (January 19, 2021), are further outlined and referenced in Attachment 1: Branch 1 Plan: Intentional Biological Incidents.

**Activating Unified Coordination Across the Federal Government**

For purposes of this annex, activation is defined as the point in time in which the LFA 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 the “Roles and Responsibilities of Federal Agencies with Primary Authority for

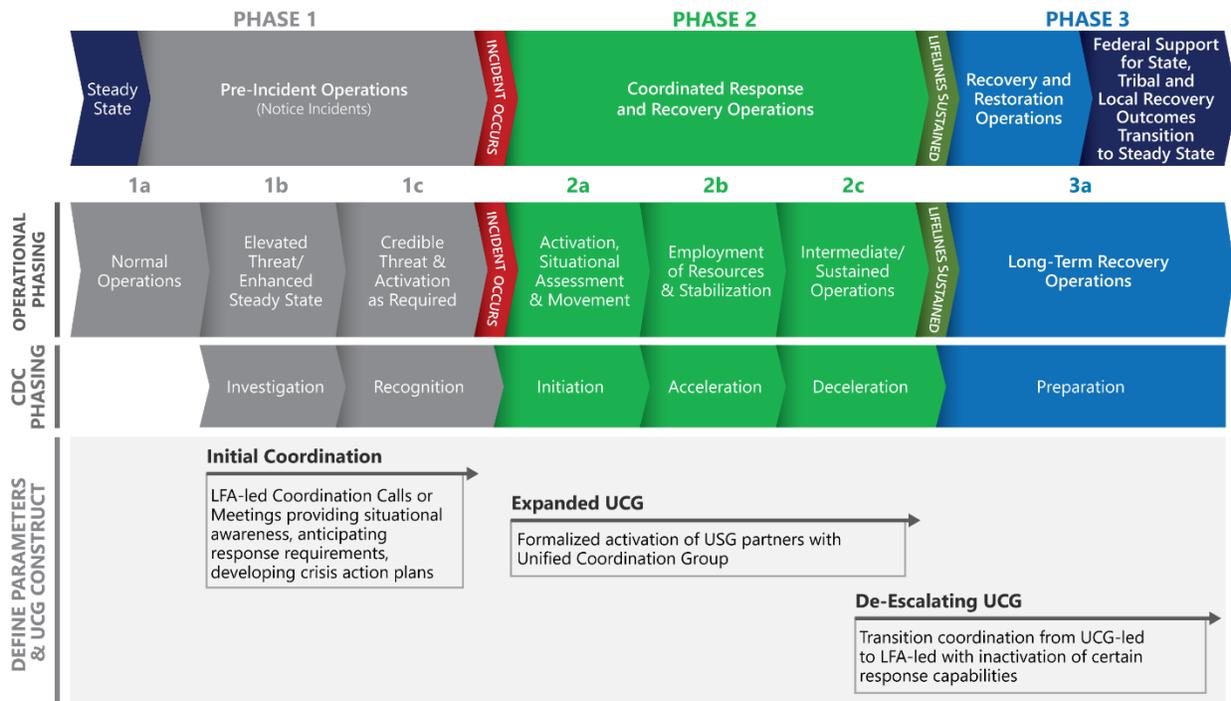
Federal Response to a Biological Incident” section of Appendix A). It should be noted that LFA pre-incident coordination with the NSC begins during phases 1b and 1c for High Consequence Emerging Infectious Disease Threats and Biological Incidents. Additionally, the LFA may request incident management augmentation from DHS/FEMA any time prior to a Stafford Act declaration. Therefore, unified coordination occurs with or without Stafford Act declarations. As history has shown that most biological incidents are managed without a Stafford Act declaration, unified coordination occurs more commonly in this scenario.

### *Unified Coordination*

At the SLTT level, a Unified Command (UC) may be established since SLTT jurisdictions have public health and emergency management authorities to respond to a large-scale biological incident within their jurisdictions. Unified Coordination occurs at higher levels than the incident and provides support to the UC (or Incident Command [IC]).

Biological incidents may evolve in unique ways, providing a challenge for interagency coordination. Different types of biological incidents may call for differing ways of coordinating federal activities related to biological incident response. As noted above, some departments or agencies respond as part of their statutory authorities before UC is initiated by the LFA. For example, HHS/CDC continues to work with SLTT public health agencies in conducting epidemiological investigations and enhancing public health laboratory testing and, in coordination with HHS/Food and Drug Administration (FDA), the diagnostics capabilities specific to a biological agent. HHS components, as another example, may be working with SLTT grantees using their public health grant funds, focusing on a given biological incident response as per the declared PHE.

Figure 3 illustrates how UC efforts are integrated into the operational phases and operational tempo of response and recovery operations.



**Figure 3: Unified Coordination Integration with Phasing<sup>20</sup>**

In the early stages of a threat or incident, a formally staffed 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 LFA with little to no staff dedicated to the incident outside of their typical work responsibilities. Depending upon location, disease spread, illness severity, and other factors, the federal government and SLTT jurisdictions are likely postured at various response stages for heightening their response actions or their preparatory phases. For example, federal departments and agencies (e.g., HHS/CDC, DOJ/FBI, HHS/FDA) may activate their operations centers. The operational tempo may increase to include more frequent meetings and more formal staffing of a UCG, depending on incident parameters and as determined by the LFA. Conversely, the incident may dictate the immediate establishment of a robust national-level UCG or multiple UCGs at various government levels.

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

For some limited-outbreak scenarios, the LFA may be able to provide initial estimates of anticipated duration of the UCG.

<sup>20</sup> Although not depicted in this figure, during intentional threats and incidents such as terrorism or other criminal acts, law enforcement prevention activities may occur during and continue through each phase of response, recovery, and restoration operations.

### *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. The LFA, or DHS/FEMA in a Stafford Act declaration, should first identify federal partners that should be involved in UCG meetings. When established, a national-level UCG assists the LFA and senior response officials in executing the following responsibilities:

- Developing goals and objectives for the federal response to the biological threat or incident.
- Identifying the federal capabilities necessary to support SLTT governments in response to a biological incident as well as any resource gaps.
- Coordinating response and recovery strategy and operations with federal and SLTT officials as well as private sector and non-governmental entities.
- Coordinating with senior federal government officials to raise and resolve resource and policy issues related to response and recovery.
- Facilitating information sharing with federal and SLTT officials, as appropriate, including the 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.
- Developing metrics to define and measure progress on goals and achievements.

### *Construct of UCG*

The LFA is responsible for determining the relevant departments and agencies required for participation in unified coordination as well as the level of unified coordination needed. At a minimum, all ESF #8 supporting departments and agencies are notified of any biological incident meriting unified coordination.

A unified coordination construct should include the following key activities:

- Participating entities sharing their information on resources provided to impacted SLTT communities.
- Public messaging coordination to ensure broad alignment across the federal government.
- Ongoing horizontal coordination and collaboration across all participating entities.
- Establishing and maintaining, through the LFA and UCG, effective communications with the NSC as well as to DHS/FEMA and HHS regions, who are communicating directly with their SLTT partners.
- Engaging with NGOs and the private sector. Certain decisions and critical information requirements may be of paramount importance early in the interagency coordination process (refer to the “LOE Critical Information Requirements” section of Appendix C).

The UCG construct should be scalable and as flexible as needed to achieve the given end states described in this BIA but specific to the biological incident. Whatever construct is developed, criteria to determine if a UCG is effective for a given biological incident and to a particular operational phase in the response should take into account the following:

- Does it achieve unity of effort across the federal government?
- Does it provide “horizontal-level” coordination and collaboration of the information and resources shared with SLTT partners?
- Does it provide “vertical-level” coordination and collaboration with White House staffing and SLTT jurisdictions to ensure transparency of the information and resources shared and available?
- Through the ESF #15 (External Affairs) process, does it facilitate effective coordination and collaboration on public messaging to ensure federal agencies are aligned?

For each incident, an organizational chart is developed that is tailored to the incident and is focused on the positions necessary to accomplish goals and objectives. The “Federal Response Coordination Constructs” section of Appendix A provides examples of coordination constructs along with recommended unified coordination structures that are scalable to incorporate additional functional responsibilities for managing a significant public health or medical incident. In a non-Stafford Act incident, UCG leadership may include a Senior Response Official (HHS) and a Deputy Response Official, chosen by the department or agency head with primary responsibility for the incident response. In a Stafford Act incident, UCG leadership may include a Federal Coordinating Officer (FCO) in close collaboration with an HHS Senior Response Official. If the Stafford Act is declared for multiple regions, the President, as advised by the DHS Secretary and DHS/FEMA Administrator, may assign a FCO by DHS/FEMA region or for each individual state or territory, as appropriate.

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

The Operations Section can be designed using the LOEs but does not need to mirror them exactly. For example, an Operations Section should consider the LOEs described in this BIA to establish functional branches, such as a Healthcare Resilience Branch, Testing and Diagnostics Branch, and Community Mitigation Branch, as required and appropriate.

The NRCC and department-level Emergency Operations Centers (EOCs) may be structured according to the Incident Support Model (ISM) structure identified in the National Incident Management System (NIMS), including a Situational Awareness Section, Planning Section, Resource Support Section, Logistics and Finance Section, and Center Support Section.

**Table 3: Example Indicators Identifying Potential Need for National Unified Coordination Group (UCG)**

Example – “Compelling” Indicators
Administration establishes the requirement: <ul style="list-style-type: none"> <li>• Interagency support with streamlined reporting;</li> <li>• Presidential Policy Directive (PPD)- 44; or</li> <li>• Stafford Act Declaration.</li> </ul>
Federal departments and agencies have overlapping authorities.
LFA requests federal-to-federal assistance.

**Table 4: Example Indicators Identifying Potential for De-escalation of a National Unified Coordination Group (UCG)**

Example – “Compelling” Indicators
Original, pre-established goals of UCG have been achieved.
Administration indicates UCG actions no longer required.
Interagency agrees UCG actions no longer required.

***UCG 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 LFA:

- Assignment of emergency management personnel and others to form a UCG at the HHS SOC.
- Assignment of emergency management personnel and others to form a UCG at the HHS/CDC EOC.
- The NRCC may be used as a location of the UCG for a national response.
- If necessary, the UCG can be activated and located at the RRCC level or SLTT level, depending on the size and scope of the incident.
- If an incident with regional impacts minimally impacts the rest of the nation, a Joint Field Office (JFO) may be a more appropriate UCG location, with a federal headquarters coordination center established to provide incident support to the JFO.
- During intentional incidents, a FBI-led WMDSG serves in a coordination function (e.g., information sharing and deconfliction of law enforcement and consequence management operations) and connects to UCGs. (See Attachment 1: Branch 1 Plan: Intentional Biological Incidents.)

It is important to understand that depending on the nature of the biological 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.

Regional-level UCGs may be established in the HHS or FEMA region(s) that are significantly affected by a large-scale biological incident. Regional-level UCGs would coordinate and collaborate with the private sector and NGOs 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.

In most cases, 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 less likely event of a Stafford Act Declaration, responding departments or agencies provide representatives to the NRF and NDRF elements (e.g., JFO, National Operations Center [NOC]) when appropriate. In addition, during Stafford Act incidents, DHS/FEMA may issue mission assignments to federal agencies to support response and recovery activities. In a Stafford Act event, the DHS/FEMA NRCC serves as the designated facility for the unified coordination effort.

### **BIA Lines of Effort (LOEs)**

For consequence management, the UCG response to a recognized biological incident is organized around six LOEs. The LOEs are defined as specific activities required to achieve the intended outcome by linking multiple tasks to goals, objectives, and end states. These LOEs form the core of 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 LOEs would then provide qualified and sufficient representation to the UCG to ensure effective collaboration, coordination, and information sharing. The LOEs in a UCG construct may be incorporated as branches or task forces (TF) and may be staffed with units to execute national-level objectives and to maintain span of control.

Furthermore, LOEs are a starting point for response operations and may be added to, modified, or omitted based on the circumstances and requirements of a specific response. Effective, accurate, and timely actionable communications between agencies, partner organizations, the public, and other relevant stakeholders is essential for all LOE activities, helping to coordinate efforts, limit impacts, and improve outcomes. The six LOEs are listed in Table 5 below. More expansive definitions are provided in Appendix C.

**Table 5: BIA Lines of Effort (LOEs)**

Line of Effort (LOE)	Primary Activities
Detect, Prevent, and Characterize the Threat	Activities to define and track the medical and health characteristics and impacts of the disease outbreak
Control the Spread of Disease	Activities to control, arrest, or minimize the threat posed by the biological agent
Augment Provision of Mass Care and Human Services to the Affected Population	Activities to implement or support mass care and human services for those affected by the outbreak
Healthcare Resilience	Activities to implement or support health and medical services for the affected population
Medical Countermeasure (MCM) Development and Acquisition	Activities to prevent, mitigate, or treat the adverse health effects of an emerging biological agent threat resulting in a nationwide public health emergency
Augment Essential Services and Facilitate Long-Term Recovery	Activities to conduct U.S. Government initiatives to implement or support health and medical services for the affected population to facilitate long-term recovery efforts

## Federal-to-SLTT Coordination

The mechanisms employed for coordination among federal, SLTT, and private sector partners can expand and contract in accordance with the level of operational coordination taking place at the national level. Table 6 identifies what the parallel degrees of coordination at the national and state and local levels may look like. Although HHS may be in direct coordination with SLTT public health entities during public health incidents, there is another layer of coordination that occurs between the RRCC and the SLTTs. The Critical Infrastructure Protection (CIP) Division coordinates the analysis and mitigation of risks to the Healthcare and Public Health (HPH) Sector. CIP coordinates and collaborates with partners across ESF #8 and ESF #14 (Cross-sector Business and Infrastructure) on public health and medical needs to support senior leadership decision making and provide information to private sector partners.

See Appendix A, Federal Response Coordination, for examples of recommended unified coordination structures that are scalable, range from a response that can be managed at the local level to a response managed at the highest federal response level, and incorporate, as required, increased functional responsibilities for managing a significant public health or medical incident. Focus areas that this federal-to-SLTT coordination encompasses should include but not be limited to the following, as appropriate:

1. Detect, Prevent, and Characterize the Threat:
  - Sufficient public health resources and personnel to conduct epidemiological investigations
  - Clinical testing (e.g., possibly expand testing sites, including field locations, to increase access)

- Coordinated environmental sampling and analysis
  - Availability of accurate, rapid-response biological agent point-of-need diagnostic tool to characterizing known and unknown agents<sup>21</sup>
2. Control the Spread of Disease:
    - Sufficient MCMs that are effective against the disease
    - Resource prioritization of MCMs if constrained resources exist
    - Availability of qualified HCWs to treat patients in healthcare facilities
  3. Augment Provision of Mass Care and Human Services to the Affected Population:
    - Considerations for congregate versus non-congregate sheltering
    - Use of NPIs for both survivors and mass care staff
  4. Healthcare Resilience:
    - Temporarily expanding existing healthcare facility spaces to accommodate additional patient treatment
    - Considerations and support to building Alternate Care Sites (ACSs) and ways to maximize their usage during large patient surges
    - Ways to address HCW staffing shortages, including adequate critical care staff and staff trained in infection prevention
    - Track industrial capabilities for PPE production and supply
  5. Medical Countermeasure (MCM) Development and Acquisition:
    - Estimate quantities required of MCMs and required ancillary equipment and supplies
    - Storage requirements at SLTT level (e.g., cold storage)
    - Shipping and delivery requirements
  6. Augment Essential Services and Facilitate Long-Term Recovery:
    - Environmental cleanup and remediation
    - Determination of re-occupancy standards, to include methods of verification
    - Phasing out of NPI measures based on risk management

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<sup>21</sup> Point-of-care tests (POCT) and point-of-need tests (PONT) have been established in order to directly provide accurate and rapid diagnostics at field level, the patient bed-side or at the site of outbreaks. These assays can help physicians and decision makers to take the right action without delay. Typically, POCT and PONT rely on genomic identification of pathogens or track their immunological fingerprint. Recently, protocols for metagenomic diagnostics in the field have been developed. In this review, we give an overview of the latest developments in portable diagnostic methods. In addition, four mobile platforms for the implementation of these techniques at point-of-care and point-of-need are described. These approaches can provide reliable diagnostics and surveillance, especially in low resource settings as well as at the level of One Health.

**Table 6: Examples of Federal-State/Local Coordination by Incident Scale<sup>22</sup>**

Scenario	National	State/Local
<b>Steady State</b>	<ul style="list-style-type: none"> <li>• HHS/CDC coordinates with state and local health departments.</li> <li>• HHS/ASPR Hospital Preparedness Program (HPP) is the primary source of federal funding for healthcare system preparedness and response.</li> <li>• HHS/CDC Public Health Emergency Preparedness fund provides funding to build public health preparedness and response capabilities nationwide.</li> <li>• HHS Regional Emergency Coordinators (RECs) work with states and coordinate with DHS/FEMA on a regular basis.</li> </ul>	<ul style="list-style-type: none"> <li>• State and local public health entities coordinate with HHS/CDC.</li> <li>• State and local emergency management organizations coordinate with appropriate DHS/FEMA region.</li> <li>• FEMA region coordinates with DHS/FEMA Headquarters, Homeland Security Advisors, and Fusion Centers.</li> </ul>
<b>Small-Scale Incident</b>	<ul style="list-style-type: none"> <li>• Unified coordination is initiated at the federal level.</li> <li>• HHS RECs coordinate with DHS/FEMA Regional Administrators.</li> </ul>	<ul style="list-style-type: none"> <li>• State and local government entities continue to coordinate with HHS/CDC.</li> <li>• State and local emergency management organizations coordinate with appropriate DHS/FEMA region.</li> <li>• State and local emergency management and public health entities engage with HHS RECs.</li> </ul>
<b>Large-Scale Incident</b>	<ul style="list-style-type: none"> <li>• National-level UCG established with a Federal Health Coordinating Officer (FHCO) designated for affected states.</li> </ul>	<ul style="list-style-type: none"> <li>• State-level UCG may be established.</li> <li>• State and local public health organizations coordinate with HHS/CDC.</li> </ul>
<b>Large-Scale, Widespread Incident</b>	<ul style="list-style-type: none"> <li>• National-level UCG established.</li> </ul>	<ul style="list-style-type: none"> <li>• State-level unified coordination may be established.</li> <li>• State and local emergency management and public health entities coordinate.</li> <li>• State and local public health organizations coordinate with HHS/CDC.</li> </ul>

<sup>22</sup> For a suspected intentional biological threat or incident, including one that is a suspected terrorist threat or incident, DOJ, acting through the FBI, serves as the LFA for the operational law enforcement response, including any investigative activities.

Scenario	National	State/Local
<b>International Incident</b>	<ul style="list-style-type: none"> <li>National-level unified coordination established.</li> <li>State(s) encouraged to prepare for appearance of domestic cases.</li> </ul>	<ul style="list-style-type: none"> <li>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.</li> <li>State and local public health organizations coordinate with HHS/CDC.</li> </ul>

## Key Federal Decisions

Table 7 illustrates key topics relevant to biological incident response and recovery and the associated key federal decisions associated with each.

**Table 7: Key Federal Response and Recovery Decisions**

Topic	Decision Point
National Declarations: Issuing a National Emergencies Act, Public Health Emergency, and/or a Stafford Act emergency or major disaster declaration can provide additional federal resources, capabilities, and/or authorities for the response. <sup>23</sup>	<ul style="list-style-type: none"> <li>HHS Secretary declares a PHE.</li> <li>Presidential declaration under the Stafford Act.</li> <li>President declares a National Emergency.</li> </ul>
Operational Coordination: Unified coordination is deemed necessary based on international or domestic incident parameters.	<ul style="list-style-type: none"> <li>Formally establish unified coordination at the national, regional, or SLTT levels based on the extent of the scenario.</li> </ul>
Continuity	<ul style="list-style-type: none"> <li>Provide incident-specific guidance in order to ensure the continued performance of essential functions.</li> <li>Provide guidance on continuity strategies and workforce protection measures in support of organizational continuity plans.</li> <li>For the Federal Executive Branch, monitor continuity and reconstitution status reports. As necessary and in coordination with appropriate stakeholders, provide additional guidance on reconstitution and recovery.</li> <li>Throughout the incident, collect relevant data in order to conduct analysis for future planning efforts.</li> <li>Ensure that emergency operations and/or coordination groups have continuity plans in place. Ensure that appropriate continuity plans, to include devolution, are current and appropriate for the incident or threat for federal entities.</li> </ul>

<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
<p>Public Information and Warning: Providing accurate, timely, and actionable public information—accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities) and individuals who are limited English proficient—is critical to the success of response and recovery from a biological incident.</p>	<ul style="list-style-type: none"> <li>• Prepare public messaging with fundamental information about the biological incident, protective measures, treatment measures, and other general concepts. Ensure that messaging includes clarity on why future versions of guidance may change (based on new knowledge of disease process).</li> <li>• Establish a national Joint Information Center (JIC) in support of the UCG to coordinate messaging with SLTT entities regarding topics such as NPIs, MCMs, decontamination, etc.</li> <li>• Consider use of Integrated Public Alert and Warning System (IPAWS).</li> </ul>
<p>Personal Protective Equipment (PPE): Federal agencies may need to actively coordinate and prioritize purchasing of PPE and other protective items for the response. This could include addressing the needs of federal departments and agencies.</p>	<ul style="list-style-type: none"> <li>• Prioritize PPE purchasing and distribution.</li> <li>• Track industrial capabilities for PPE production and supply.</li> <li>• Consider deployment of technical assistance in support of responder health and safety, such as National Institute for Occupational Safety and Health (NIOSH) and Department of Labor (DOL)/ Occupational Safety and Health Administration (OSHA) multi-disciplinary teams.</li> <li>• Make recommendations to prevent worker injury and illness.</li> </ul>
<p>Defense Production Act (DPA) Resource Adjudication: There is likely to be scenarios in which multiple departments and agencies use DPA priority ratings for health/medical resources that may be considered scarce and essential to national defense (e.g., PPE, MCM) to respond to a pandemic. Adjudication of these resources should be coordinated across the involved departments and agencies in accordance with the process outlined in EOs 13603 and 13911.</p>	<ul style="list-style-type: none"> <li>• Assist in the prioritization and allocation of resources subject to the DPA priority ratings.</li> <li>• Initiate use of the DPA for PPE, vaccines, and other resources.</li> <li>• Initiate use of the DPA via EO 13603 for PPE, vaccines, and other resources.</li> </ul>
<p>Causal Agent and Disease Characterization</p>	<ul style="list-style-type: none"> <li>• Determine need to obtain international samples (e.g., sequencing, test development).</li> <li>• Establish case definitions.</li> <li>• Establish reporting requirements and methodologies from SLTTs, etc.</li> </ul>

Topic	Decision Point
<p>Screening: Certain contagious pathogens may necessitate screening of travelers to control disease spread.</p>	<ul style="list-style-type: none"> <li>• Determine when screening at international and/or interstate borders is indicated and likely to be beneficial.</li> <li>• Determine when to restrict movement to prevent the spread of a biological agent from within the United States to the international community.</li> <li>• Determine when to begin and end international and/or interstate border screening.</li> <li>• Determine locations, protocols, and SLTT support necessary for screening.</li> </ul>
<p>Medical and NPIs: If available and/or effective against the infectious agent, demand for MCMs may be high.</p>	<ul style="list-style-type: none"> <li>• Determine necessity and feasibility for NPIs.</li> <li>• Identify appropriate candidate MCMs based on available scientific evidence for safety and effectiveness.</li> <li>• Make recommendation to federal agencies and SLTTs for NPI implementation.</li> <li>• Determine resource support required for SLTT implementation of NPIs.</li> <li>• Establish parameters to monitor impacts of NPIs on infrastructure, economies, and vulnerable populations.</li> <li>• Determine necessity for and coordinate deployment of SNS resources.</li> <li>• Determine prioritization of funding to affected areas/states.</li> <li>• Determine appropriate methods of support to SLTT establishment of supply chains and delivery.</li> <li>• Consider approaches for evaluating MCMs for safety and effectiveness. Determine appropriate regulatory mechanism to facilitate access to those determined to be needed.</li> <li>• Determine need for private sector funding and methods to establish new MCMs.</li> <li>• Determine need for MCMs in animal population and veterinary medical support to protect human health.</li> </ul>
<p>Health and Medical Services: Limited capability exists within the federal government to deliver medical care, but there may be situations in which the federal government can support SLTTs in the delivery of medical care.</p>	<ul style="list-style-type: none"> <li>• Determine need for public health support personnel, teams, etc.</li> <li>• Determine need for diagnostic personnel teams, resources, etc.</li> <li>• Determine need for medical providers.</li> <li>• Determine need for assistance in processing deceased (e.g., Disaster Mortuary Operational Response Teams [DMORTs]).</li> <li>• Determine need for personnel to assist with MCM distribution and dispensing.</li> </ul>

Topic	Decision Point
<p>Modeling: Modeling can be of assistance in projecting disease outbreak and/or dispersal.</p>	<ul style="list-style-type: none"> <li>• Determine utility of modeling and coordinate model development across federal departments and agencies and the private sector.</li> </ul>
<p>Decontamination Standards and Clearance Goals: IC/UC coordinates with appropriate SLTT public health agencies to determine final clearance goals. This decision is a judgment call as to whether the criteria for decontamination verification and clearance have been met. Federal departments and agencies 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, Compensation, and Liability Act (CERCLA) provisions, offsite disposal of CERCLA waste is subject to the offsite rule, 40 Code of Federal Regulations (CFR) 300.440.</p>	<ul style="list-style-type: none"> <li>• In coordination with SLTT entities, determine acceptable clearance level.</li> <li>• In coordination with SLTT entities, make ultimate clearance decision regarding the success of remediation.</li> </ul>
<p>Infrastructure Remediation: 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>	<ul style="list-style-type: none"> <li>• Assist IC/UC in prioritization of infrastructure remediation.</li> <li>• Stand up a technical working group of multi-disciplinary technical experts to provide input for planning and implementing remediation.</li> </ul>

Topic	Decision Point
<p>Waste Management: Hazardous Materials Regulations, promulgated by DOT (HMR; 49 CFR 171-180), regulate “hazardous materials,” which means a substance or material that the Secretary of Transportation has determined can pose 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 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 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>	<ul style="list-style-type: none"> <li>• Tailor Pre-Incident Waste Management Plans, as identified in Appendix U, to incident-specific conditions.</li> <li>• Provide additional resources to implement waste management and disposal operations.</li> </ul>

Topic	Decision Point
<p>Relocation, Alternative Housing, and Re-occupancy: Long-term and permanent housing solutions may require unique consideration and implementation compared to other major disasters due to the potential for contamination and the need for decontamination. 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 requires closely coordinated decision making and communications with both impacted and host jurisdictions. Re-occupancy decision making and timing is integrally linked to remediation planning.</p>	<ul style="list-style-type: none"> <li>• Support SLTT officials in decision making and implementation of relocation, alternative housing, and re-occupancy strategies.</li> </ul>
<p>Patient Transportation: A biological incident requires the transport of patients from incident sites to hospitals. When the need arises, certain decisions are required by the federal government.</p>	<ul style="list-style-type: none"> <li>• Determine needs and methodologies for returning exposed/infected U.S. citizens from overseas locations.</li> <li>• Determine movement need and methodology between designated facilities.</li> </ul>
<p>Funding</p>	<ul style="list-style-type: none"> <li>• Determine whether supplemental appropriations are required and submit a supplemental funding request to Congress.</li> </ul>

## ADMINISTRATION, RESOURCES, AND FUNDING

### Administration

The PHSA directs HHS to lead all federal public health and medical responses to public health emergencies while also providing authorities to extend temporary assistance to requesting SLTT entities to meet health emergency capability requirements. HHS does not receive appropriations from a dedicated response fund, however, and may need additional funding to provide support during a large-scale 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. These include PHSA authorities to issue grants to activate a surge workforce capability, to build and sustain SLTT public health preparedness and response capabilities through the CDC Public Health Emergency Preparedness (PHEP) Cooperative Agreement, and to rapidly fund SLTT health departments when funding is made available for

a PHE that exceeds jurisdictional capacity to respond through the CDC Crisis Response Cooperative Agreement.

The declaration of a Public Health Emergency (PHE) is made by the HHS Secretary to trigger the availability of special funding (if Congress chooses to appropriate funds to the PHEF), 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 the response and short-term recovery activities associated with this annex, the Stafford Act establishes management and oversight responsibilities for all administrative and logistics requirements that support response and short-term recovery operations. DHS/FEMA is the primary agency for funding associated with Stafford Act declarations.

## Resources

Federal agencies are responsible for personnel augmentation to support operations under this plan. Each federal department and agency possess individual policies for personnel augmentation that are predicated on the agency's authorities, policies, memoranda of understanding (MOUs), and mutual aid agreements (MAAs). 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 the "Federal Response Capability Inventory" section of Appendix D.)

## Funding

Federal funding to support federal response operations is 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: non- Stafford Act and Stafford Act funding.

Funding sources for non-Stafford and Stafford Act incidents are detailed in Table 8.

**Table 8: Funding Sources for Non-Stafford and Stafford Act Incidents**

Source	Types of Funding	Administered By	Description
<b>Public Health Emergency Fund (PHEF)</b>	Supplemental appropriations that 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 PHE. 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 PHE declaration.
<b>Non- Stafford Act</b>	Appropriated funds	Each department/ agency	As established by Congress (specific guidance from agency financial management offices and legal counsel should be obtained).
<b>Non- Stafford Act</b>	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.
<b>Stafford Act</b>	Pandemic Coverage (Emergency Assistance for Human Influenza Pandemic Disaster Assistance, Policy 9523.17. November 25, 2009)	FEMA	Direct Federal Assistance (DFA) is available through Public Assistance (PA) grants for Stafford Act declarations related to pandemic influenza. Assistance provided by DHS/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 (OFAs), including HHS.
<b>Stafford Act</b>	FEMA Policy 104-009-2: Public Assistance Program and Policy Guide v. 4 (PAPPG) (June 2020) at 85-86	FEMA	FEMA may reimburse for eligible work performed through mutual aid agreements. Such reimbursement is subject to the Public Assistance Program’s eligibility requirements.
<b>Stafford Act</b>	Disaster Relief Fund (Robert T. Stafford Relief and Emergency Assistance Act of 1988)	FEMA	Disaster relief funding limits are established by Congress.

# OVERSIGHT, COORDINATING INSTRUCTIONS, AND COMMUNICATIONS

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## 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 perform roles and responsibilities congruent with their statutory authorities in coordination with HHS as the LFA. NSC staff provides policy coordination and deconfliction, as required.

## Coordinating Instructions

The HHS SOC is the primary HHS element for resource coordination at the national/headquarters level. The HHS SOC provides public health and medical coordination and incident support functions to the regions and/or JFO, conducts operational planning, deploys national-level resources, and collects and disseminates incident information to maintain a common operating picture (COP).

Consistent with the NRF and in accordance with Homeland Security Presidential Directive -5 (HSPD-5), the Secretary of DHS, through the DHS/FEMA Administrator or other appropriate officials, coordinates federal resources used 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 Attorney General and the Secretary of Homeland Security have established appropriate relationships and mechanisms for cooperation and coordination between their two departments.

## Telecommunications and Operational Communications

Clear, timely, and actionable information—accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities) and individuals who are limited English proficient—that is culturally appropriate for all affected populations should be provided. Public messaging should adhere to the principles of risk communications, even in areas unaffected by the incident, and include information regarding any threat or hazard as well as information on the actions being taken and assistance being made available.

Communications 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. (Refer to the Response and Recovery FIOF, Annex K, for communications tools.)

Unless otherwise directed and in accordance with applicable Presidential policy directives, the HHS Secretary or designee serves as the primary spokesperson for the public health and medical response, supported by SMEs 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 is imperative to coordinate federal teams and assets in a diverse environment under a range of different timelines and authorities.

Consideration of the early establishment of a JIC is critical. The collection and dissemination of numerous data elements from across SLTT governments is also critical.

Coordination of risk communications through a single federal spokesperson is essential. 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., HHS/CDC, HHS/National Institutes of Health [NIH], HHS/FDA) to take the lead on public affairs activities, with the responsibility of consulting with the HHS/ASPR as they move forward to manage incident communications. In the instance of a terrorist or other federal criminal incident, the DOJ/FBI shall be consulted before issuing sensitive media/press releases to ensure the protection of any law enforcement sensitive information.

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 is determined based on the nature of the incident but may be from HHS, DHS, NSC, SLTT entities, or elsewhere, in accordance with applicable Presidential policy directives.

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# Appendix A: Federal Response Coordination

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## Situation

Biological incident response is 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 federal 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 can require expansion of functional capabilities within incident management and multi-agency coordination systems, such as those at multiple SLTT levels, Joint Field Offices (JFOs), or federal department operations centers. The activities at each incident management level and location can vary significantly and across multiple organizations, including the private sector. Informed decision making requires obtaining data from varied and disparate sources, along with the ability for rapid processing of data into useable information. This enhances the ability to understand the current situation and, more importantly, to project the evolving situation so that effective actions can be initiated and coordinated across the incident.

This appendix outlines possible federal response coordination constructs that may be employed in a biological incident response. It is not intended to be proscriptive but rather to be illustrative in outlining all potential necessary functions that would require coordination in an exceedingly complex biological incident.

## 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 (HHS/IHS)

- Administration for Strategic Preparedness and Response (HHS/ASPR)
  - Biomedical Advanced Research and Development Authority (HHS/BARDA)
- Centers for Disease Control and Prevention (HHS/CDC)
- Food and Drug Administration (HHS/FDA)
- Administration for Children and Families (HHS/ACF)
- Health Resources and Services Administration (HHS/HRSA)
- National Institutes of Health (HHS/NIH)
- Substance Abuse and Mental Health Services Administration (HHS/SAMHSA)
- Centers for Medicare & Medicaid Services (HHS/CMS)
- Department of Homeland Security (DHS):
  - Federal Emergency Management Agency (DHS/FEMA)
  - Cybersecurity & Infrastructure Security Agency (DHS/CISA)
  - U.S. Coast Guard (DHS/USCG)
  - Customs and Border Protection (DHS/CBP)
  - Countering Weapons of Mass Destruction Office (DHS/CWMD)
  - Science and Technology (DHS/S&T)
  - Office of Health Security (DHS/OHS)
  - Transportation Security Administration (DHS/TSA)
- Department of Justice (DOJ):
  - Federal Bureau of Investigation (DOJ/FBI)
  - Bureau of Alcohol, Tobacco, Firearms and Explosives (Emergency Support Function [ESF] #13 (DOJ/ATF))
- U.S. Department of Agriculture (USDA):
  - Animal and Plant Health Inspection Service (USDA/APHIS)
  - Food Safety and Inspection Service (USDA/FSIS)
  - Food and Nutrition Service (USDA/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 (DOT/FAA)
  - National Highway and Traffic Safety Administration (DOT/NHTSA)
  - Pipeline and Hazardous Materials Safety Administration (DOT/PHMSA)
  - Federal Highway Administration (DOT/FHWA)
  - Federal Motor Carrier Safety Administration (FMCSA)

- Federal Transit Administration (FTA)
- Federal Railroad Administration (FRA)
- Great Lakes Saint Lawrence Seaway Development Corporation (GLS)
- Maritime Administration (MARAD)
- Department of the Interior (DOI):
  - National Park Service (DOI/NPS)
  - U.S. Geological Survey (DOI/USGS)
  - Fish and Wildlife Service (DOI/FWS)
- Department of Commerce (DOC):
  - National Oceanic and Atmospheric Administration (DOC/NOAA)
- Department of Labor (DOL):
  - Occupational Safety and Health Administration (DOL/OSHA)
  - Employment Training Administration (DOL/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 below.

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/ASPR Regional Emergency Coordinators (RECs) coordinate with HHS/CDC, their counterparts at the National Operations Center (NOC), DHS/OHS, and DHS/FEMA. Regional health administrators, regional advisory councils, and regional directors may work with SLTT senior health officials and representatives from health associated non-governmental organizations (NGOs) to support decision making and provide guidance.

## Department of Health and Human Services

HHS is the principal federal 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, several national strategies and Presidential Directives identify HHS as the lead federal department responsible for the protection of the health of the civilian population against naturally occurring, intentional, and accidental threats. HHS is also responsible for coordinating with other federal agencies and impacted SLTTs, the private sector, and non-governmental partners, as appropriate, in responding to a biological

incident. The Secretary of HHS leads all federal public health and medical activities relating to public health and medical emergencies covered by the *National Response Framework* (NRF).

### ***Administration for Strategic Preparedness and Response***

HHS/ASPR was created under the Pandemic and All-Hazards Preparedness Act (PAHPA) in the wake of Hurricane Katrina. HHS/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. HHS/ASPR focuses on providing public health and medical preparedness planning and response support; assisting locally led recovery efforts in the restoration of the public health, healthcare, and social service networks of impacted communities; building federal emergency medical operational capabilities; supporting medical countermeasure (MCM) research, advanced development, and acquisition; and providing grants to strengthen the capabilities of hospitals and healthcare systems in public health emergencies and medical disasters.

HHS/ASPR consists of the following offices:

- Incident Command and Control (ICC)
- Office of Operations and Resources (OOR)
- Biomedical Advanced Research and Development Authority (BARDA)

HHS/ASPR leads the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which comprises HHS/CDC, HHS/NIH, HHS/FDA, and their interagency partnerships with the VA, DOD, DHS, Office of the Director of National Intelligence (ODNI), and USDA. Members work together to advise the Assistant Secretary for Preparedness and Response (Assistant Secretary), who then makes recommendations to the Secretary of HHS on MCMs—including vaccines, treatments, devices, and personal protective equipment (PPE)—that may be used to protect the American people during an emergency or other disaster. Additionally, HHS/ASPR, in collaboration with HHS/CDC and in coordination with the Secretary of Homeland Security, determines the stockpiling, allocation, and distribution of Strategic National Stockpile (SNS) products. HHS/CDC provides scientific recommendations to HHS/ASPR, and HHS/ASPR makes the decision on the allocation of assets to SLTTs. HHS/ASPR provides federal support, including medical professionals through the National Disaster Medical System (NDMS), to augment state and local capabilities during an emergency or disaster.

Under the Public Health Service Act (PHSA), HHS is the lead agency for ESF #8. Consistent with provisions established in statutes under the PAHPA and Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), the Secretary of HHS delegates to HHS/ASPR the leadership role for all health and medical services support functions in a health emergency or public health incident and the lead responsibility within the department for emergency preparedness and response policy coordination and strategic direction. Additionally, HHS/ASPR and the HHS Office of Global Affairs (OGA) co-manage the

International Health Regulations (IHR) National Focal Point (NFP), consisting of the ASPR, the IHR program in HHS/OGA, and the HHS Secretary's Operations Center (SOC), which serves as the official pathway for notifications to the World Health Organization (WHO) of incidents that may have potential international impact.

### *Centers for Disease Control and Prevention*

HHS/CDC is an operational component of HHS that is responsible for the nation's health protection. HHS/CDC 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 domestic.

The following critical functions may be executed by HHS/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 biological agents.
- Provide environmental assessment consultations and/or conduct environmental sampling to support epidemiologic and surveillance activities and identify exposure pathways to support implementation of intervention strategies.
- Provide guidance on identification, diagnosis, and clinical management of human cases.
- Provide guidance on strategies and use of non-pharmaceutical interventions (NPIs).
- Provide guidance on use of MCMs (e.g., antimicrobials, vaccines, immunotherapeutics) that may be used for prophylaxis and treatment and monitor for any safety concerns.
- Develop effective infection control practice recommendations for healthcare settings.
- Mitigate risk of importation and spread of communicable disease into the United States through traveler education, illness detection and response at U.S. ports of entry, post-arrival risk assessment and management of travelers and other mobile populations, and technical support to source countries.
- Provide guidance on mitigation NPIs and 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 provide timely, accurate, clear, consistent, credible, and actionable information. Ensuring that the information is accessible to older adults (who may not have smartphones),

individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities), and individuals who are limited English proficient is a key component in providing equitable access to programs and services. 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 impacted areas and to the HHS/CDC Emergency Operations Center (and other EOCs) for technical and administrative missions.
- Provide funding to SLTTs and public health partner organizations for public health emergency preparedness and response.

### *Centers for Medicare & Medicaid Services*

As the largest single health payer in the United States, CMS administers Medicare, Medicaid, the Children’s Health Insurance Program (CHIP), and the federal healthcare marketplace—<https://www.healthcare.gov>. Over 150 million Americans rely on CMS programs for high-quality health coverage.

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

- Provide data to enable Provision of Care for those with access and functional needs during response and recovery.
- Under authority granted during a PHE, supply regulatory waivers and modifications for federal requirements, as needed, and authorities for some healthcare actions.
- Waive sanctions under the Emergency Medical Treatment and Labor Act (EMTALA) for up to the duration of the PHE. (In the case of a PHE involving pandemic infectious disease, the general EMTALA waiver authority continues in effect until the termination of the PHE declaration.)
- Redirect an individual who “comes to the emergency department,” as that term is defined at § 489.24(b), to an alternate location for a medical screening examination (MSE), pursuant to a state emergency preparedness plan or, as applicable, a state pandemic preparedness plan. Even when a waiver is in effect, there is still the expectation that everyone who comes to the emergency department (ED) receives an appropriate MSE if not in the ED then at an Alternate Care Site (ACS) to which they are redirected or relocated.
- Inappropriately transfer an individual protected under EMTALA when the transfer is necessitated by the circumstances of the declared emergencies. Transfers may be inappropriate under EMTALA for several reasons.
- Perform Life Safety Code (LSC) surveys of long-term care facilities, including parts of the physical environment standards applicable to long-term care facilities.

- Provide technical assistance to SLTT partners for certifying temporary facilities.

### *Food and Drug Administration*

HHS/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, which may include personal protective equipment (PPE), therapeutic devices such as ventilators, and diagnostics. HHS/FDA, including through its Medical Countermeasure Initiative (MCMi), works to identify and resolve complex scientific and regulatory challenges to facilitate the development, approval/authorization, availability, and security of MCMs. HHS/FDA uses the breadth of its delegated authorities within the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the PHSA to prepare for and respond to public health emergencies of all types. In addition to review and approval of MCMs, HHS/FDA has numerous compliance programs to ensure industry compliance with the laws it administers. There are several authorities related to providing access to MCMs that are not HHS/FDA-approved, including unapproved uses of approved medical products for emergency use. For example, HHS/FDA may issue an Emergency Use Authorization (EUA) to allow emergency use of an unapproved MCM 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 chemical, biological, radiological, or nuclear (CBRN) threat agents, including emerging infectious diseases, when statutory criteria under section 564 of the FD&C Act are met, including when there are no adequate, approved, and available alternatives.

The HHS/FDA MCMi, led by the Office of Counterterrorism and Emerging Threats (OCET), provides strategic leadership and coordination for HHS/FDA counterterrorism and emerging threat portfolios, and works to identify and resolve complex scientific and regulatory challenges facing MCM development, approval, availability, and security. OCET coordinates the HHS/FDA MCMi, facilitates relevant intra- and interagency counterterrorism communications, and coordinates MCMi emergency use, including EUA activities. HHS/FDA has several authorities related to providing access to investigational and/or unapproved, as well as unapproved uses of approved, medical products for emergency use. HHS/FDA also has compliance programs to evaluate industry compliance with the FD&C Act and other laws administered by HHS/FDA.

### *Health Resources and Services Administration*

HHS/HRSA fosters access to quality healthcare for people who are uninsured, isolated, or medically vulnerable. HHS/HRSA programs and grants help build a skilled workforce and support healthcare innovation to foster health equity. During response and recovery, HHS/HRSA can provide a communications channel with funded programs and health centers. While HHS/HRSA does not have direct control over program or center management, they help contribute to situational awareness on resources and capabilities.

### *National Institutes of Health*

HHS/NIH is an operational component of HHS and the lead agency for U.S. biomedical research response. HHS/NIH conducts research on emerging and re-emerging infectious diseases and facilitates the discovery and development of MCMs, including diagnostics, therapeutics, and vaccines, to prevent, treat, and control diseases in the U.S. and globally. HHS/NIH provides subject matter and technical expertise for senior leader decisions, health professionals, and the public. HHS/NIH also has roles in safety training of workers and in post-incident, follow-up research. Research that addresses important health questions that emerge during a biological event in key population groups can be a part of the response framework, and the HHS/NIH Disaster Response Research (DR2) program is the framework that HHS/NIH recommends for such action. Considerations for research should be made early in the response and recovery phase after a biological incident event. Topics include causes, diagnosis, treatment, control, and prevention of diseases.

The HHS/NIH/National Institute of Environmental Health Sciences (NIEHS) Worker Training Program (WTP)<sup>24</sup> and its grantees have been involved in several infectious disease-related training and response efforts. The NIEHS WTP develops and disseminates resources aimed at protecting the health and safety of individuals who work in industries with the potential for exposure to infectious diseases as well as other hazards. The NIEHS WTP is also a part of the NRF under the *Worker Safety and Health Support Annex*. If the NRF is activated, OSHA may ask the NIEHS WTP to provide training and technical assistance, such as instructional staff, curriculum development experts, subject matter experts (SMEs), and other professional staff. This includes providing training and technical assistance for activities such as respirator fit-testing and distribution of PPE.

### *Office of Assistant Secretary of Health*

HHS/Office of the Assistant Secretary for Health (OASH) oversees response and recovery activities of the U.S. Public Health Service (USPHS) Commissioned Corps. HHS/OASH also advises federal officials on response and recovery-related cross-cutting public health, climate change, health equity, and science initiatives. HHS/OASH also advises on population-based public health and clinical preventive services, including blood and tissue product supply issues. The Assistant Secretary for Health (ASH) and the Surgeon General (SG) advise the Secretary on public health matters and can be available to deliver critical communications.

Through the authorities of the ASH, the Commissioned Corps Headquarters' Readiness and Deployment Branch (RDB) deploys officers to support ESF #8 mission assignments and agency partners by ensuring stable continuous operations of critical community, business, and government functions that are essential to human health and safety. Through these deployments, the Commissioned Corps can provide operational coordination and

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<sup>24</sup> Information on NIEHS WTP can be found at this website: <https://tools.niehs.nih.gov/wetp/index.cfm?id=2554>.

communications; mission intelligence and information sharing; risk and fatality management; environmental response, health, and safety support; and provision of mass care services. To engage in these deployments, requests for assets are received and vetted by the RDB. If the mission is appropriate, the mission is assessed to identify the most appropriate USPHS asset to support. These assets may include the newly established Public Health Emergency Response Strike Team (PHERST), Regular Active-Duty Corps, and/or Reserve Corps. PHERST officers have the ability to deploy within 8 hours in support of an immediate need for community stabilization related to unexpected events, threats to public health, or severe impacts to life, health, and/or property. Regular Active-Duty Corps officers deploy within 36 hours of being put on alert status. These officers offer clinical and public health augmentation expertise to communities experiencing threats to public health or severe impacts to life, health, and/or property. Ready Reserve Force officers deploy within 5 days of being activated for service. These officers offer clinical and public health expertise to communities experiencing adverse events, threats to public health, or severe impacts to life, health, and/or property. PHERST and Ready Reserve assets allow the RDB greater flexibility in reducing agency requests and supporting communities until they are truly ready to transition to recovery operations.

## Department of Homeland Security

The Secretary of DHS is the principal federal official for domestic incident management. The Secretary is responsible for coordinating federal preparedness activities and operations within the United States to respond to and recover from terrorist attacks, major disasters, and other emergencies, including biological incidents. DHS provides biosurveillance capabilities to detect 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 for in HSPD-5.

The DHS Chief Medical Officer (CMO) and Director of DHS/OHS oversee all medical, public health, and workforce health and safety activities of the department. In coordination with the DHS Office of Partnership and Engagement, the Office of Intergovernmental Affairs serves as the department's primary liaison and coordinator with other federal departments and agencies, as well as state, local, and tribal governments, and the medical community, on medical, public health, workforce health and safety, and health security issues.

- Coordinate the Department's efforts related to defending the food, agriculture, and veterinary systems of the United States against terrorism and other high-consequence events that pose a high risk to the homeland.
- Manage the Department's MCM program and serves as the Department's Designated Agency Safety and Health Official.

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.

DHS serves as an information conduit across multiple agencies and to the National Security Council (NSC) for the following:

- Operational coordination
- Situational awareness and decision support through the NBIC/National Biosurveillance Information System (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, Recovery Support Functions (RSFs), and funding support to impacted areas during response operations pursuant to Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) disasters. For biological incidents, DHS/FEMA primarily manages coordinating centers, funding sources, and non-medical supply resourcing and supports ESFs/RSFs.

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

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

### ***U.S. Coast Guard (USCG)***

DHS/USCG conducts port and waterway 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 counterterrorism operations. In addition, DHS/USCG enforces quarantines in the maritime environment under its cognizant authority and per the direction of HHS/CDC. Coast Guard Deployable Specialized Forces, including the National Strike Force (NSF) and Marine Security Response Teams (MSRTs), provide highly trained, experienced personnel and specialized equipment to DHS/USCG and other federal agencies to facilitate preparedness for and response to biological incidents to protect public health and the environment. DHS/USCG On-Scene Coordinators (OSCs) are responsible for coordinating the removal of oil and hazardous substances in the Coastal Zone.

### ***Customs and Border Protection (CBP)***

For biological incidents suspected or detected inside or at U.S. borders or for those individuals that may travel to the United States from abroad, DHS/CBP may detain and/or quarantine individuals until medical authorities have been alerted. DHS/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. DHS/CBP may detain hand-carried or shipments of biological materials that have the potential to cause a biological incident until the appropriate regulatory authorities have been alerted as per the MOU titled Ensuring the Safe and Lawful Importation of Biological Materials, Including Biological Select Agents and Toxins into the United States.

### ***DHS/Cybersecurity and Infrastructure Security Agency (CISA)***

DHS/CISA 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 (CIKR). DHS/CISA forges strong relationships with federal and SLTT government mission partners and private sector stakeholders to enhance public/private collaborative efforts to protect critical infrastructure. DHS/CISA's regions remain focused on contingency outreach to owners and operators of critical infrastructure regarding an evolving biological incident.

DHS/CISA sustains communications with the respective Sector Coordinating Councils (SCCs) and sector-specific Government Coordinating Councils regarding appropriate information sharing related to an evolving biological incident.

### ***DHS/Science and Technology Directorate (S&T)***

DHS/S&T is the primary research and development arm of DHS, promoting the development of homeland security technologies and providing the scientific expertise, assessments, and knowledge products that enable risk-based funding and deployment decisions by the Homeland Security Enterprise (HSE). For incidents involving suspected biological agents, DHS/S&T will perform rapid agent analyses through the National Biological Threat Characterization Center (NBTCC) at the National Biodefense Analysis and Countermeasures Center (NBACC) to rapidly fill knowledge gaps in agent characteristics crucial to operational response (e.g., environmental stability, decontamination effectiveness, toxic dose estimation). In addition, DHS/S&T, in coordination with the Assistant Secretary for CWMD, produces the CBRN Strategic Risk Assessment. Since this assessment includes a significant number of biological agent scenarios, it will be used to inform immediate mitigation measures, including protective and consequence management efforts. Lastly, DHS/S&T will provide timely and accurate input and guidance from technical SMEs on biological agents, leveraging experts from the NBACC, the Chemical Security Analysis Center (CSAC), and the Hazard Awareness and Characterization Technology Center (HAC-TC).

## DHS/Transportation Security Administration (TSA)

During a communicable disease outbreak, the Transportation Security Administration (TSA) utilizes its available authorities, processes, and technologies to protect its workforce and the traveling public while simultaneously maintaining its mission-essential functions/services in order to preserve the transportation system as part of a national response. By virtue of its role and level of consistent public engagement across the transportation system, TSA's Federal Security Directors, Federal Air Marshals, and Transportation Security Officers serve as critical customer interfaces between the federal government, private sector, and traveling public on a regular and routine basis.

## Department of Justice

### *Federal Bureau of Investigation*

The Attorney General, 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 (JTTFs), 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, acting through the FBI Director, has primary responsibility for searching for, finding, and neutralizing weapons of mass destruction (WMDs) 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 (e.g., hostage rescue, tactical response operations) continuously during the response. Additionally, the FBI On-Scene Commander (OSC) has primary responsibility for conducting, directing, and overseeing crime scenes, to include those involving WMD, their security, and evidence management, through all phases of the response. The FBI Critical Incident Response Group (CIRG) maintains national-level and regionally based response forces that are specifically trained and equipped to respond to WMD threats and incidents. FBI CIRG provides the combined surveillance, tactical, and technical response capability to resolve WMD threats or incidents, including those involving biological devices.

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

In the case of substantial credible threats or incidents, the FBI notifies appropriate senior leaders of departments and agencies, to include the National Counterterrorism Center, DHS, HHS, USDA, and DOD, and stands up the interagency Weapons of Mass Destruction

Strategic Group (WMDSG). The WMDSG is an FBI-led interagency crisis action team that supports information exchange and the deconfliction of WMD law enforcement and counterterrorism operations to prevent imminent threats, while simultaneously coordinating the efforts of federal agencies responsible for public health, homeland security, and other consequence management activities to save lives and protect property and critical infrastructure.

The FBI has a WMD Coordinator assigned to each of its field offices. WMD Coordinators are responsible for managing the office WMD program and they serve as points of contact for emergency responders and public health officials at the state and local levels 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. The FBI also has Special Agent Bomb Technicians (SABTs) assigned to each of its field offices. FBI SABTs are responsible for responding to and conducting WMD device defeat and mitigation actions for WMD devices and materials and they serve as points of contact for public safety bomb squad coordination at the state and local levels in a threat scenario or incident potentially involving a WMD. FBI/CIRG, through its responsibilities of training and certifying all Public Safety Bomb Technicians at the FBI's Hazardous Devices School, ensures that all Public Safety Bomb Squads are trained and equipped with and understand the protocols for responding to and coordinating their response to all WMD incidents, including biological incidents, with FBI SABTs.

Terrorist threat-related information collected domestically, including suspicious activity reporting involving suspected federal crimes of terrorism, must be shared comprehensively and immediately with the FBI JTTF so that threats can be investigated and resolved. Terrorist threat-related information must also be shared promptly with the National Counterterrorism Center and, in addition and as authorized by law, with the Threat Screening Center, DHS, and DOD. Specific terrorism-related threat information and collection and investigative activities related thereto are coordinated with and through 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 HHS/CDC, is used to test for the presence of specific panels of biological threat agents in most 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. The FBI directs the forensic analysis of hazardous biological materials and associates evidence at the National Bioforensic Analysis Center (NBFAC). 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.

### *The Bureau of Alcohol, Tobacco, Firearms, and Explosives*

The Attorney General, acting through the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) and the ESF #13 (Public Safety and Security) National Coordinator, is responsible for the coordination of federal law enforcement resources that, when activated through the NRF, may assist federal and SLTT agencies in maintaining public safety and security in areas affected by a WMD/biological incident. The consequences of a WMD/biological incident are potentially significant and could warrant both an FBI and ESF #13 response. Should this occur, the Attorney General may appoint a Senior Federal Law Enforcement Official (SFLEO), whose responsibilities are to represent DOJ intelligence and criminal investigative interests. ATF, as the DOJ lead agency for ESF #13, coordinates federal public safety and security assistance to federal and SLTT agencies overwhelmed by an actual or anticipated emergency, disaster, or act of terrorism. In the context of a biological incident and in addition to providing law enforcement assistance to federal and SLTT agencies, ESF #13 may provide more specific public safety and security assistance relevant to the unique requirements of a biological incident. Examples of support may include quarantine enforcement and the security of outer perimeters, decontamination of sites, evidence, checkpoints, and specialized equipment. ESF #13 may provide its assistance to a biological incident response when authorized to do so under the NRF, meaning that the incident has been determined to require a whole-of-government approach. This may be evidenced through an appropriate authority, such as a declaration of a public health emergency by the HHS Secretary under the PHS Act or a declaration of an emergency or major disaster by the President under the Stafford Act.

### **Department of Agriculture**

USDA serves as the federal government's primary agency for securing the commercial production of USDA-regulated foods and managing outbreaks and/or attacks that may occur in animals used in the commercial production of USDA-regulated foods. USDA, HHS, DHS, and DOJ/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. 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, extraordinary emergency, and agricultural disaster declarations.

USDA National Animal Health Laboratory Network (NAHLN) laboratories perform routine diagnostic tests for endemic animal diseases as well as targeted surveillance and response testing for foreign animal diseases, protecting animal and human health through early

detection of animal diseases, 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 may include nutrition assistance; response to animal and agricultural health issues; technical expertise in support of animal and agricultural emergency management; measures to ensure the safety and defense of the nation's supply of meat, poultry, and processed egg products; and protecting natural, cultural, and historical resources. ESF #11 can provide support during a biological incident. It should be noted that USDA typically does not employ the Stafford Act for responses, but usually uses the Animal Health Protection Act. The normal ways that mission assignments are allotted for incidents that cross over to the agricultural sector may not be the standard Stafford Act way in which mission assignments and subsequent reimbursements are handled.

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***

USDA/APHIS works closely with DHS/FEMA to provide coordination and assistance during all-hazards emergencies. USDA/APHIS may provide technical assistance that includes 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. USDA/APHIS may also provide technical assistance to help with livestock rescue/care and carcass management. The agency may provide epidemiology and diagnostic support during a biological incident.

USDA/APHIS maintains the National Veterinary Stockpile to address foreign animal disease in livestock and poultry. USDA/APHIS staffs wildlife disease biologists, wildlife biologists, and wildlife specialists who, in coordination with SLTT wildlife agencies and DOI, provide expertise to support wildlife disease monitoring and surveillance and removal of wildlife to protect agriculture, natural resources, property, and human health and safety. USDA/APHIS also has veterinarians and animal health technicians that provide expertise to support livestock disease monitoring and surveillance, as well as depopulation, disposal, and decontamination in a foreign animal disease outbreak to protect agriculture and human health and safety.

USDA/APHIS operates the National Veterinary Services Laboratories (NVSL) and coordinates the NAHLN. These laboratories provide diagnostic testing of animal samples and may provide surge capacity for diagnostic testing of human samples.

#### ***Food Safety and Inspection Service***

USDA/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. USDA/FSIS works to lower the incidence of

pathogens that cause foodborne illness and limit the occurrence of outbreaks in the products it regulates. USDA/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

Through the DOI Office of Emergency Management, DOI/FWS, DOI/NPS and DOI/USGS, DOI supports the response to naturally occurring biological threats in wildlife (aquatic and terrestrial) and the environment. Under ESF #11, DOI/USGS serves as the federal lead on zoonotic and wildlife diseases. DOI/USGS assists through mapping, modeling, monitoring, testing wildlife (terrestrial and marine), and designing sampling strategies for wildlife and environmental reservoirs. DOI/USGS has tools and capabilities to help assess how environmental processes (e.g., soil geochemistry, hydrologic flows, water quality) influence the occurrence, viability, and transmission of zoonotic or vector-borne disease agents. DOI/USGS provides guidance for disease prevention and control of zoonotic diseases in wildlife and the environment.

The DOI/FWS National Wildlife Refuge System's Wildlife Health Office, DOI/NPS Wildlife Health Branch, and DOI/NPS Office of Public Health conduct critical work in health and disease surveillance, response, and management to support national wildlife refuges and the National Park System. The DOI/NPS Wildlife Health Branch seeks to address service-wide wildlife health issues, while the DOI/NPS Office of Public Health is charged with protection of visitor health. The DOI/NPS Office of Public Health serves as the operating division to recruit, support, and manage HHS Public Health Service (PHS) Commissioned Corps officers assigned to DOI to provide public health capacity to support disease prevention, detection, and management.

## Environmental Protection Agency

The 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 (OSCs), also provides technical assistance and operational support for sampling, characterization, decontamination, clearance, and waste management efforts; federal contractors; EPA special teams, specifically its CBRN Consequence Management Advisory Team; the EPA Homeland Security Research Program; and the Environmental Response Laboratory Network. If there is potential for environmental contamination due to a biological incident, HHS collaborates with the EPA in developing and implementing sampling strategies and sharing results. The EPA may conduct environmental response activities under the Comprehensive

Environmental Response, Compensation, and Liability Act or an ESF #10 (Oil and Hazardous Materials) 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 only DOD but also provide support to lead federal agencies and SLTT entities. To ensure advanced warning of threats, the Defense Intelligence Agency (DIA)/National Center for Medical Intelligence (NCMI) provides intelligence assessments of foreign health threats, including pandemic warnings, 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 Division (AFHSD), conducts comprehensive health surveillance of DOD forces. The AFHSD serves a key role in biosurveillance to detect disease and understand the threats from endemic and emerging infectious diseases relevant to DOD forces. Although the focus is on infectious disease threats relevant to DOD forces, the AFHSD serves as a significant source of information to inform the larger U.S. biosurveillance mission and to maintain situational awareness.

To ensure that DOD can assist in the response to and recovery from a biological incident, the protection of DOD personnel, installations, and other assets to provide mission assurance is the 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 (DSCA) to support responses and minimize the consequences of incidents, when requested by a lead agency and approved by the Secretary of Defense. DOD response capabilities may include specialized MCM research, diagnostics, emergency medical and lifesaving capabilities, logistics, and transportation support. Depending on the size and scope of an 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 healthcare system. The DOD healthcare system, which likely would be equally affected during a large-scale (e.g., regional epidemic/pandemic) biological incident, may be able to provide surge capabilities (e.g., laboratory, emergency care, logistics) for more finite incidents. Additionally, and when requested, DOD may provide medical logistic support and general support, such as transportation, to enable the movement of civilian responders.

DOD has assigned a senior officer, known as the Defense Coordinating Officer (DCO), to each of the 10 FEMA RRCCs, including Hawaii to cover SLTTs in the Pacific. The DCO is the primary conduit between FEMA and the Secretary of Defense for DSCA. Under the Stafford

Act, DOD may be tasked by FEMA to assist using the mission assignment process. For all other non-Stafford Act incidents (e.g., PHE), DOD may assist federal agencies through the Economy Act.

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 a specific constitutional or statutory authority to engage in such activities. One such authority, 10 U.S.C. § 282, 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 or elements of involved weapons.

Lastly, DOD capabilities in biological forensics and technical analysis may be called upon to support the DOJ/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 federal government's lead coordinating agency for foreign relations, DOS is responsible for all communications and coordination during any domestic incident between the U.S. Government and foreign governments. Specifically, DOS coordinates support to foreign missions in the United States regarding consequence management efforts of a biological incident in the U.S. DOS coordinates 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 foreign national casualties and injuries occur, facilitating communications with first responders, hospitals, and morgues as well as facilitating 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 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 federal government 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 SMEs. 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 federal government international humanitarian assistance and disaster response, as specified under the Foreign Assistance Act of 1961. Specifically, the USAID 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, the USAID/OFDA approach to a biological response focuses on providing lifesaving assistance (e.g., food, water, shelter, medicine) to affected populations, 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 within the U.S. Procedures highlight the need for continuous collaboration in the planning process for disaster response as well as regular and sustained communications between mission disaster relief officers and USAID/OFDA regional staff to ensure timely, appropriate, and effective federal government emergency response and humanitarian assistance.

### **Department of Transportation**

The DOT/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, DOT/PHMSA 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 proper packaging and transport of hazardous materials, including regulated medical waste, Category A waste, and any special permits required. 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 DOT/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 DOT/FAA-certificated airmen worldwide. More specifically, the DOT/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, DOT/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, DOT/FAA entered a memorandum of understanding (MOU) with

DOL/OSHA that states that DOL/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 crews). The DOT/FAA also enforces DOT/PHMSA Hazardous Materials Regulations in the aviation mode.

DOT/FAA maintains an agreement with HHS/CDC to ensure that the agencies relay notifications of reports they receive regarding deaths, suspected cases of communicable disease, or other public health risks on board aircraft.

The DOT/NHTSA, in coordination with HHS/CDC and other federal partners, promulgates guidance for pre-hospital care. Through the Federal Interagency Committee on Emergency Medical Services, DOT/NHTSA identifies current practice, training, and equipping issues and, in conjunction with federal and private sector partners, develops materials and policies to fill any gaps.

## **Department of Labor**

OSHA assures safe and healthful working conditions by setting and enforcing standards and by providing training, outreach, education, and assistance. DOL/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. DOL/OSHA can provide technical assistance and support to protect response and recovery 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
- Incident-specific worker safety and health training

During a biological incident, HHS/CDC should consult DOL/OSHA and the National Institute for Occupational Safety and Health (NIOSH) when working with SLTT senior health officials to protect first responders, first receivers, CIKR workers, and public health workers.

### ***Employment Training Administration***

DOL/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.

## 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>25</sup>

During a biological incident, all three response objectives—communications, coordination, and collaboration—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.

## Private Sector

Private sector public health and medical service organizations and infrastructure provide local response capabilities during a biological incident. Hospitals, nursing homes, 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-governmental medical or disaster relief organizations, including animal care and health professionals (e.g., veterinarians), as well as culture- and faith-based organizations can also bolster and assist local response capabilities.

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<sup>25</sup> For detail on healthcare coalitions, see <http://www.phe.gov/preparedness/planning/mscc/documents/mscctier2jan2010.pdf>, accessed Dec. 1, 2016.

## Coordination Constructs

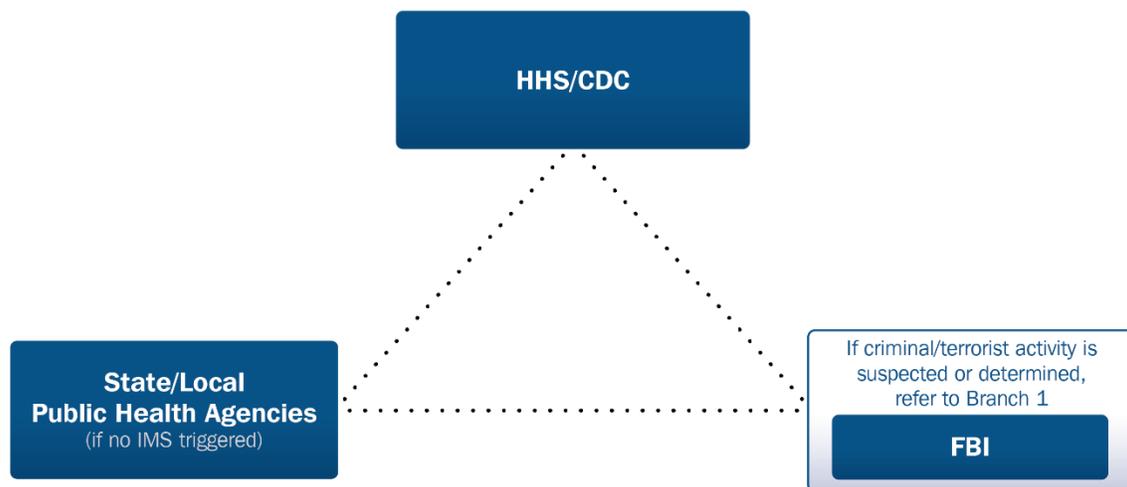
The constructs presented are based upon a graduated scale that ranges from localized early detection and reporting of a biological incident that requires no additional federal resources to incidents that require a large-scale federal response.

As incidents escalate or de-escalate in size and complexity, and federal coordination constructs change to meet the scale of the response, implementation of a transition period to preserve or adjust established processes should be considered.

Leadership and staff should expect to experience some disruption and confusion when there is a change in federal coordination. If they identify possible roles and responsibilities for new coordination constructs, command chains can help minimize disruption of response efforts. The unified coordination leadership group should consider identifying an approval process for public messaging and for data sharing (within the federal government and non-federal partners) to provide staff clarity on information sharing in a response with new leadership and priorities. The Response and Recovery FIOF provides a notional process flow for ESF #15 (External Affairs) that may be adapted to a specific incident.

The constructs identified below serve as examples to describe the level of coordination required between SLTT and federal response agencies/organizations based on a graduated scale. The coordination constructs are based on the size and complexity of an incident and are designed to provide for escalation or de-escalation, depending upon resource requirements. Example coordination constructs are provided from previous responses to illustrate how unified coordination has been established in other biological incidents.

### SLTT/Federal Coordination with HHS/CDC Lead



**Figure A-1: Example of State/Local Federal Coordination**

An SLTT health department contacts the HHS/CDC EOC to report an initial biological incident. Initial reporting to the HHS/CDC may also occur through the Integrated Consortium of Laboratory Networks (ICLN), consisting of participating state and privately

owned/operated clinical laboratories that confirm the presence of reportable diseases or detection of an unknown and novel biological agent.

If there is suspicious activity, state/local health departments should contact the DOJ/FBI field offices/WMD Directorate to begin coordinating information sharing to determine credibility of the threat. The DOJ/FBI, through the Threat Credibility Evaluation (TCE) process, may contact HHS/CDC, informing the agency of a suspected or confirmed presence of a biological agent that may pose a public health risk.

HHS/CDC assists state and local health authorities by providing scientific or technical guidance on incident-specific issues. HHS/CDC may employ an Incident Management Structure (IMS) if the emerging biological incident requires significant intra-agency coordination and resources to support international efforts and/or domestic support to SLTT public health authorities.

In support of SLTTs, HHS/CDC is the lead agency for the following BIA LOEs or components of the LOEs, which are emphasized early in the biological incident:

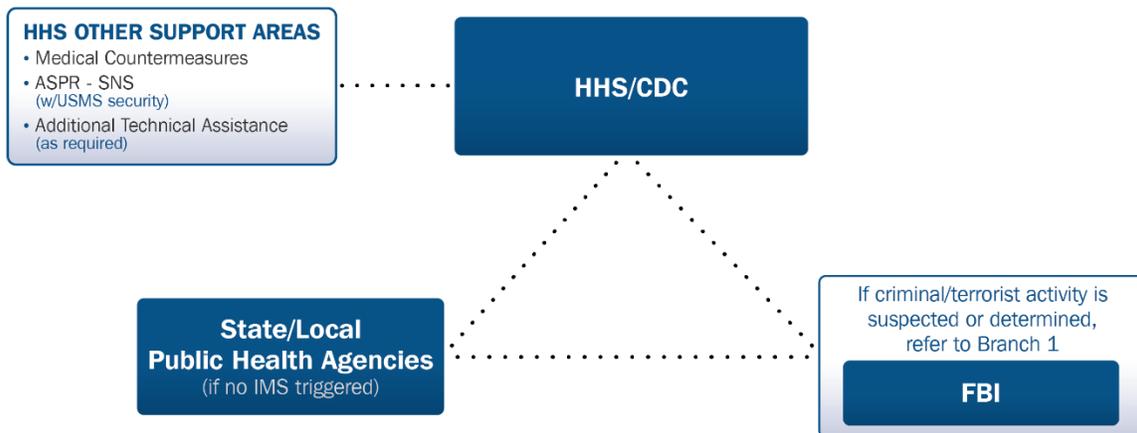
- Detect, Prevent, and Characterize the Threat
  - HHS/CDC leads the “detect” and “characterize” components for this LOE and may provide technical assistance only to the “prevent” component.
- Control the Spread of Disease
- Healthcare Resilience

The HHS/CDC may provide technical assistance to the following LOEs:

- Detect, Prevent, and Characterize the Threat
  - HHS/CDC may provide technical assistance only to the “prevent” component of this LOE.
- Augment Provision of Mass Care and Human Services to the Affected Population

The HHS/CDC should coordinate with HHS/ASPR, DHS/CISA, and other appropriate federal departments/agencies to address the following BIA LOEs, depending on the size, scope, complexity, and current impacts of the emerging biological threat:

- Medical Countermeasure (MCM) Development and Acquisition
- Augment Essential Services and Facilitate Long-term Recovery



**Figure A-2: Example of SLTT/Federal Coordination with Federal Assistance**

SLTT requests for additional resources at this early response phase predominantly come from public health authorities. HHS/CDC receives these requests, appropriately responds, and, if necessary, seeks other federal agency assistance.

If there is intentional activity, DOJ/FBI Hazardous Evidence Response Teams (HERTs) may be deployed for the jurisdiction or region, depending on the scope or outbreak.

DOS is contacted when there are international aspects to the incident (e.g., potential for incident to cross international borders, impacts to foreign nationals or diplomatic facilities, impacts to DOS domestic facilities).

### **HHS as Lead Federal Agency (Non-Stafford Act)**

As described in the BIA for parameters to enhance federal interagency coordination in a non-Stafford Act event involving a biological incident, HHS coordinates the federal public health response from the HHS SOC or the respective agency’s EOC.

HHS/CDC retains its authorities to conduct epidemiological investigations and advises on public health mitigation measures. The BIA LOEs in which HHS/CDC serves as the initial lead agency would transition to the HHS/ASPR as the incident progresses. HHS/CDC personnel, while integrated within the HHS/ASPR coordination construct, continue to support the LOEs but ensure that information, resources, and assets related to those LOEs are shared and well-integrated with HHS/ASPR’s federal lead role in the biological incident response.

These groups (or working groups report to HHS, the SOC Director, and the designated Federal Health Coordinating Officer (FHCO) and share efforts with all HHS incident support functions. HHS/ASPR may reach out to HHS Operating and Staff Divisions and component agencies for additional subject matter expertise, policy analysts, and other appropriate specialties to integrate with these designated groups.

HHS/ASPR can also reach out to various other federal departments and agencies for support and formalize such support through an Interagency Agreement (IAA).

### National-level Response Requiring a UCG

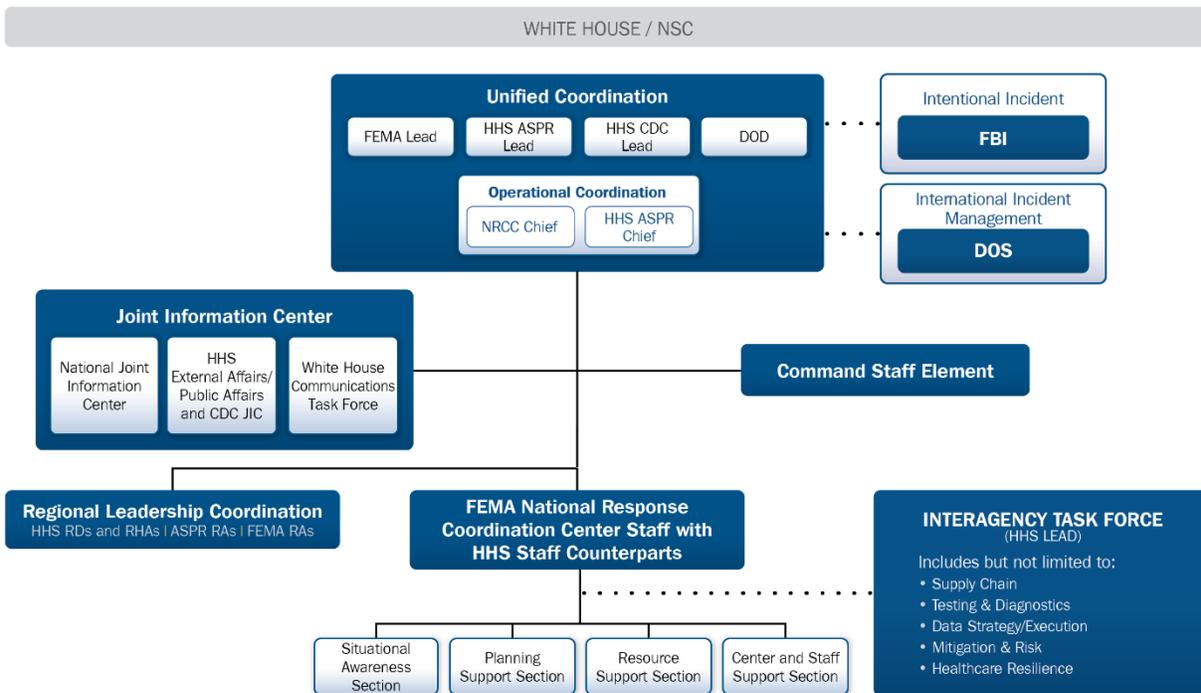
Due to the complexities of a response to a national biological incident, a UCG that integrates departments and agencies with equities in response is often indicated. The location and construct for this management structure can vary but is likely centered within HHS's infrastructure.

In a non-Stafford Act incident, UCG leadership may include a Senior Response Official (HHS) and a Deputy Response Official, the latter of which may be staffed by DHS/FEMA or another federal agency with primary authority for a portion of the response.

In a biological incident involving a Presidential Stafford Act Emergency or Disaster Declaration, the federal response coordination moves from HHS SOC to the DHS/FEMA NRCC. Activation of the NRCC is established by the DHS/FEMA Administrator based on HHS and DHS/OHS input and the scale, size, and complexity of the biological incident. When there is potential for the biological incident to cause significant illness and fatalities and exceed both public health and emergency management response capabilities at the SLTT level, DHS/FEMA and DHS/OHS may activate initially to the highest level (i.e., Level I), preferably early in the initial operational phase of a biological incident, to achieve meaningful mitigation of adverse impacts. The national UCG is co-led by both senior HHS and senior DHS/FEMA and DHS/OHS representatives to ensure integration of public health and emergency management functions.

Where a biological incident may impact primarily an SLTT or a region, a Regional Response Coordination Center (RRCC) may be more appropriate to facilitate support to impacted SLTT jurisdictions rather than activating the NRCC.

Within this construct, the UCG establishes a coordination construct based on the LOEs described in this BIA. The UCG should establish these LOEs as groups (or working groups), defined as an organization level that divides a biological incident according to functional levels of operation, often across geographic boundaries, such as Testing and Diagnostics or Healthcare Resilience. These groups report to the Chief of the NRCC/JFO and share efforts with all incident support functions (e.g., Situational Awareness Support, Planning Support, Resource Support Section, and Staff Support). The groups should also be comprised of federal interagency representation from departments and agencies that are providing resources and staffing support to the biological incident response.



**Figure A-3: Example of Stafford Act Unified Coordination Group**

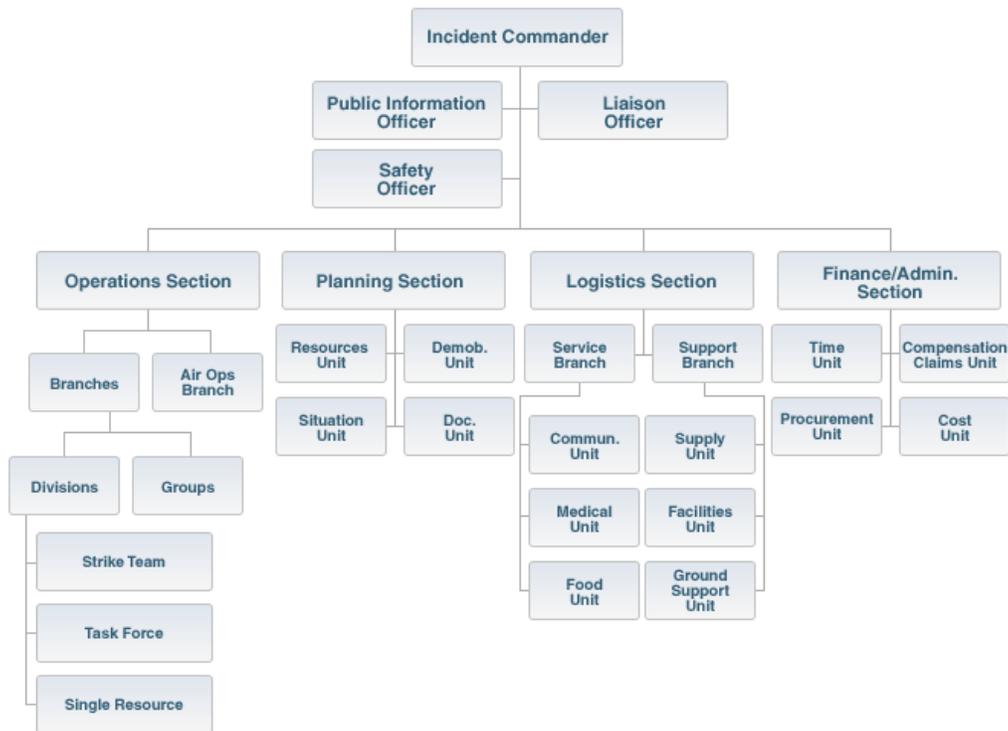
Figure A-3 displays an example of how the LOEs, as described in the previous paragraph, and components described in the base annex would be integrated in a UCG construct during a biological response at the national level.

### Examples of Unified Coordination Constructs

Various incident management entities have adopted models for the management of biological incidents based on the Incident Command System (ICS), which is designated by the National Incident Management System (NIMS) for all domestic emergency response operations. A standard organizational chart used in ICS is presented in Figure A-4. ICS provides a consistent methodology and organizational construct for the management of complex response systems. It is intended to be flexible and scalable to adapt to the response parameters encountered.

The following constructs are examples of how UCGs may be structured when responding to a biological incident. When a UCG is initiated, a planning team from HHS and DHS/FEMA, with other agencies as required, assesses the situation and coordinates with various partners to identify mission requirements and interagency solutions to shortfalls and to bridge gaps prior to transitioning to a UCG.

## Medical and Health Incident Management (MaHIM)



**Figure A-4: ICS Organizational Chart**

The ICS response construct adapted for the Medical and Health Incident Management (MaHIM) model (Figure A-4) demonstrates a construct that is more appropriate at the SLTT level but it can be adopted for use at other jurisdictional levels depending on the scale and complexity of a biological threat/incident.

In developing the MaHIM model, which may be applied to many different public health incident types, investigators first identified and examined medical and public health response efforts for a range of mass casualty incidents. They identified recurring issues that challenge effective coordination between the disparate entities working in a response effort. An assessment and analysis 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. Although intended to be an all-hazards model, MaHIM is particularly suited to a complex biological incident response.<sup>26</sup>

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<sup>26</sup> Barbera, J.A., and 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,

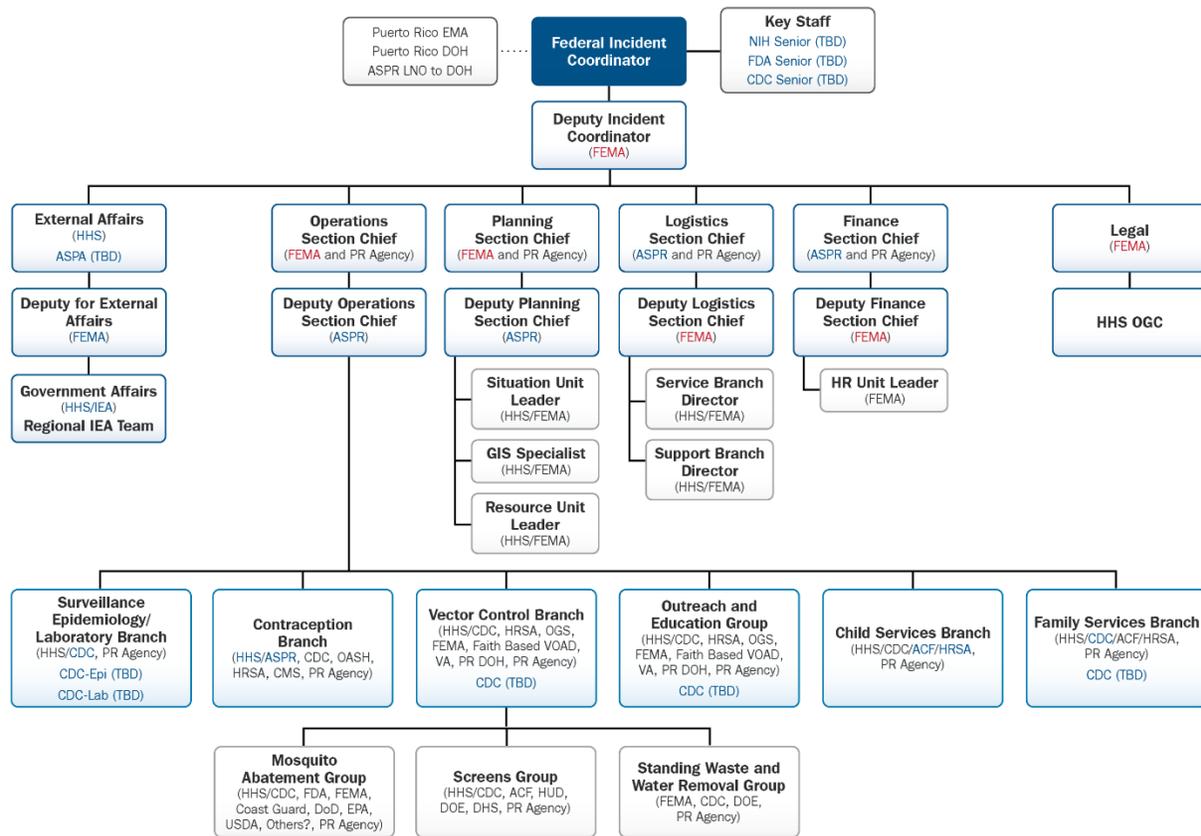
As noted above, a biological incident response at the incident management level most commonly involves management by the relevant public health authority. The authors of the model chose “management” as opposed to “command” to describe this set of activities due to the nature of multiple organizations 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, using a management-by-objective approach based on the prospective establishment of incident and operational period objectives that are constantly evaluated and revised throughout incident action-planning operations. For some biological responses, “management” could be unified in nature using ICS unified coordination principles, but relevant public health authorities usually function as the lead agency.

An example of unified coordination including federal departments with an SLTT agency as the lead agency is the widely praised 9/11 response to the Pentagon attack. The Arlington County (Virginia) Fire Department was the lead agency, with the DOJ/FBI, DOD, and DHS/FEMA also participating in management-level decision making.

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and Risk Management, The George Washington University. Washington, D.C., October 2002. (Supported by a grant from the Alfred P. Sloan Foundation.)

- FEMA Lead
- Other Agency Lead



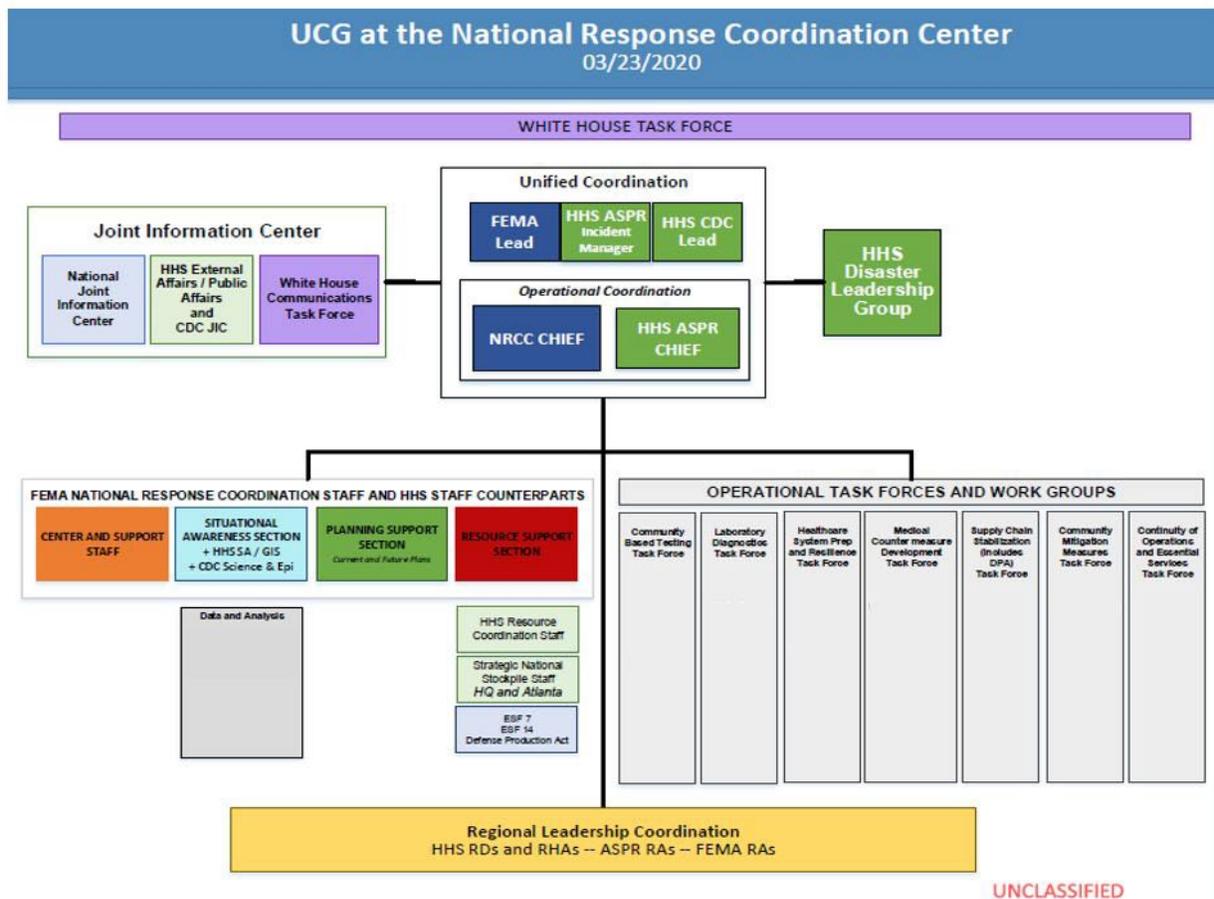
**Figure A-5: Zika Unified Coordination Group**

A Public Health Emergency was declared for the Zika Virus Outbreak in Puerto Rico in August 2016 and a UCG was established at the regional level. This UCG structure (Figure A-5) supported specific LOEs deemed essential to responding to the Zika Encephalitic Virus Disease (EVD) in the U.S. territory of Puerto Rico. The UCG and designated Federal Senior Health Coordinator brought the disparate Ministries of Health, Environmental Protection, and Emergency Management together with various Jurisdictional Mayors not seen prior to UCG implementation. The UCG structure also ensured that all federal response efforts of HHS, DHS/FEMA, EPA, and DOL were well coordinated in support of Puerto Rico, but under non-Stafford Act arrangements.

The NSC directed the establishment of a Zika UCG in Puerto Rico. A Joint Crisis Action Planning (JCAP) team that included DHS/FEMA, HHS/ASPR, and HHS/CDC was formed to conduct an information analysis of the situation and outline initial goals, objectives, and tasks for the UCG. The UCG, working in Puerto Rico, had an organizational construct that followed an ICS-type structure. The UCG included a Federal Incident Coordinator led by a Public Health Service Admiral assigned to HHS/FDA. The Puerto Rico Emergency

Management Agency (PREMA) and Puerto Rico Department of Health (PRDH) were integrated into the UCG structure. The Operations Section, Planning Section, Logistics Section, and Finance Section were co-led by either DHS/FEMA or HHS/ASPR and a representative from PREMA. HHS/CDC led more specific health-related LOEs, which were organized into branches under the Operations Section. The UCG demobilized in November 2016. Lead operational assignments transitioned from DHS/FEMA to HHS, with continued support and technical assistance from DHS/FEMA as required.

*Coronavirus Disease 2019 (COVID-19)*



**Figure A-6: COVID-19 Unified Coordination Group, as established March 2020**

During COVID-19, a UCG jointly led by DHS/FEMA and HHS was established in March 2020 (see Figure A-6) when a Stafford Act declaration was made and the response was moved from HHS headquarters to the NRCC. Working groups that were originally led by HHS/ASPR evolved into a larger interagency task force (TF) with leadership representation from DHS/FEMA, HHS, and HHS/CDC. The TFs were aligned with the then 2017 BIA Operational Areas to organize LOEs in the escalated response. A Data and Analysis Task Force was created to manage data requirements and reporting information to understand the

magnitude of the situation, and a Supply Chain Task Force was created to understand and manage resource requirements and priorities.

Initially, the UCG coordinated major decision making across interagency partners that focused on resource allocation but subsequently focused on priority projects to be funded by the federal government. The permitted coordinated approach prevented duplication of effort or contradictory approaches.

In June 2020, the UCG was revised to support a transition of the response from a jointly led effort to an HHS-led effort with DHS/FEMA support. In this revised UCG construct, a Joint Coordination Cell (JCC) was created to assist in transitioning established LOEs from the NRCC to HHS components to sustain LOE efforts under their respective authorities. DHS/FEMA continued to serve as the lead agency for consequence management efforts to COVID-19 under Stafford Act authorities. The JCC was demobilized in February 2021 in response to the President's National Strategy for COVID-19 Response and Pandemic Preparedness (published on January 21, 2021) and DHS/FEMA was mobilized again through its joint-lead role (this time with HHS/CDC representing HHS) within the federal interagency coordination structure to conduct a mass COVID-19 vaccination campaign.

## Support and Coordination Elements

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

### Interagency Modeling and Atmospheric Assessment Center

The Interagency Modeling and Atmospheric Assessment Center (IMAAC) is an interagency coordination element responsible for the 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 Incident Command (IC) and national response organizations. This capability is achieved through a partnership of DHS, DOD, HHS, DOC/NOAA, 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/FEMA is the federal agency responsible for the IMAAC program. The Defense Threat Reduction Agency (DTRA), 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

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 local, county, and/or state public health agencies; the facility or property owner; local government; and SMEs from the federal government. The decision that clearance goals have been met will be made through Unified Command (UC), with input from the DHS/OHS, HHS/CDC and EPA. The final decision on clearance is usually made by the lead local health agency.<sup>27</sup>

## Domestic Emergency Support Team

The Domestic Emergency Support Team (DEST) is a rapidly deployable interagency team that supports the FBI. As part of its mission, the DEST supports the FBI On-Scene Commander (OSC) and other officials (e.g., the National Assets Commander) and supports the integration of law enforcement and counterterrorism operations with consequence management operations that may be taking place simultaneously. Based upon threat and requirements, FBI determines the composition of the DEST and maintains operational control throughout its activation. The DEST can provide the FBI with expert advice and guidance that can inform prevention mission operations and may include a ready roster from DHS/FEMA, DOJ/FBI, DOD, HHS/ASPR, DOE, EPA, and others as may be appropriate. The DHS/FEMA Administrator, in support of the DOJ/FBI, is responsible for policies and planning governing the use of the DEST in accordance with agreed-upon policies and procedures.

## Weapons of Mass Destruction Strategic Group

The WMDSG is an FBI-led interagency crisis action team. When facing a credible WMD threat or incident, the FBI-led WMDSG is activated within the FBI's Strategic Information and Operations Center (SIOC). The FBI-led WMDSG supports information exchange and deconfliction of law enforcement and counterterrorism operations to prevent imminent threats, while simultaneously coordinating with federal agencies responsible for public health and other consequence management activities to save lives and protect property and critical infrastructure. Through its collection of interagency representatives and SMEs, the FBI-led WMDSG facilitates the integration and sharing of real-time investigative information, intelligence, and technical analysis; facilitates the identification and use of interagency assets; and enhances the synchronization and deconfliction of prevention and response mission operations. The FBI-led WMDSG can include SMEs from different departments and agencies depending on the nature of the threat and its modality (e.g., representatives from HHS, HHS/ASPR, and HHS/CDC during biological threats; the DOE NNSA for radiological and nuclear threats, and the EPA during chemical threats). The FBI-led WMDSG, with its

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<sup>27</sup> Federally owned and operated facilities are managed primarily by the unified command, to include HHS/CDC and EPA.

collaborative environment and through the dissemination of its products, including the WMD Threat Profile, contributes to risk-informed decision making at all levels of response, including, when appropriate, with SLTT, public health, private sector, and international partners. The FBI-led WMDSG connects with other FBI command posts (e.g., the FBI CIRG National Assets Command Post regarding all technical information represented by and collected from the WMD device) within the FBI SIOC, and to the operations centers of other federal agencies. It also connects to other FBI Field Office(s) and appropriate local/regional partners through FBI Joint Operations Centers (JOCs).

### **Consequence Management Coordination Unit**

FEMA staffs and manages the FBI-led WMDSG's Consequence Management Coordination Unit (CMCU), which has reach-back to the DHS/FEMA home team. The CMCU is the principal advisory unit for consequence management considerations within the FBI-led WMDSG and provides strategic recommended and integrated consequence management courses of action that consider ongoing and evolving counterterrorism operations. The CMCU links operational coordination and information sharing to DHS and sector risk management agency response and protection activities. The CMCU is supported by federal technical capabilities provided through DOE/NNSA, HHS, DOD, and DHS. CMCU responsibilities include:

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

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# Appendix B: Intelligence and Surveillance

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This appendix summarizes the elements of information, including those related to risk and operational impacts, that decision makers must have to accomplish the mission. This appendix supports and informs decision making through the organized and timely collection, processing, analysis, and dissemination of situational awareness products about critical impacts and the extreme and extenuating conditions of significant events and impending incidents. The desired end state is achieved when leaders have accurate intelligence about situational awareness so they can make informed, data-driven operational decisions.

## Information, Surveillance, and Sources

In public health, the term *surveillance* encompasses all data required to effectively establish an epidemiological 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 naturally occurring and intentional biological incidents, information related to the size and scope of 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 an 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 for mounting 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 an 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 on public health entities for collection and analysis:** Biological incident data collection relies substantially on reporting (often from private sector laboratories and clinicians) and state, local, tribal, and territorial (SLTT) public health officials who verify case identification and conduct contact tracing and epidemiological investigation, all of which requires a mix of clinical, laboratory, and epidemiological 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.

Table B-1 provides examples of some potential sources of initial information with follow-on verification processes for a potential biological incident. It should be noted that, in some instances, detection can predictably occur after an outbreak/incident is well underway, resulting in numerous infections prior to initial detection.

**Table B-1: Examples of Initial Detection of a Biological Pathogen**

Source of Information	Examples of Initial Information Received	Verification Processes
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, Laboratory Response Network (LRN), or U.S. Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) laboratory confirmation may be required.</li> <li>• Epidemiologic investigation to confirm patterns of similarity.</li> </ul>
Individual practitioner or healthcare facility laboratory	<ul style="list-style-type: none"> <li>• Suspected sentinel case reported through local public health agency.</li> <li>• Confirmed sentinel case reported through local public health agency.</li> </ul>	<ul style="list-style-type: none"> <li>• Private sector, LRN, or HHS/CDC laboratory confirmation may be required.</li> </ul>
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 HHS/CDC laboratory confirmation required, similarly Department of Agriculture (USDA)/National Veterinary Services Laboratories (NVSL) confirmation may be required for an animal/zoonotic pathogen.</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 the federal 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>• Initial confirmation by USDA/NVSL and/or HHS/CDC may be required. Outbreak support testing by SLTT, LRN, National Animal Health Laboratory Network (NAHLN), and private sector laboratories all possibly dependent on zoonotic agent and extent of outbreak.</li> </ul>

Source of Information	Examples of Initial Information Received	Verification Processes
Law enforcement and intelligence	<ul style="list-style-type: none"> <li>Credible threat of use of pathogen of concern.</li> </ul>	<ul style="list-style-type: none"> <li>Law enforcement investigations, paired with public health expertise, if appropriate.</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 (BAR).</li> </ul>	<ul style="list-style-type: none"> <li>BioWatch has internal verification processes and may conduct additional sampling. If additional environmental verifications are necessary to support SLTT's, such follow-on sampling and analysis is coordinated with the Environmental Protection Agency (EPA), HHS/CDC, USDA, and Department of Justice (DOJ)/Federal Bureau of Investigations (FBI), as appropriate.</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 initial data points.

**Initial Incident Identification**

Biological incident recognition can occur on a continuum and in a 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 many forms, including, in many instances, initial information that requires deliberative verification and adds time to recognition.

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

**Table B-2: National-level Incident-specific Communications Resources**

Information-Sharing Process	Description
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 National Security Memorandum-2 (NSM-2) or a succeeding policy. The NSC is the President's principal means for coordinating the implementation of national security policy.

Information-Sharing Process	Description
Health Alert Network (HAN)	Primary HHS/CDC 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 in all 50 states, the District of Columbia, and eight territories as well as the 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, Public Health and Medical Services. This conference line enables HHS public affairs personnel to work from dispersed sites during the crisis yet be able to receive guidance or direction and/or provide information to those needing it.
National Incident Coordination Conference Line (NICCL)	While the Department of Homeland Security (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 outbreak.
National Public Health Information Coalition (NPHIC)	Leverages a network of state and local public health communicators to exchange information, increasing the likelihood of consistent messaging and communications activities between federal and SLTT 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 call to share information on a potentially significant biological incident. This 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 an NBIS agency.
NBIC Products and Services	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. 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. Biosurveillance Event Reports, updated as appropriate and 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 that are designed to provide one-time, rapid communication of a high-priority event but offer no subsequent updates. Both Biosurveillance Event Reports and Spot Reports are produced as needed rather than on a regular production schedule.
Epidemiological Data	Sources of information may include clinical, epidemiological, animal health, and laboratory data from different sources, such as providers/private sector and local, state, and federal public health entities. Epidemiological data tracks changes in disease and death rates over calendar time, ranging from hours to months. It also tracks whether spikes are periodic due to environment or consistent.

Information-Sharing Process	Description
Epidemic Information Exchange (Epi-X)	Epi-X is a web-based communications solution for public health professionals. Through Epi-X, HHS/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.
Biological Incident Notification and Assessment (BINA) Protocol	The BINA Protocol provides a consistent means for NSC staff to convene agencies pursuant to the interagency policy process outlined in NSM-2, providing the federal government the ability to rapidly develop a common understanding of an evolving, potentially acute high consequence biological incident or threat and allowing for rapid decision making and coordinated action among agencies, as directed by the President.
BioWatch National Conference Call (BWNCC)	Occurs within two (2) hours of a BioWatch Actionable Result (BAR) declaration and after the local jurisdictional BioWatch Advisory Committee (BAC) call. The BWNCC determines if there is the potential for at least a significant health event or indicators that the BAR could have been caused by an intentional act. It begins with a summary provided by the BAC chair and other local public health, law enforcement, and emergency management representatives on laboratory testing data and the current local situation to provide situational awareness of follow-on activities and potential requests for assistance from other federal agencies (e.g., DHS, HHS/CDC, DOJ/FBI, EPA, Department of Defense [DOD], USDA) and/or the Strategic National Stockpile (SNS).It also includes a decision regarding the next conference call time.

Once a biological pathogen is verified, the information is disseminated across relevant federal, SLTT, and private sector partners so that it is appropriately shared. Examples of sources/types of exposure and their relevant information-sharing methods are included in Table B-3.

**Table B-3: Identification Process and Information-Sharing Methods for a Biological Incident**

Source of Information	Examples of Initial Information Received	Verification Processes	Methods of Information Sharing
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 HHS/CDC laboratory confirmation may be required.</li> <li>Epidemiologic investigation to confirm patterns of similarity.</li> </ul>	<ul style="list-style-type: none"> <li>Health Alert Network (HAN)</li> <li>National Public Health Information Coalition (NPHIC)</li> <li>Clinician Outreach and Communication Activity (COCA)</li> </ul>

Source of Information	Examples of Initial Information Received	Verification Processes	Methods of Information Sharing
Individual practitioner or healthcare facility laboratory	<ul style="list-style-type: none"> <li>• Suspected sentinel case reported through local public health agency.</li> <li>• Confirmed sentinel case reported through local public health agency.</li> </ul>	<ul style="list-style-type: none"> <li>• Private sector, LRN, or HHS/CDC laboratory confirmation may be required.</li> </ul>	<ul style="list-style-type: none"> <li>• HAN</li> <li>• NPHIC</li> <li>• COCA</li> </ul>
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 HHS/CDC or USDA laboratory confirmation may be required.</li> </ul>	<ul style="list-style-type: none"> <li>• HAN</li> <li>• BINA</li> <li>• COCA</li> <li>• NPHIC</li> <li>• Public Affairs Conference Line (PACL)</li> <li>• National Biosurveillance Integration System (NBIS) Protocol</li> </ul>
Novel emerging or reemerging infection reported by international partners or federal government stakeholders operating in a foreign country under international health regulations 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 the federal government.</li> </ul>	<ul style="list-style-type: none"> <li>• HAN</li> <li>• COCA</li> <li>• NPHIC</li> <li>• PACL</li> <li>• NBIS Protocol</li> <li>• International Health Regulations (IHR)</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, HHS/CDC, SLTT, NAHLN, or private sector laboratory confirmation all possible.</li> </ul>	<ul style="list-style-type: none"> <li>• HAN</li> <li>• BINA</li> <li>• COCA</li> <li>• NPHIC</li> <li>• PACL</li> <li>• NBIS Protocol</li> </ul>
Law enforcement intelligence	<ul style="list-style-type: none"> <li>• Credible threat of use of pathogen of concern.</li> </ul>	<ul style="list-style-type: none"> <li>• Law enforcement investigations paired with public health expertise.</li> </ul>	<ul style="list-style-type: none"> <li>• Law Enforcement Sensitive (LES) Bulletin</li> <li>• National Security Council (NSC) process</li> <li>• NICCL</li> <li>• FBI Threat Credibility Evaluation (TCE) Process</li> </ul>

Source of Information	Examples of Initial Information Received	Verification Processes	Methods of Information Sharing
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>	<ul style="list-style-type: none"> <li>NSC/Deputies Committee (DC) process</li> <li>NICCL</li> <li>Follow-on HAN</li> <li>COCA</li> <li>NPHIC</li> <li>PACL</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 (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 federal government support to SLTT sample to verify.</li> </ul>	<ul style="list-style-type: none"> <li>BioWatch National Conference Call</li> <li>BINA</li> <li>NSC process</li> <li>NICCL</li> <li>Follow-on HAN</li> <li>COCA</li> <li>NPHIC</li> <li>PACL</li> <li>NBIS Protocol</li> </ul>

A critical initial consideration regarding any identified pathogen is whether 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 that may not be known initially. Risk communication is contingent upon some of these most basic attributes of the pathogen, and any intelligence or information related to these parameters is 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, including the following:

- Intentional incident:** Some incidents may initially appear naturally caused but could, in fact, be intentional. It is the government’s policy to consider all potential terrorist biological incidents as terrorist incidents until otherwise determined by the Attorney General, acting through the FBI Director.
- Area and size of population impacted:** Although it is rare that the size of the area and populations impacted is known during initial epidemiological investigations, initial estimates can be developed in some cases. 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 and make a pathogen appear more virulent than it is.
- Populations at risk:** Early epidemiological information can provide insight regarding populations at risk (hence requiring information, countermeasures, etc.). For

example, extremes of age, individuals in particular vocations, or individuals with specific 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 NPIs, including personal protective equipment (PPE), can be important but must be shaped in the context of what is initially known about the pathogen and the fact that NPIs may need to change as more knowledge becomes available.

Ongoing situational assessment, as mentioned above, heavily relies on data from the private sector and SLTT entities. The summary and analysis of this data is essential for tailoring the federal response. In addition, the federal government can apply resources not always available at SLTT levels of response, such as comprehensive geographic information systems (GIS) mapping.

The goal of collecting epidemiological, clinical, laboratory, and environmental data is to help drive the appropriate response for a biological incident. Although not complete, the following list provides 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)
- 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 (e.g., medical equipment, personnel, pharmaceuticals, vaccines)
  - At SLTT level
  - At federal level (for self-protection/COOP plan)
- Areas of environmental contamination
- Infrastructure and economic impacts
  - Primary: Caused by disease itself

- Secondary: Caused by implementation of public health actions

The federal government also has a significant role in conducting surveillance and in supporting SLTT surveillance efforts. Examples of the numerous surveillance systems and information sources that help to create a common operating picture (COP) during a biological incident are listed in Figure B-1.

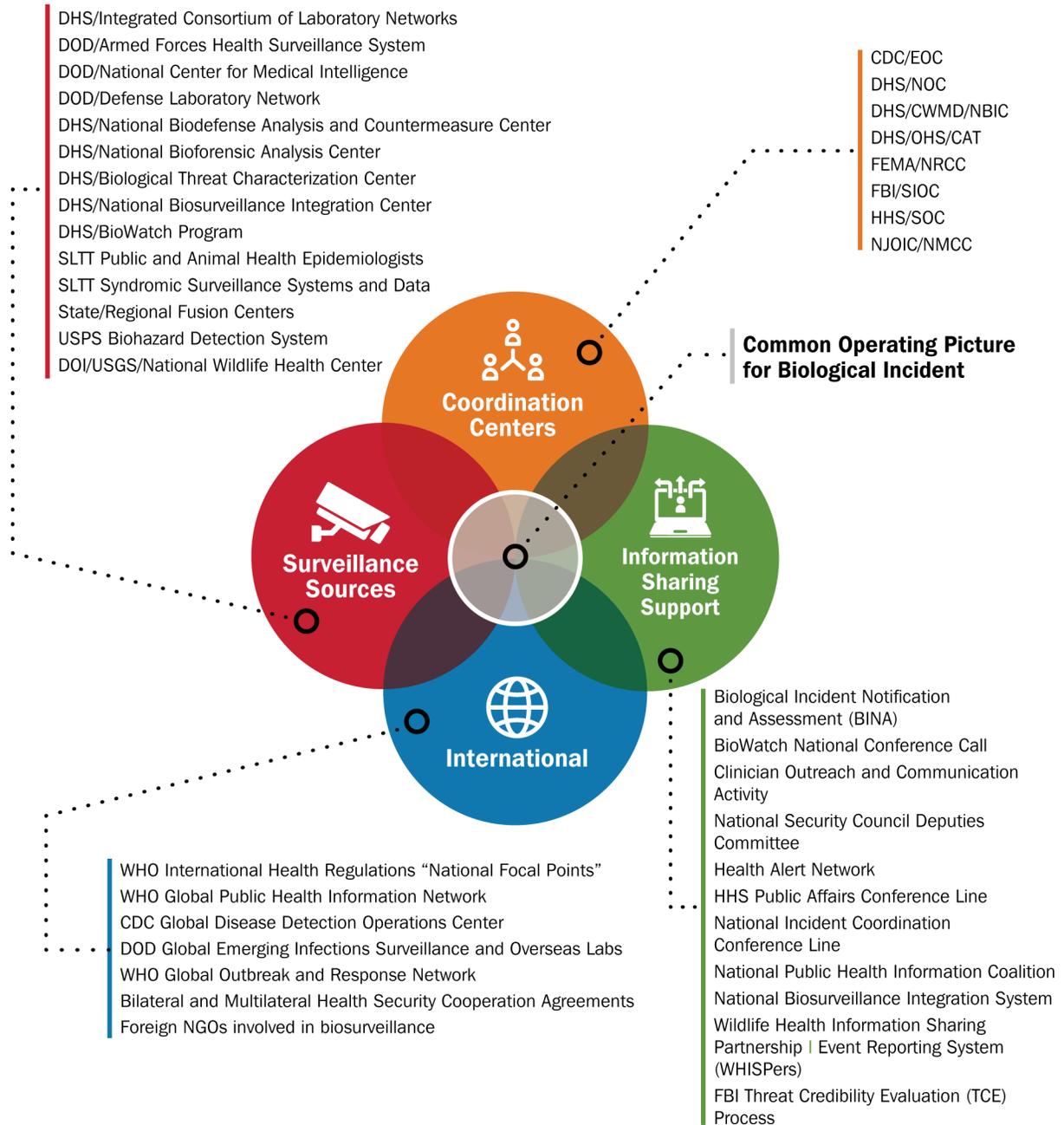


Figure B-1: Surveillance and Information Sources

Another vital resource used to support intelligence gathering and surveillance activities is the Integrated Consortium of Laboratory Networks (ICLN). The ICLN, shown in Figure B-2, 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 provides the framework, methods, and tools that link these federal departments, federal lab networks, and lab network members so that they can share data, analysis, methods, and samples during an emergency. Each national lab network focuses on analyzing threat agents and toxic substances in a specific type of sample, whether from food, plants, animals, or people. The ICLN partnership, consisting of nine federal departments and agencies and including seven national lab networks, are also comprised of 450 public and private sector laboratories around the nation. A brief description of the capabilities of the nine federal departments can be found in Table D-6, Integrated Consortium of Laboratory Network Capabilities (Appendix D). For more information, see <https://www.icln.org/>.

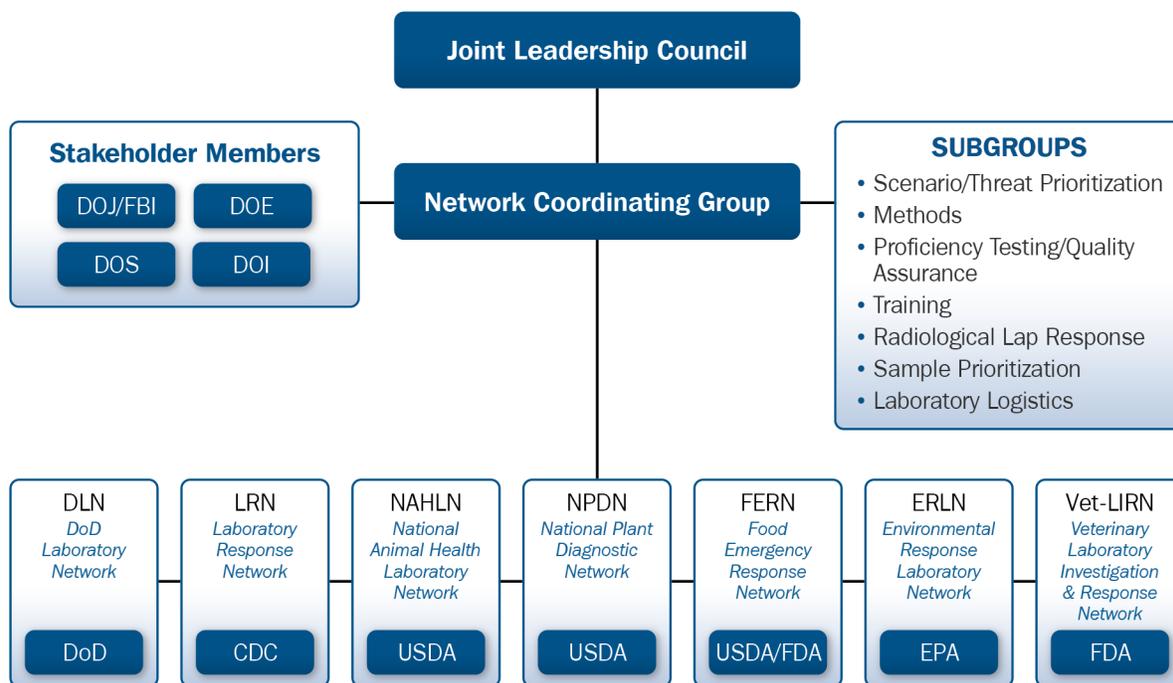


Figure B-2: Description of the Integrated Consortium of Laboratory Networks (ICLN)

## 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* [FAIA] to the *Response and Recovery Federal Interagency Operational Plan* [FIOP].)

HHS, the Department of Labor (DOL), USDA, Department of the Interior (DOI), and other federal and SLTT agencies have the authority and capabilities to take action 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 (MCMs), and mitigation, including quarantine, movement, disposition, depopulation, and appropriate carcass disposal.

The primary 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 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 the 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 (temporary or permanent) when owners or facilities are unable to care for them (e.g., congregate housing, zoos, wildlife rehabilitators, research facilities, shelters, sanctuaries, farms, breeders) to prevent further negative outcomes.
- Animal movement restrictions due to biological incident using subject matter experts (SMEs) (e.g., 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.
- Unique and potentially significant challenges for disease management (e.g., endangered species, conservation issues, animal migration) related to captive and free-ranging wildlife, which have the potential to transmit or transport a biological agent.
- Potential risk of animals as vectors and reservoirs with novel or genetically modified zoonotic organism.

- Risk communication to the animal industry (e.g., veterinarians, agriculture, zoos, wildlife rehabilitators) 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.
- Mitigate potential zoonotic disease entry into the U.S. by requiring permits for specific species.

The capabilities for conducting a field response to animal health emergencies (including farmed animal and wildlife health) and enacting disease control and management actions include the following:

- Biological Safety Level (BSL)-3 laboratories to diagnose known or novel emerging diseases
- Regional and national-scale wildlife disease surveillance
- Carcass disposal facilities
- Risk assessment, risk mapping, and epidemiological modeling
- BSL-3 facilities to conduct research on wildlife-associated zoonotic diseases

# Appendix C: Operations

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This appendix describes the operational formation and structure necessary to implement a coordinated response to a biological incident. Primary and secondary impacts may significantly disrupt Community Lifelines and complicate regional, national, and international response efforts. An effective response may require immediate lifesaving and life-sustaining capabilities from outside the impacted area to support response and recovery operations.

## Lines of Effort (LOEs)<sup>28</sup>

### Background

While the *Response and Recovery Federal Interagency Operational Plan* (FIOP) identify key elements for all-hazard response and recovery operations, there are several LOEs specific to this *Biological Incident Annex* (BIA). The BIA-specific LOEs define the specific activities required to achieve the intended outcomes by linking multiple tasks to goals, objectives, or the end state for a biological incident response. These LOEs guide the lead federal agency (LFA) and federal unified coordinated response to a biological threat/incident. Depending upon the size and complexity of the biological incident, certain LOEs may require a higher emphasis than others.

These LOEs identify specific goals, response capabilities, functions, and subsequent supporting activities. For each LOE, there are Critical Information Requirements (CIRs) intended to be answered for a given set of capabilities, functions, and supporting activities. These CIRs not only inform situational awareness reporting but also inform key federal decisions on providing technical assistance, support, and/or resources to either the LFA or, in an event involving a Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act) declaration, federal assistance to impacted state, local, tribal, and territorial (SLTT) jurisdictions. Leveraging private sector and non-governmental organization (NGO) assets through collaboration, coordination, and outreach are required to achieve the given goals. Among key assets available are Sector Risk Management Agencies that can serve as important sources of information and guidance for LOEs. A complete list of Sector Risk Management Agencies and their capabilities is available through the following website: <https://www.cisa.gov/sector-risk-management-agencies>.

### Biological Incident Annex LOEs

Activities specific to a biological incident are organized into six LOEs:

1. Detect, Prevent, and Characterize the Threat
2. Control the Spread of Disease
3. Augment Provision of Mass Care and Human Services to the Affected Population

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<sup>28</sup> Some of the information in the LOE section was taken from the *Medical and Health Incident Management (MaHIM) System* document. Also see footnote in Section 6.4.1 of that document regarding the MaHIM system.

4. Healthcare Resilience
5. Medical Countermeasure Development and Acquisition
6. Augment Essential Services and Facilitate Long-term Recovery

To assist state and local authorities, the federal government can contribute personnel, resources, and other support to aid 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. Federal agencies may become involved in a biological incident under their own missions and authorities as part of a UCG led by the LFA or under a Stafford Act declaration.

### ***LOE #1 – Detect, Prevent, and Characterize the Threat***

This LOE involves those activities that define and track the medical and public health impacts of a disease outbreak, to include characteristics of the etiological agent. This effort shall confirm the *initial* incident/disease outbreak and diagnosis. For intentional biological threats and incidents, this LOE also includes those activities that would prevent threat actors from carrying out an attack, attribute the threat or incident to the threat actors, and hold the threat actors accountable. (For more information, see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

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 that the federal government may be primarily responsible for, may have a role in supporting, or may collect to confirm to inform initial threat identification.

- Influx of patients with similar disease symptoms indicating new disease pathogen
- Sentinel case suspected or confirmed in private sector and reported to appropriate SLTT public health entity
- 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 additional spread
- Credible threat of deployment of pathogen of concern
- Announced release of deployment of pathogen of concern
- Environmental surveillance system (e.g., BioWatch) detection of pathogen of concern

As stated, there are numerous biological incident detection methods, including presentation of a 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. Such detection and subsequent investigations, conducted by Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) and SLTT health jurisdictions as well as the World Health Organization (WHO) and foreign health entities, may result in the detection of 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 of time.

#### Public Health and All-Hazards Response Capabilities Applicable to LOE #1

- Conduct public health surveillance and epidemiological investigations.
- For intentional biological threats and incidents, this LOE also includes those activities that would prevent threat actors from carrying out an attack, attribute the threat or incident to the threat actors, and hold the threat actors accountable (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).
- For zoonotic outbreaks, conduct surveillance and epidemiological investigations using a One Health approach.

#### Key LOE #1 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, impact, and duration of the incident as it progresses.
- Support initial and ongoing decision making using evolving threat/hazard information.
- For intentional biological threats and incidents, this LOE also includes those activities that would prevent threat actors from carrying out an attack, attribute the threat or incident to the threat actors, and hold the threat actors accountable (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

#### Key LOE #1 Tasks

The list below expands the tasks identified in Table C-2. For intentional biological threats and incidents, this LOE also includes those activities that would prevent threat actors from carrying out an attack, attribute the threat or incident to the threat actors, and hold the threat actors accountable (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

## Conduct or Support Biological Incident-specific Surveillance<sup>29</sup>

This function's aim is to conduct or support ongoing systematic collection, analysis, interpretation, and management of public health-related data to effectively detect, verify, characterize, and manage a threat, hazard, risk, or incident of public health concern throughout and following an incident.

The U.S. Government enables, through the Laboratory Response Network for Biological Threats (LRN-B), detection of biological threats and emerging infectious diseases quickly and accurately. National laboratories, including those operated by HHS/CDC, Department of Defense (DOD)/U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID), the National Biodefense Analysis and Countermeasures Center (NBACC), and the Naval Medical Research Center (NMRC), are responsible for specialized characterization of organisms, select agent activity, and handling highly infectious biological agents. Reference laboratories, often called LRN member laboratories, are responsible for public health investigation and/or referral of specimens. Additionally, sentinel laboratories play a key role in the early detection of biological agents through rule-out and referral steps in the identification process.

The U.S. Government coordinates 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 the federal government and SLTT partners to support initial and ongoing decision making, using evolving threat information.

For international threats, the U.S. Government conducts ongoing liaison and participates in the management of federal government international response efforts to ensure capture of appropriate threat information as it pertains to potential domestic impacts.

A critical task is to coordinate modeling efforts to ensure unity of effort for models employed in support of decision making. Modeling capabilities exist within the federal government, therefore the government may primarily conduct some of these activities or support the efforts of other organizations.

Tasks under this function include the following:

- Engage stakeholders to support public health surveillance and investigation.
- Conduct or support routine and biological incident-specific surveillance.
  - This task requires the use of data to conduct and support health-related surveillance.

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<sup>29</sup> Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission, HHS/CDC, 2021

- Support the Integrated Consortium of Laboratory Networks (ICLN),<sup>30</sup> which coordinates laboratory response capabilities during a crisis.
- Conduct ongoing situational assessments to continually determine the 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:
  - Epidemiological, laboratory, clinical, and other relevant data collected to help inform 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 International Health Regulations (IHR)
- Surveillance data sources may include:
  - Case findings
  - Population-based surveys
  - Pre-hospital emergency medical services (EMS) records
  - Reportable disease surveillance
  - Syndromic surveillance
  - Vital records
  - Animal surveillance (particularly involving suspected or confirmed zoonotic biological threats)
  - Environmental surveillance
- The federal government must also ensure that all SLTT public health laboratories have the necessary resources (e.g., supplies, and personnel) required to perform diagnostic or confirmatory testing specific to the biological incident.
- Coordinate data management and share surveillance findings with SLTT stakeholders and federal agencies.
  - This task requires data management from various surveillance activities and then the sharing of this data and the communicating of statistical analyses of surveillance data to the jurisdictional public health agency and other applicable jurisdictional leaders, healthcare providers, and data providers to assist with the prompt identification of potentially affected populations at risk for adverse health

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<sup>30</sup> For additional information on the ICLN, please see Figure B-2: Description of the Integrated Consortium of Laboratory Networks (ICLN) in Appendix B and Table D-6: Integrated Consortium of Laboratory Networks (ICLN) Capabilities in Appendix D.

outcomes and to enable rapid decision making involving a specific biological incident.

- Maintain and improve surveillance systems.
  - As a biological incident evolves, surveillance systems may require continual assessment and strengthening to support bi-directional information exchange between the federal government and SLTT/private sector partners to respond promptly to the specific biological threat.

#### Conduct Public Health and Epidemiological Investigations<sup>31</sup>

- In collaboration with SLTT health authorities, conduct epidemiological investigations and, where appropriate, joint criminal-epidemiological (Crim-Epi) investigations.
  - HHS/CDC and SLTT health authorities are required to investigate diseases, injuries, and exposures in response to specific biological incidents, including, where appropriate, joint Crim-Epi investigations.
- Provide support to SLTT public health and epidemiological investigations.
  - HHS/CDC should also provide clinical and public health-related consultations to support public health agency investigations.
- Share public health and epidemiological investigation findings.
  - HHS/CDC reports investigation results to impacted communities and jurisdictional and federal partners.

#### ***LOE #2 – Control the Spread of Disease***

The goal of this LOE is to define and conduct federal government activities to control, stop, or minimize the threat posed by the biological agent. This LOE entails multiple activities involving human-based (and possibly animal-based) control measures as well as environmentally based measures, depending on the size, scale, and complexity of the biological incident. For intentional biological threats and incidents, this LOE also includes those activities that would prevent threat actors from carrying out an attack, attribute the threat or incident to the threat actors, and hold the threat actors accountable (see Attachment 1: Branch 1 Plan: Intentional Biological Incidents).

The federal government may also carry out national-level functions and support SLTT jurisdictions in halting the spread of disease through the coordination and implementation of both medical countermeasures (MCMs) and non-pharmaceutical interventions (NPIs). For controlling disease spread, this LOE focuses on MCM dispensing and distribution, recognizing that MCM research, development, and acquisition is an important, but separate, LOE described in this document. NPIs include an expansive array of activities, including

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<sup>31</sup> Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission [CDC, 2021]

public health interventions to limit the spread of disease, environmental controls, personal protective equipment (PPE), and personal hygiene activities. All 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.

#### Public Health and All-Hazards Response Capabilities Applicable to LOE #2

- Assessment of Public Health Needs
- Public Health Laboratory Testing
- Community Mitigation
- Environmental Response/Health and Safety
- MCM Dispensing and Administration
- NPI/PPE Procurement and Dispensing
- Public Information and Warning

#### Key LOE #2 Objectives

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

#### Key LOE #2 Tasks

Listed below are the key tasks and sub-tasks for the *Control the Spread of Disease* LOE, organized by capability.

##### Assessment of Public Health Needs

Based on the disease and the etiological agent characteristics derived from the *Detect, Prevent, and Characterize the Threat* LOE, the federal government should then revise or develop MCM treatment and/or prophylaxis guidelines, if needed.

- This function involves reviewing and identifying shortfalls in existing public health guidance in these areas.
- HHS, through the Administration for Strategic Preparedness and Response (ASPR)/ Biomedical Advanced Research and Development Authority (BARDA), HHS/CDC, and the HHS/Food and Drug Administration (FDA) should evaluate candidate MCMs for potential patient use and, as appropriate, consider regulatory mechanisms for making such products available.

Based on identified resource shortfalls and locations with rising disease incidence rates and/or at-risk populations susceptible to serious illness or fatalities, the federal government should also determine resource requirements, allocations, and, possibly, prioritization (if limited resources are available).

- Based on resource requests from SLTT jurisdictions, the federal government should determine resource availability for resources such as PPE or essential medical equipment and supplies (e.g., dialysis, ventilators) in the Strategic National Stockpile (SNS) or other federally operated distribution center.

#### Public or Animal Health Laboratory Testing

Overlapping with *Detect, Prevent, and Characterize the Threat* LOE, this public or animal health capability requires the conduct of appropriate laboratory testing involving clinical, and/or environmental specimens.

- The federal government should ensure that private sector and SLTT laboratories can perform appropriate laboratory testing to detect and confirm suspected cases and report the disease and/or biological agent using established protocols and procedures.

The federal government should ensure seamless coordination with the Laboratory Response Network Biological (LRN-B), state public health laboratories, and National Animal Health Laboratory Network (NAHLN) laboratories to oversee the quality and efficiency of testing and reporting.

- The federal government should conduct frequent coordination calls with LRN-B and/or NAHLN with the appropriate laboratories to identify any testing capability gaps, conduct quality assurance/quality control of existing testing reagents and kits, and appropriately share information on clinical, environmental, and to recognized entities, forensics results, which may inform ways to control disease spread.

The federal government should also provide support and, in some cases, oversee laboratory studies as part of larger research efforts in examining the dynamics of disease transmissibility to then inform prompt ways to control disease spread across the U.S.

- This function is informed by supporting activities described in the *Detect, Prevent, and Characterize the Threat* LOE in the planning, executing, and reporting of appropriate laboratory studies.
- The federal government should work collaboratively with academic and non-governmental research institutions who are performing studies on the same biological incident so a broader share of the research results may inform federal guidance on controlling disease spread.

#### Community Mitigation<sup>32</sup>

- Based on the findings derived from the *Detect, Prevent, and Characterize the Threat* LOE as well as the capabilities described, community mitigation is developed and implemented to slow the spread of infection and to protect all individuals, especially

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<sup>32</sup> Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission [CDC, 2021]

those at increased risk for severe illness, while minimizing the negative impacts of these strategies.

- Each community is unique. Appropriate mitigation strategies should be based on the best available data. Decision making varies based on the level of community transmission and local circumstances.
- As communities adjust mitigation strategies, the federal government should ensure that the healthcare system capacity is not exceeded. Precautions should be taken to protect healthcare professionals and other critical infrastructure workers. Communities need to assure that healthcare systems have adequate staffing, a surplus of inpatient and Intensive Care Unit (ICU) beds, and critical medical equipment and supplies, such as PPE.
- As communities adjust mitigation strategies, the federal government should ensure that public health capacity is not exceeded. Public health system capacity relies on detecting, testing, contact tracing, isolating those who are sick, and quarantining those who have been exposed to known or suspected cases of the biological agent. It is important to stop broader community transmission and prevent communities from having to implement or strengthen further community mitigation efforts.
- The federal government should pay particular attention to people who are at higher risk for severe illness when determining and adjusting community mitigation strategies.
- Factors in determining community mitigation strategies should include the following critical considerations, which are further illustrated in Table C-1.<sup>33</sup>
  - Epidemiology
  - Community characteristics
  - Healthcare capacities
  - Public health capacities
- The federal government should provide guidance to control the spread of disease across borders. Once an outbreak has occurred in a foreign country, there may be interventions that can mitigate disease spread to the U.S. Although not all infectious diseases are susceptible to border interventions, activities such as screening and risk assessment at point of entry with post-arrival management in coordination with SLTT governments. This requires a significant coordinated effort.
- The federal government should assist in the prevention of interstate spread of disease and is authorized to take measures to prevent the spread of communicable disease between states.

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<sup>33</sup> Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission [CDC, 2021]

- The federal government should 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 federal government, in the development of recommendations, works with SLTT partners and the private sector to gauge these impacts.
- Internationally, the federal government should assist foreign governments with an outbreak (as requested) to control spread to the U.S. by controlling it at its source. Although domestic support to an international response is covered in the *National Response Framework (NRF) International Coordination Support Annex*, linkages from the domestic response to the international effort must be made. The federal government has a series of frameworks that can be used without linkages to a domestic response.

#### Environmental Response/Health and Safety

The federal government should provide recommendations and guidance on research and development of PPE and associated infection control practices (e.g., cleaning/disinfection methods for healthcare facilities and the transportation sector) as well as development of recommendations and/or provision of support for hygiene practices and surface decontamination, including the use of PPE and associated infection control practices, to protect the workforce.

- PPE practices have traditionally focused on the healthcare community, but specialty recommendations may be needed for different sectors, such as first responders and caretakers providing personal assistance services to people with disabilities or older individuals in the home, nursing homes, correctional populations, critical infrastructure workers, homeless populations, other responders, or the public.
- Development of these recommendations should include adequate representation from the disciplines in question.

The federal government should also provide recommendations and guidance on waste management and requirements for decontamination of individuals, animals, and the environment.

The federal government provides recommendations and/or support for:

- Patient decontamination, as necessary.
- Identification of environmental contamination controls to minimize or prevent the spread of biological agents, resulting in further disease transmission.

## Medical Countermeasure (MCM) Dispensing and Administration

Based on either existing or newly developed and acquired MCMs for the biological agent of concern, the federal government should determine appropriate dispensing and administrative strategies for at-risk populations.

- The federal government should work collaboratively with SLTT health jurisdictions in their dispensing and administration plans.
- The federal government should develop and update MCM dispensing or administration guidance strategies to address critical populations and health equity.

The federal government should ensure the establishment of a network of dispensing and administration sites.

- This entails formalized partnerships with private retail pharmacies covering most of the U.S. population geographically to meet current healthcare needs.
- The federal government, while evaluating SLTT health jurisdiction dispensing/administration plans, should evaluate SLTT requirements to provide sufficient staffing and resources.
- The federal government should then evaluate gaps in SLTT-available staffing and resources to identify other mechanisms to fill those gaps (e.g., contracted healthcare personnel, mutual assistance with surrounding SLTT jurisdictions, and federal assets and resources).

In situations where the federal government plays either a significant federally supported or federally managed/operated role in MCM dispensing and administration, the federal government should then develop plans to identify and assign response roles, resources, and doctrine to provide this capability.

- Planning and execution of federally supported or managed MCM dispensing and administration sites should involve close collaboration and coordination with SLTT health jurisdictions and emergency management agencies.

## Public Information and Warning

- Based on the science of the biological threat and the exposure risks that may result in illness and/or death, the federal government should provide clear and concise public health measures (often referred to as community mitigation) to control disease spread.
- Public officials should deliver timely, accurate, clear, and actionable public messaging that is accessible to older adults (who may not have smartphones), individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities), and individuals who are limited English proficient, as this is a key component in providing equitable access to programs and services. The federal government should coordinate on the development, review, and dissemination of public health

messaging across the federal agencies involved in the unified coordinated response to ensure clarity and consistent understanding of messages.

- The federal government should also, as with other disaster responses, monitor news and social media outlets to understand and appropriately address common concerns or perceptions about the biological incident and promptly issue appropriate messages through these various pathways to reach the entire community, including to address disinformation, malinformation, and misinformation.
- Federal websites (e.g., HHS/CDC, HHS/ASPR Technical Resources, Assistance Center, and Information Exchange [TRACIE]) should reflect the same clear, consistent, reliable, and actionable information issued through news and social media outlets as well as tailored information for specific communities, such as healthcare providers and first responders.

### ***LOE #3 – Augment Provision of Mass Care and Human Services to the Affected Population***

This LOE identifies and articulates the key non-clinical, life sustaining infrastructure necessary to protect and maintain delivery of Mass Care and Human Services resources during biological incidents. The delivery of these services is necessary to prevent additional suffering and loss of life. Mass Care includes the provision of hydration, feeding, sheltering, temporary housing, evacuee support, reunification, and distribution of emergency supplies. Biological incidents may pose threats to feeding and sheltering activities.

When a biological incident occurs, community partners must work together to provide a holistic response that extends beyond addressing clinical impacts to public health. Sudden, widespread, incident-caused unemployment may place unprecedented strain on social services programs and increase food insecurity. Disease burden, income loss, economic hardship, disruptions to the supply chain,<sup>34</sup> and necessary mitigation measures, such as social distancing and the closure of schools, may undermine both community and individual resiliency. Unanticipated consumer demand may limit domestic production, and disrupted supply chains may lead to substantial cascading impacts that destabilize the nation's food supply chain, which may not be mitigated or overcome by either state/local governments or the private sector. Important considerations include:

- Supply chains and municipal services may face significant disruptions due to restrictions and/or quarantines.
- Transportation restrictions and disruptions may substantially slow the movement of essential supplies.
- Compounding challenges may result in fundamental shifts in the way people acquire food.

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<sup>34</sup> Refer to the Advisory Memorandum on Identification of Essential Critical Infrastructure Workers During Covid-19 Response, dated March 28, 2020, for clarification of the logistics supply chain.

- Significant resource deployment, activation of previously sequestered “disaster” programs, and changes in agency policies may be required of the federal government to mitigate these impacts.
- Early, rapid destabilization of life-sustaining infrastructure was heretofore unknown/unrecognized as a national/global threat during a major biological incident.

Congregate sheltering approaches, including standards for capacities, equipment requirements, and assessment of vulnerable populations, may require dramatic adjustments at the federal, state, and local levels. These modifications, while costly and complex, may be necessary to support the health and safety of survivors and emergency management staff. Non-congregate sheltering assistance that is independent of natural disaster declarations may be necessary to protect public health and save lives. Targeted population groups may include:

- Those who had been exposed but do not require hospitalization
- Asymptomatic and/or high-risk individuals, including people with disabilities or other chronic health conditions, needing social distancing as a precautionary measure
- Healthcare workers (HCWs) and first responders
- Those who cannot safely socially distance at home

Additional support under this LOE that may be required includes the following:

- Crisis Counseling Assistance and Training programs to mitigate emotional and behavioral health impacts related to public health measures implemented to limit the spread of a pathogen, including social distancing and self-isolation
- Financial assistance for funeral expenses resulting from a biological incident
- Donations management to identify and connect donors with NGOs who can provide critical aid to communities
- Planning and coordination support for NGO staffing of MCM sites
- Invitational travel for deployed volunteers supporting the federal government’s treatment and prophylaxis mission

Response Mission Area Core Capabilities Applicable to LOE #3

- Mass Care Services

Recovery Mission Area Core Capabilities Applicable to LOE #3

- Health and Social Services
- Housing

Key LOE #3 Objectives

- Evaluate the impact of public health response measures on community social services support systems.

- Assess the need for modifications to DHS/FEMA disaster assistance policy to support communities impacted by a biological incident.
- Evaluate congregate/non-congregate sheltering approaches, including standards for capacities, equipment requirements, and accessibility for people with disabilities.
- Empower a volunteer workforce to support state and local communities responding to a biological incident.
- Assist private sector donors willing to provide critical aid to communities through donated resources to NGOs.

#### Key LOE #3 Tasks

Listed below are the key tasks and sub-tasks for the *Augment Provision of Mass Care and Human Services to the Affected Population* LOE.

- 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 the 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 the burden on high-demand components of the healthcare infrastructure, always taking into consideration the self-determination of the individual and the individual's need not to be separated from caregivers, family support, and/or personal care attendants:
  - Commissioned Corps of the U.S. Public Health Service (USPHS)
  - Individual Assistance-Technical Assistance Contract (IA-TAC)
  - Delivery services
  - NGOs or VOADs, such as the American Red Cross and The Salvation Army
- Provide public distancing guidance for regular shelters (with infectious disease considerations) during a simultaneous disaster or for shelters designed to assist with the biological incident response.
- Assist SLTT governments with housing requirements that have occurred due to public health actions (e.g., quarantine).
- Provide resources to support SLTT commodity distribution to meet the needs of individuals with disabilities and others with access and functional needs. Address care needs and placement/disposition of 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 special needs population at congregate care facilities when normal caregivers are absent (e.g., nursing homes, prisons).
- Address care needs of pets or animals without owners/caretakers due to the incident. (e.g., congregate animal facilities such as zoos).
- Support long-term social services to promote resilience, health, and well-being.

#### ***LOE #4 – Healthcare Resilience***

The goal of LOE #4 is to conduct federal government activities to implement or support health and medical services for the affected population impacted by the biological incident.

SLTT or private entities may experience shortfalls in the availability of personnel, materiel, space, and systems required to meet the demands on medical and health systems during a biological incident, particularly a contagious disease outbreak. Though healthcare delivery is predominantly conducted in the private sector, there are federal delivery mechanisms like VA Medical Centers that require integration into planning and response efforts. The federal government supports affected areas with available federal resources and assists in their prioritization and coordination throughout incident progression.

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 the need for coordination of these two response efforts. Healthcare resilience may also involve support for meeting community behavioral health and mental health requirements.

This LOE is not solely focused on human healthcare needs. In cases involving zoonotic diseases, healthcare resilience may require addressing veterinary medical support, including triage and treatment. In incidents where significant human fatalities may occur, this LOE may require the need to include advisement on fatality management issues, to include addressing capabilities at the SLTT or federal level to maintain resilience of this function.

#### **Public Health and All-Hazards Response Core Capabilities Applicable to LOE #4**

- Public Health, Healthcare, and Emergency Medical Services

#### **Key LOE #4 Objectives**

- Identify key issues impacting healthcare delivery due to the biological incident.
- Provide focused guidance and support to healthcare communities in areas at risk or already experiencing patient surges due to the biological incident.
- Provide guidance and technical assistance to enable and support health systems to deliver care for all priority health needs during a biological incident.

#### **Key LOE #4 Tasks**

Listed below are the key tasks and sub-tasks for the *Healthcare Resilience* LOE.

### Identify Key Issues Impacting Healthcare Delivery Due to the Biological Incident

- Conduct periodic needs assessment of pre-hospital, inpatient, ambulatory, and long-term care facilities through frequent (e.g., weekly) listening sessions or other engagement activities.
- Evaluate data from various data repositories (e.g., HHS Protect) focused on hospitalization rates, new incident rates, and staffed ICUs to understand and identify adverse healthcare delivery impacts.
- Evaluate data on HCW staffing levels by healthcare facility type (e.g., hospitals, EMS facilities, long-term care facilities, ambulatory care facilities), particularly in impacted communities.
- Evaluate availability of critical MCMs and PPE, as well as adequacy of training and other requirements related to using these items effectively, at various healthcare facilities.

### Provide Focused Guidance and Support to Healthcare Communities Experiencing Patient Surges

- Develop and share guidance on development, planning, and operations of Alternate Care Sites (ACSs) for healthcare facilities significantly impacted by patient surges.
- Develop and share resources addressing HCW shortages, MCM and PPE resupply challenges, and inadequate facility spacing.

### Provide Guidance and Technical Assistance to Enable and Support Health Systems to Deliver Care for All Priority Health Needs During a Biological Incident

- Conduct training with specific healthcare coalitions, associations, and healthcare facilities to share existing guidance on healthcare delivery in response to a biological incident.
- Conduct periodic visits to impacted healthcare facilities to assess and to provide solutions to those facilities experiencing patient care delivery challenges.
  - Visits can take the form of healthcare resilience-type strike teams with diverse health and medical expertise.
- Advise HHS/BARDA, HHS/CDC, and other entities conducting MCM dispensing and administration of new drugs or medical devices, operating under an Emergency Use Authorization (EUA), to maximize patient use and to assist in evaluating efficacy against the specific biological agent threat or illness.

### ***LOE #5 – Medical Countermeasure (MCM) Development and Acquisition***

The goal of this LOE is to conduct research, development, acquisition, production, and delivery of biological products, drugs, and/or devices to prevent, mitigate, or treat the adverse health effects of an emerging biological agent threat that could result in a nationwide public health emergency. MCM examples include drugs such as monoclonal

antibodies, biological products such as vaccines, as well as devices such as diagnostics, ventilators, and PPE.

In a response to an emerging biological threat agent, the federal-level MCM enterprise requires a significantly increased operational tempo to rapidly perform the described activities, based on the assumption that no effective MCMs are available. During steady state, these activities are ongoing, with the goal of receiving an approval from the HHS/FDA. Because of the rapid time requirement for MCMs during a biological incident, the MCM may require an appropriate regulatory mechanism, such as an EUA or expanded access protocol, to make it available for patient use.

#### Public Health and All-Hazards Response Capabilities Applicable to LOE #5

- Public Health, Healthcare, and Emergency Medical Services

#### LOE #5 Key Objectives<sup>35</sup>

- Identify needs to protect Americans against current and emerging threats.
- Develop strategies and coordinate with PHEMCE members and partners to address identified gaps and assess opportunities for continuous improvement.
- Provide recommendations to the HHS Secretary and communicate MCM needs to all stakeholders based on the best available evidence combined with situational awareness and field deployment realities.

#### Key LOE #5 Tasks<sup>36</sup>

Listed below are the key tasks and sub-tasks for the *MCM Development and Acquisition* LOE.

#### Identify, Create, Develop, Manufacture, and Procure Critical MCM

- The federal government works with federal, SLTT, and private sector partners to identify biological products, drugs, and/or devices needed to save lives against an emerging biological agent threat.
- The federal government identifies responsible parties for MCM capability through appropriate federal acquisitions processes and policies.
- HHS/FDA ensures the purity, potency, safety, and effectiveness of these items prior to patient use.

#### Establish and Communicate Clear Regulatory Pathways to Facilitate Rapid MCM Development and Use

- HHS/FDA determines an appropriate regulatory mechanism to make MCMs available based on the assessment of scientific evidence.

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<sup>35</sup> 2022 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan, <https://aspr.hhs.gov/PHEMCE/2022-SIP/Documents/PHEMCE-SIP-2022-508.pdf>

<sup>36</sup> 2022 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan, <https://aspr.hhs.gov/PHEMCE/2022-SIP/Documents/PHEMCE-SIP-2022-508.pdf>

- HHS/FDA reviews scientific evidence about MCM safety and effectiveness against a biological agent, and based on the assessment of the data, determines the most appropriate regulatory mechanism to make the MCM available for use, such as through an EUA or expanded access protocol.
- As part of the risk/benefit assessment and authorization or approval of the MCM, HHS determines which types of healthcare providers are authorized or approved to administer MCMs.

#### Develop Logistics and Operational Plans for Optimized Distribution and Administration of MCMs at All Response Levels

- The federal government ensures that seamless delivery, storage, handling, and other requirements of new MCMs are clearly articulated to federal, SLTT, and private sector healthcare stakeholders.
- The transition from production/delivery to MCM dispensing and administration should occur at federal and SLTT jurisdictional locations in a seamless and well-coordinated manner.
- For limited MCM quantities available nationwide, the federal government determines resource allocations and eligible populations for use of new MCMs to achieve maximum impact as additional MCMs become available.

#### Address MCM Gaps for All Sectors of the American Civilian Population

- The federal government identifies and addresses gaps in MCM distribution and administration, with a focus on ensuring health equity.
- The federal government identifies federal and SLTT capability gaps in the receiving, storage, and handling of MCM in their communities and develops appropriate solutions to address those gaps.
- The federal government ensures that clear, coordinated, consistent, and unified public messaging is developed with federal entities implementing the *Control the Spread of Disease* LOE specific to new MCMs.

**Table C-1: Factors to Consider for Determining Mitigation Strategies<sup>37</sup>**

Factor Type	Factor Considerations
Epidemiology	<ul style="list-style-type: none"> <li>• Level of community transmission: more extensive mitigation needed when there is greater community transmission</li> <li>• Number and type of outbreaks in specific settings or with vulnerable populations, including, but not limited to, nursing homes and other long-term care facilities, correctional facilities, meat and poultry processing plants, and the homeless population</li> <li>• Severity of the disease</li> <li>• Impact of the level of community transmission and any outbreaks on delivery of healthcare or other critical infrastructure or services</li> <li>• Epidemiology in surrounding jurisdictions</li> <li>• Factor Considerations to include “Epidemiology” in other host or vector species</li> <li>• Potential for zoonosis</li> </ul>
Community Characteristics	<ul style="list-style-type: none"> <li>• Size of community and population density</li> <li>• Level of community engagement and support</li> <li>• Data related to race, ethnicity, individuals with disabilities, individuals over the age of 65, incarcerated individuals, percentages of the population who speak languages other than English. Access to healthcare</li> <li>• Healthcare disparities in rates of infection, illness, and death</li> <li>• Transportation infrastructure (e.g., availability and use of mass transit)</li> <li>• Type of business or industry</li> <li>• Congregate settings (e.g., correctional facilities, homeless shelters, nursing homes, skilled nursing facilities)</li> <li>• Planned large events/gatherings, such as sporting events</li> <li>• Relationship of community to other communities (e.g., transportation hub, tourist destination, volume of commuting, other attributes)</li> </ul>
Healthcare Capacity	<ul style="list-style-type: none"> <li>• Healthcare workforce</li> <li>• Number of healthcare facilities (including ancillary healthcare facilities)</li> <li>• Testing activity</li> <li>• Intensive care capacity</li> <li>• Availability of PPE</li> </ul>
Public Health Capacity	<ul style="list-style-type: none"> <li>• Public health workforce and availability of resources to implement strategies (e.g., resources to detect, test, track, and isolate cases)</li> <li>• Available support from other state/local government agencies and partner organizations</li> </ul>

***LOE #6 – Augment Essential Services and Facilitate Long-Term Recovery***

The goal of this LOE is to conduct federal government activities to sustain the various Community Lifelines described in the NRF that have been impacted by the biological incident while also supporting SLTT jurisdictions in recovery efforts for non-medical or non-public health infrastructure.

<sup>37</sup> Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission [CDC, 2021]

The operation of critical infrastructure may be limited during a biological incident due to personnel exposure, operator illness, 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 public. Longer-term activities may be required after a biological incident to support community resiliency.

#### Response and Recovery Core Capabilities Applicable to LOE #6

- Economic Recovery
- Health and Social Services
- Fatality Management

#### Key LOE #6 Objectives

- Ensure continuity of primary mission-essential function (PMEF) 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 while taking appropriate measures to control the introduction, transmission, and spread of disease.
- Facilitate the movement/delivery of supplies critical to response and recovery.
- Secure critical infrastructure assets that are still in operation (e.g., public transportation, including transportation equipment accessible to individuals with mobility disabilities.)

#### Key LOE #6 Tasks

##### Support Infrastructure Systems

- Coordinate critical infrastructure assessments (potential sources include a combination of sector-specific agencies, Sector Coordinating Councils (SCCs), and Government Coordinating Councils; related Emergency and Recovery Support Functions [ESFs/RSFs]; and the National Interagency Coordination Center).
- Recommend prioritization of MCM dispensing and administration to critical infrastructure operators 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 restoring economic and business activities (including food and agriculture) that have been impacted by illnesses, quarantines, business closings, and other social distancing interventions.
- 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>38</sup>

### Facilitate Whole Community Multi-agency Coordination with Non-governmental Agencies for Animal Response Activities

- Support ESFs #6, #8, and #11 to coordinate an integrated federal response to meet the mass care and emergency assistance needs of animals, including household pets and service animals, and their owners.
- Provide technical assistance and subject matter expertise regarding animal response issues.

### Provide Disaster Food Assistance

- Non-Stafford Act Authority: Locate and secure supplies of food, including U.S. Department of Agriculture (USDA) foods in state inventories, to supplement those in the disaster area to the extent funds appropriated to USDA/Food and Nutrition Service (FNS) for disaster food assistance are available.
- Stafford Act Authority (Sec. 412 and 413): Provides disaster food assistance, in accordance with ESF #11, including USDA foods for congregate feeding, infant formula and food, as well as authorization of the Disaster Supplemental Nutrition Assistance Program (D-SNAP) for declared major disasters with Individual Assistance.
- Additional programs include:
  - The Emergency Feeding Assistance Program (TEFAP)
  - Commodity Supplemental Food Program (CSFP)
  - National School Lunch Program (NSLP)
  - Summer Food Service Program (SFSP)
  - Seamless Summer Option (SSO)
  - Supplemental Nutrition Assistance Program (SNAP)
    - Food Distribution Program on Indian Reservations (FDPIR)
    - School Breakfast Program, and others that may be relevant
    - Farmers Market Nutrition Program
    - Fresh Fruit and Vegetable Program

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<sup>38</sup> These responsibilities are coordinated by the Economic and the Health and Social Services RSFs.

## LOE Key Federal Roles & Responsibilities

### LOE #1 – Detect, Prevent, and Characterize the Threat

Table C-2: Coordinating/Supporting Federal Departments/Agencies for LOE #1

Key Activity for LOE #1 - Detect, Prevent, and Characterize the Threat	Lead Federal Agency	Supporting Agencies
<p>Conduct biological incident-specific surveillance through engagement with SLTT public health authorities and other domestic and international partners.</p>	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• Department of Homeland Security (DHS)/ Countering Weapons of Mass Destruction Office (CWMD)/ National Biosurveillance Integration Center (NBIC)</li> <li>• DHS/OHS</li> <li>• DOD</li> <li>• Department of the Interior (DOI)</li> <li>• Department of Justice (DOJ)/Federal Bureau of Investigation (FBI)</li> <li>• Department of State (DOS) (for international)</li> <li>• Environmental Protection Agency (EPA)</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• SLTT Public Health Authorities</li> <li>• USDA</li> <li>• Department of Veterans Affairs (VA)</li> </ul>
<p>Conduct ongoing situational assessments to continually determine the size, scope, and impact of the biological incident, as required.</p>	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CWMD</li> <li>• DHS/FEMA</li> <li>• DHS/OHS</li> <li>• DHS/TSA</li> <li>• DOD</li> <li>• DOI</li> <li>• DOJ/FBI</li> <li>• DOS (for international)</li> <li>• DOT</li> <li>• EPA</li> <li>• HHS/CDC</li> <li>• HHS/ASPR</li> <li>• USDA</li> <li>• VA</li> </ul>

Key Activity for LOE #1 - Detect, Prevent, and Characterize the Threat	Lead Federal Agency	Supporting Agencies
Leverage the results of the ongoing DHS Chemical, Biological, Radiological, and Nuclear (CBRN) Strategic Risk Assessment, a scenario-based risk assessment that includes a range of biological agent scenarios, to help identify priorities for protective and consequence management efforts.	<ul style="list-style-type: none"> <li>• DHS/CWMD</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CBP</li> <li>• DHS/CISA</li> <li>• DHS/FEMA</li> <li>• DHS/OHS</li> <li>• DHS/S&amp;T</li> <li>• DHS/USCG</li> <li>• DHS/USSS</li> <li>• DOD</li> <li>• DOJ/FBI</li> <li>• EPA</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• USDA</li> </ul>
Conduct biological threat-specific characterization research to inform MCM deployment or development.	<ul style="list-style-type: none"> <li>• DHS/Science &amp; Technology (S&amp;T)</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• DOJ/FBI</li> <li>• HHS/CDC</li> </ul>
Ensure that all SLTT Public Health and National Animal Health laboratories have the necessary resources (e.g., supplies and personnel) required to perform diagnostic and/or confirmatory testing specific to the biological incident.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/FEMA</li> <li>• DOD</li> <li>• DOI</li> <li>• DOS (for international)</li> <li>• HHS/CDC</li> <li>• HHS/ASPR</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>
Identify threat actors, prevent them from carrying out criminal and terrorist biological incidents, and attribute the threat to them.	<ul style="list-style-type: none"> <li>• DOJ/FBI</li> </ul>	<ul style="list-style-type: none"> <li>• Federal and SLTT law enforcement partners</li> </ul>
Coordinate data management and share surveillance findings with SLTT stakeholders and federal agencies.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CWMD</li> <li>• DHS/FEMA</li> <li>• DHS/OHS</li> <li>• DOD</li> <li>• DOS (for international)</li> <li>• HHS/CDC</li> <li>• HHS/ASPR (i.e., HHS Protect)</li> <li>• VA</li> </ul>

Key Activity for LOE #1 - Detect, Prevent, and Characterize the Threat	Lead Federal Agency	Supporting Agencies
In collaboration with SLTT health authorities, conduct epidemiological investigations and, where appropriate, joint Crim-Epi investigations.	<ul style="list-style-type: none"> <li>• HHS</li> <li>• DOJ/FBI</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/OHS</li> <li>• DOD</li> <li>• DOS (for international)</li> <li>• Federal and SLTT law enforcement and public health partners</li> <li>• HHS/CDC</li> <li>• SLTT Public Health Authorities</li> <li>• USDA (see <i>Food and Agriculture Incident Annex</i> [FAIA])</li> <li>• VA</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

## LOE #2 – Control the Spread of Disease

**Table C-3: Coordinating/Supporting Federal Departments/Agencies for LOE #2**

Key Activity for LOE #2 - Control the Spread of Disease	Lead Federal Agency	Supporting Agencies
Revise or develop MCM treatment and/or prophylaxis guidelines for the biological agent.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/BARDA</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>
Assess public health needs and identify for further study and evaluation candidate MCMs that may be effective against the specific threat agent.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>
Determine resource requirements, allocations, and possibly resource prioritization.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• DHS/FEMA (under Stafford Act)</li> <li>• DOD</li> <li>• USDA (see FAIA)</li> <li>• VA</li> </ul>
Ensure the conduct of appropriate Public Health Laboratory Testing and seamless coordination among LRN-B network and conduct frequent coordination activities with LRN-B network to ensure information sharing.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>

Key Activity for LOE #2 - Control the Spread of Disease	Lead Federal Agency	Supporting Agencies
<p>Work collaboratively with academic and non-governmental research and private sector institutions performing studies on the biological agent so broader share of research results may occur.</p>	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CWMD</li> <li>• DHS/OHS</li> <li>• DHS/S&amp;T</li> <li>• DOD</li> <li>• HHS/CDC</li> <li>• HHS/ASPR</li> <li>• HHS/FDA</li> <li>• HHS/NIH</li> <li>• USDA (see FAIA)</li> <li>• VA</li> </ul>
<p>Develop and implement community mitigation measures, including clear, coordinated, consistent, and unified public messaging that is accessible to older adults (who may not have smartphones), individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities), and individuals who are limited English proficient.</p>	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CWMD</li> <li>• DHS/FEMA</li> <li>• DHS/OHS</li> <li>• DHS/S&amp;T</li> <li>• DOD</li> <li>• DOT</li> <li>• EPA</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• SLTT Public Health Authorities</li> <li>• VA</li> </ul>
<p>Provide guidance to control disease spread across borders, both to and from the United States and its territories.</p>	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/Customs and Border Protection (CBP)</li> <li>• DHS/OHS</li> <li>• DHS/S&amp;T</li> <li>• DOS</li> <li>• DOD</li> <li>• DOT</li> <li>• HHS/CDC</li> <li>• HHS/ASPR</li> <li>• USDA (see FAIA)</li> <li>• VA</li> </ul>
<p>Prevent follow-on criminal and terrorist biological incidents.</p>	<ul style="list-style-type: none"> <li>• DOJ/FBI</li> </ul>	<ul style="list-style-type: none"> <li>• Federal and SLTT law enforcement partners</li> </ul>

Key Activity for LOE #2 - Control the Spread of Disease	Lead Federal Agency	Supporting Agencies
Develop recommendations, guidance, and regulatory policies on health and safety measures, including the use of PPE and associated infection control practices, to protect the workforce.	<ul style="list-style-type: none"> <li>Department of Labor (DOL)/ Occupational Safety and Health Administration (OSHA)</li> <li>HHS</li> </ul>	<ul style="list-style-type: none"> <li>DHS/CISA</li> <li>DHS/OHS</li> <li>DHS/S&amp;T</li> <li>DOD</li> <li>DOT</li> <li>HHS/CDC</li> <li>HHS/FDA</li> <li>HHS/Office of the Assistant Secretary for Health (OASH)</li> <li>USDA (see FAIA)</li> <li>VA</li> </ul>
Update or develop MCM dispensing or administration guidance and strategies to address critical populations and health equity.	<ul style="list-style-type: none"> <li>HHS</li> </ul>	<ul style="list-style-type: none"> <li>DHS/FEMA</li> <li>DHS/OHS</li> <li>DOD</li> <li>HHS/ASPR</li> <li>HHS/CDC</li> <li>HHS/FDA</li> <li>VA</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

### *LOE #3 - Augment Provision of Mass Care and Human Services to the Affected Population*

**Table C-4: Coordinating/Supporting Federal Departments/Agencies for LOE #3**

Key Activity for LOE #3 - Augment Mass Care and Human Services LOE	Lead Federal Agency	Supporting Agencies
Develop recommendations for mass care services or support actual implementation of these services with specifics applicable to contagious disease incident.	<ul style="list-style-type: none"> <li>DHS/FEMA (under Stafford Act)</li> </ul>	<ul style="list-style-type: none"> <li>HHS/ASPR</li> <li>HHS/CDC</li> <li>Supporting agencies under ESF #6 (Mass Care, Emergency Assistance, Temporary Housing, and Human Services)</li> </ul>
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.	<ul style="list-style-type: none"> <li>HHS</li> </ul>	<ul style="list-style-type: none"> <li>DHS/FEMA</li> <li>HHS/Administration for Children and Families (ACF)</li> <li>HHS/ASPR</li> <li>HHS/CDC</li> <li>Supporting agencies under ESF#6</li> </ul>

Key Activity for LOE #3 - Augment Mass Care and Human Services LOE	Lead Federal Agency	Supporting Agencies
Provide guidance for regular shelters (with infectious disease considerations) during a simultaneous disaster or for shelters designed to support the response to the outbreak to assist with social distancing.	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• Supporting agencies under ESF#6</li> </ul>
Assist SLTT governments with housing requirements that have occurred due to public health actions (e.g., quarantine).	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• Supporting agencies under ESF#6</li> </ul>
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.	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• Supporting agencies under ESF#6</li> </ul>
Augment SLTT capabilities to identify and support management and care of dependents at congregate care facilities (e.g., nursing homes, prisons, homeless shelters, and congregate animal facilities such as zoos) when normal caregivers are absent.	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/OHS</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• Supporting agencies under ESF#6</li> </ul>
Develop and share guidance on the development, planning, and operations of Alternate Care Facilities (ACFs) for healthcare facilities impacted by patient surges.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/FEMA</li> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/Centers for Medicare &amp; Medicaid Services (CMS)</li> <li>• HHS/Health Resources and Services Administration (HRSA)</li> <li>• VA</li> </ul>
Support long-term social services to promote resilience, health, and well-being.	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• Supporting agencies under ESF#6</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

**LOE #4 – Healthcare Resilience**

**Table C-5: Coordinating/Supporting Federal Departments/Agencies for LOE #4**

Key Activity for LOE #4 - Healthcare Resilience	Lead Federal Agencies	Supporting Agencies
Conduct periodic assessments of prehospital, inpatient, ambulatory, and long-term care facilities preparedness and prevention capabilities and needs.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CMS</li> <li>• HHS/FDA</li> <li>• DHS/FEMA</li> <li>• HHS/HRSA</li> <li>• VA</li> </ul>
Evaluate data related to hospitalization rates, new incident rates, and staffed ICU and other data to examine adverse healthcare delivery impacts.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/CMS</li> <li>• HHS/FDA</li> <li>• HHS/HRSA</li> <li>• VA</li> </ul>
Evaluate availability of MCMs, including PPE, as well as adequacy of training and other requirements.	<ul style="list-style-type: none"> <li>• HHS</li> <li>• DHS/FEMA (under Stafford Act)</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/CMS</li> <li>• HHS/FDA</li> <li>• HHS/HRSA</li> <li>• VA</li> </ul>
Develop and share guidance on the development, planning, and operations of Alternate Care Facilities (ACFs) to include crisis standard of care guidelines for healthcare facilities impacted by patient surges.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/FEMA</li> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/CMS</li> <li>• HHS/HRSA</li> <li>• VA</li> </ul>
Provide guidance and technical assistance to enable and support health systems to deliver care.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• DOT</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/CMS</li> <li>• HHS/FDA</li> <li>• HHS/HRSA</li> <li>• VA</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

**LOE #5 – Medical Countermeasure (MCM) Development and Acquisition**

**Table C-6: Coordinating/Supporting Federal Departments/Agencies for LOE #5**

Key Activity for LOE #5 - MCM Development, and Acquisition, Distribution, and Administration	Lead Federal Agencies	Supporting Agencies
Identify, create, develop, manufacture, and procure critical MCMs.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/BARDA</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>
Establish and communicate clear regulatory pathways to facilitate rapid MCM development and use.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/BARDA</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• VA</li> </ul>
Develop logistics and operational plans for optimized distribution and administration of MCMs at all response levels.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/FEMA</li> <li>• DOD</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> <li>• Federal and SLTT public health partners</li> <li>• VA</li> </ul>
Address MCM gaps such as identifying eligible populations for MCMs, federal and SLTT capability gaps in receiving, storage, and handling of MCMs, and clear, coordinated, consistent, and unified public messaging.	<ul style="list-style-type: none"> <li>• HHS</li> </ul>	<ul style="list-style-type: none"> <li>• HHS/CDC</li> <li>• HHS/ASPR</li> <li>• HHS/FDA</li> <li>• DHS/FEMA</li> <li>• DOD</li> <li>• VA</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

**LOE #6 – Augment Essential Services and Facilitate Long-Term Recovery**

**Table C-7: Coordinating/Supporting Federal Departments/Agencies for LOE #6**

Key Activity for the Augment Essential Services and Facilitate Long-Term Recovery LOE	Lead Federal Agencies	Supporting Agencies
Support infrastructure systems through coordinated assessments with SCCs.	<ul style="list-style-type: none"> <li>• DHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CISA</li> <li>• DHS/FEMA and various ESFs</li> <li>• DOT</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> </ul>

Key Activity for the Augment Essential Services and Facilitate Long-Term Recovery LOE	Lead Federal Agencies	Supporting Agencies
Recommend MCM prioritization for essential critical infrastructure workers to minimize disruptions to supply chain.	<ul style="list-style-type: none"> <li>• DHS</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/CISA</li> <li>• DHS/FEMA</li> <li>• DOJ/FBI and various ESFs</li> <li>• DOT</li> <li>• HHS/ASPR</li> <li>• HHS/CDC</li> <li>• HHS/FDA</li> </ul>
Support economic recovery, assisting SLTT jurisdictions adversely impacted.	<ul style="list-style-type: none"> <li>• DHS</li> <li>• DOC</li> <li>• DOL</li> <li>• SBA</li> </ul>	<ul style="list-style-type: none"> <li>• DHS/FEMA (under Stafford Act)</li> <li>• DHS/CISA</li> <li>• DOL</li> <li>• HHS/ASPR</li> <li>• HHS/CDC and various ESFs</li> <li>• Department of Housing and Urban Development (HUD)</li> <li>• Small Business Administration (SBA)</li> </ul>

NOTE: DHS/FEMA may be called upon to lead or provide supplemental operational coordination support for the primary authority during complex incidents.

## LOE Critical Information Requirements

### *LOE #1 – Detect, Prevent, and Characterize the Threat*

#### Conduct or Support Biological Incident-Specific Surveillance CIRs

- What is the situational assessment, both domestic and overseas, related to the biological incident?
- What is the foreign disease burden and what is the spread and emergence of the specific agent overseas?

#### Conduct Public Health and Epidemiological Investigations CIRs

- What is the case definition of the disease to inform healthcare providers in diagnosis and treatment?
- What is the estimated R-naught (R0) or level of transmissibility?
- Are there modeling products estimating disease trends in new cases, hospitalizations, and fatalities, to include demographic data?
- What is the biological agent?
- What is the mode of transmission from human-to-human or animal-to-human (e.g., water, air, blood, fecal)?
- How is the biological agent identified or agent exposure suspected or confirmed in humans and/or animals?
- Are current MCMs effective to treat ill persons?
- What NPIs are appropriate to limit disease spread?

- What population-based interventions exist (e.g., contact tracing, isolation, quarantine)?
- What are the impacts to critical infrastructure, businesses, and the mental and emotional well-being of affected populations that may require mitigation measures?
- What are the environmental-based interventions (e.g., vector control, environmental cleanup, waste management)?
- Are diagnostics that are approved or in development accurate for this specific strain?
- Are diagnostics that approved or in development sensitive and specific for this specific agent and strain?
- Does the genome of this strain provide any clues as to potential for countermeasure resistance or attribution?
- Is PPE effective against this agent?
- Are there relevant animal hosts, vectors, or reservoirs?
- Does the genome of this agent or strain provide any clues as to potential for countermeasure resistance or attribution?

### ***LOE #2 – Control the Spread of Disease***

#### Assessment of Public Health Needs CIRs

- What is the effectiveness of current treatment and prophylaxis regimens against the emergent biological incident?
- Do SLTT public health agencies have the staffing and resource capacity to respond to new disease incidences and to advise their communities to control disease spread?
- What are the healthcare facility capacities to manage patient admissions due to the disease?
- What is the resource availability of PPE and other essential medical equipment and supplies in SLTT and federal distribution centers (e.g., SNS) to protect the workforce (particularly HCWs and first responders) and to treat patients?
- What are the resource and personnel gaps at the SLTT and private sector level for communities to respond effectively to the biological incident?

#### Laboratory Testing CIRs

- Do SLTT and private sector/commercial laboratories have the testing capabilities to detect and possibly to perform genomic sequencing of the specific biological agent of concern?
- What are the federal capabilities to design and develop test kits?
- What are the laboratory clinical and/or environmental sampling methodologies for informing disease transmission mechanisms and virulence among humans and animals (if there is zoonotic potential)?

### Community Mitigation CIRs

- What are the effective community mitigation strategies to control disease spread?
- What are the economic and critical infrastructure or continuity of National Essential Function (NEF) considerations in implementing these mitigation strategies?
- How will these strategies impact federal response operations to an all-hazard disaster response?
- What federal assistance and/or support is required to aid SLTT and the private sector in implementing these mitigation strategies?
- What international forms of assistance and/or support is required of the United States to aid foreign countries challenged by an emerging biological incident to prevent, or at least delay, disease transmission to the United States?
- What travel advisories and mitigation strategies are required to protect U.S. travelers to outbreak areas overseas and prevent travel-associated importation to the United States?
- What are any anticipated negative reactions to community mitigation measures, who might harbor them, and what proactive activities can ameliorate them?

### Environmental Response/Health and Safety CIRs

- What is the hierarchy of controls (e.g., engineering, safe work practices, PPE) that workplace employers and employees should use to prevent exposure?
- What are the specific controls to protect first responders and healthcare providers in various healthcare settings (e.g., hospitals, long-term care facilities, correctional facilities, ambulatory care settings)?
- What is the appropriate decontamination guidance to be issued to prevent further spread of a biological agent?
- What are the SLTT jurisdictional gaps in implementing workforce health and safety measures, to include decontamination, that are a challenge to preventing disease transmission?
- Are private sector supply chains able to make timely deliveries of PPE and other resources to protect the workforce?
- If private sector supply chains are not able to meet consumer demands for PPE and other resources that protect the workforce, are there preservation or optimization measures to extend duration of existing PPE and other materials/supplies until new supplies are received?
- What is the federal distribution centers' stock of PPE and other workforce protection resources to support SLTT and federal partner personnel?
- What are the guidelines for facility decontamination resulting from contamination of a biological agent of concern to achieve safe re-occupancy in a timely manner?

#### Medical Countermeasure (MCM) Dispensing and Administration CIRs

- What are SLTT and private sector retail pharmacy capabilities to provide MCMs to susceptible populations?
- What federal resources and personnel are necessary, if requested under the Stafford Act, to aid and/or support SLTT jurisdictions to plan, coordinate, and conduct MCM dispensing and administration?
- What federal reporting of MCM dispensing and administration activities are required to maintain a good common operating picture (COP) of the effectiveness of these activities in controlling disease spread?
- What is the federal reporting process of adverse reactions for MCMs, and what required investigative actions are necessary?
- What resource management processes and plans, to include acquisition, storage, and handling requirements, must be implemented for the MCM being used to preserve, protect, and ensure quality of the product for patients or recipients?

#### Public Information and Warning CIRs

- What are news and social media users communicating as concerns regarding the biological incident?
- What public health measures are the federal government clearly communicating in a timely manner to achieve maximal impact?
- What are the recommended outreach measures in preventing disease transmission among communities identified as having high social vulnerability indices?
- What are the federal efforts to address prophylaxis hesitancy among various racial/ethnic/religious/social communities?
- Are various federal government entities developing fact sheets, training, advisories, or other important material to prevent or control disease spread that are also undergoing a clear and efficient coordinated review by federal interagency partners to ensure completeness, accuracy, and alignment with existing public health guidance?

#### ***LOE #3 - Augment Provision of Mass Care and Human Services to the Affected Population***

- What is the food bank demand throughout the United States?
- Given potential food supply and/or service disruptions in a large-scale biological incident, what are the gaps in food security for both at-risk populations and the general population as a whole?
- Is commodities hoarding occurring nationally, regionally, or in SLTT-specific locations, impacting mass care and human services?
- What are the impacts of public health mitigation measures, such as stay-at-home and/or operating in a virtual environment recommendations, on mass care and human services?

- For zoonotic diseases, is mass livestock depopulation required to control disease spread, impacting food supply to mass care and human services in the United States or causing significant unmet mental health needs of the agricultural industry?

#### ***LOE #4 – Healthcare Resilience***

##### Identification of Key Issues Impacting Healthcare Delivery CIRs

- Are healthcare facilities experiencing significant patient surges due to the biological incident, resulting in delays in critical patient care and/or patient admissions?
- Are certain healthcare facilities more impacted than others and, if so, why is that the case?
- Are critical MCM and PPE supplies available with deliveries on-time when ordered by healthcare facilities?
- Do healthcare personnel staff have adequate training or other requirements necessary to effectively use MCMs and PPE?
- Are there diagnosis and/or treatment regimens that HCWs and facilities need to be aware of to effectively treat exposed and ill patients due to the biological agent?

##### Provision of Focused Guidance and Support to Healthcare Communities Experiencing Patient Surges CIRs

- Are public or private healthcare facilities experiencing patient surges due to the biological incident that require the use of ACSs?
- Are SLTT health department and/or emergency management officials planning and implementing ACS facilities?
- What MCM supply challenges are healthcare facilities encountering, and are there alternative forms of care available?
- What PPE supply challenges are healthcare facilities encountering, and have these facilities submitted resource requests to their SLTT health departments and emergency management agencies for support?
- For PPE supply challenges, are there other forms of exposure control (e.g., engineering controls, safe work practices, optimization practices to extend existing PPE supplies) that these facilities could use?
- For staffing shortages, what are the appropriate recommendations that healthcare facilities should use to augment existing staff (e.g., contracts, mutual aid, volunteers, federal/state resource requests for medical personnel)?
- What is the guidance for medical waste management?

##### Provision of Guidance and Technical Assistance to Enable and Support Health Systems in Delivering Care CIRs

- Is the federal government, based on data and feedback, receiving reports of effective actions to improving healthcare resilience from the outreach provided?

- What are the key messages in guidance to ensure that healthcare communities can effectively implement these actions?
- What key stakeholders should outreach activities be focused on more frequently than other stakeholders to achieve resilience in patient care?

### ***LOE #5 – Medical Countermeasure (MCM) Development and Acquisition***

#### Identification/Creation/Development/Manufacturing/Procurement of Critical MCM CIRs

- What are the biological products, drugs, or devices required for the specific biological incident?
- Are there any MCMs that have been approved or are authorized for emergency use against the biological agent of concern?
- What training and external messaging is required to ensure safe use by qualified healthcare providers for the MCM product, drug, or device?
- What are the storage and handling requirements for new products, and how are those requirements effectively communicated to healthcare facilities, providers, and all the entities involved in transportation of the new products from point of manufacture to point of administration?
- In alignment with LOE #2, *Control the Spread of Disease*, what delivery mechanisms are required to expedite MCM dispensing and administration in SLTT communities and all the entities involved in transportation of the new products from point of manufacture to point of administration?

#### Establishment of and Communications Regarding Regulatory Pathways and Operational Issues to Facilitate Rapid Development and Use CIRs

- For candidate MCMs that are not HHS/FDA-approved, is there a regulatory pathway to facilitate availability (e.g., EUA, expanded access, clinical trial, enforcement discretion)?
- Is the HHS Secretary required to issue a Public Readiness and Emergency Preparedness Act (PREP Act) declaration related to the MCM?
- Are there other regulatory issues requiring compliance at the federal, SLTT, and/or healthcare provider levels when using MCMs?

#### Development of Logistics/Operational Plans for MCM Use at All Response Levels CIRs

- What are the defined storage requirements (to include cold-chain storage, if any) for MCMs?
- What are estimated expiration dates for MCM drugs or other products?
- What are the resource allocations by SLTT and federal jurisdiction based on HHS/FDA and HHS/CDC eligibility for administering MCMs, community access, and limited MCM availability (until production catches up with demand)?

- What are the gaps between delivery from manufacturing/distribution sites to jurisdictions conducting dispensing/administration that the federal government needs to address?

#### Addressing of MCM Gaps for All Sectors of the American Civilian Population CIRs

- Do federal and SLTT health entities have the capacity and capabilities to receive and safely store and secure MCMs?
- What is the coordinated public messaging regarding MCMs that should be issued?
- Who are the eligible populations to receive the MCMs?

#### *LOE #6 – Augment Essential Services and Facilitate Long-Term Recovery*

##### Support Infrastructure Systems CIRs

- Which MCMs are deemed appropriate for the U.S. workforce to sustain critical infrastructure systems?
- Based on the assumption of limited MCMs available and eligible populations for those MCMs, what is the priority of workforce job categories to receive appropriate MCMs to maximize the sustainment of critical infrastructure systems?
- What NPIs, training, and guidance are recommended for the workforce to ensure sustainment?
- For infrastructure facilities and homes contaminated with a hazardous biological agent that prevents re-occupancy, what are the clean-up and hazardous waste management policies, processes, and protocols required to achieve safe re-occupancy within a few weeks to a few months?
- For contaminated infrastructure facilities, what are the testing protocols and consensus standards defining “cleanliness” that are required to inform safe re-occupancy?
- For displaced populations impacted by contaminated homes, what temporary and/or long-term housing options are required?

##### Support Economic Recovery CIRs

- What SLTT resource requests for federal assistance are being received to assist in economic recovery efforts?
- Based on SLTT resource requests, is there a requirement to prioritize which jurisdictions receive appropriate resources?
- What NPI measures need to remain in place to facilitate successful economic recovery?
- What interstate or overseas travel restrictions need to either remain in place or be lifted to ease economic recovery while also remaining protective of public health?

##### Economic CIRs

- Real gross domestic product trend by sector

- Unemployment rate
- Applications for unemployment benefits
- Temporary business closures
- Transportation restrictions and disruptions

#### Food Insecurity Trends CIRs

- Food bank demand – Feeding America
- USDA program participation
- Gaps in food security for at-risk populations
- Whether at-risk populations are increasing

#### Food Supply Chain Disruptions CIRs

- Widespread commodities hoarding by the public
  - Sudden, substantial increase in demand for food products
- Stay-at-home orders
- Workforce shift to virtual environment
  - School and childcare closures
  - Restaurant closures
  - Hotel/motel closures
- Reduced workforce access
- Major food manufacturers
  - Plant closures
  - Reported disease outbreaks
- Ability of manufacturers to fulfill paid contracts
  - Food banks
- Food loss/dumping
  - Loss of vendor access resulting in product dumping
  - Mass agricultural animal depopulation

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# Appendix D: Resource Management

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## Purpose

This appendix identifies any unique features of incident support as they pertain to the Logistics Section of the Unified Coordination Staff or the Resource Support Section (RSS) of the Regional Response Coordination Staff (RRCS) or the National Response Coordination Staff (NRCS). The appendix specifies logistics and resource management support that is essential to accomplishing the mission, including the locations of pre-designated staging areas and points of distribution (PODs) as well as detailed information concerning sourcing for required assets.

The Department of Health and Human Services (HHS)/Administration for Strategic Preparedness and Response (ASPR) Secretary's Operations Center Resource Coordination Section (SOC RC or RCS) provides coordinated federal assistance to supplement state, local, tribal, and territorial (SLTT) resources in response to a public health or medical disaster, potential or actual incidents requiring a coordinated federal response, and/or a developing potential health and medical emergency.

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

The SOC RC is responsible for researching, coordinating, selecting, and managing facility locations that store HHS/ASPR medical supplies and equipment to support incidents.

Applicable core capabilities include:

- Public and Private Services and Resources
- Critical Transportation

## Concept of Support

The HHS/ASPR 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.

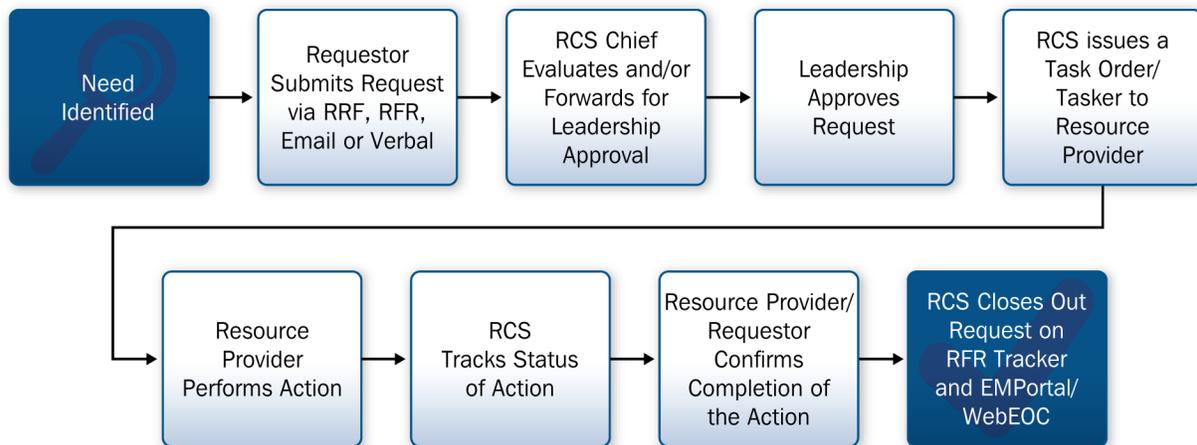
HHS/ASPR SOC RC triages and manages all requests for resources, as well as information requests related to resources, tracking all to completion and addressing unmet needs. If an SLTT request cannot be met with HHS/ASPR resources, the assistance of external Emergency Support Function (ESF) #8 (Public Health and Medical Services) partners is required.

HHS/ASPR SOC RC maintains oversight of the following public health and medical resources that can be requested by the SLTT:

- Strategic National Stockpile (SNS)
- Personal protective equipment (PPE)
- Pharmaceuticals
- Non-SNS medical supplies such as caches and information technology (IT)/communications equipment
- Field Medical Station (FMS)
- Medical staff (e.g., National Disaster Medical Systems [NDMS] teams, U.S. Public Health Services [USPHS] staff)

In a non-Stafford Act incident, the process of requesting resources from HHS begins at the SLTT-level, where SLTT entities identify an unmet resource need. The Federal Health Coordinating Officer (FHCO) reviews and validates the unmet need and submits a Resource Request Form (RRF), Request for Resource (RFR), email or verbal request to HHS/ASPR.

Figure D-1 outlines how a request is processed during an incident.



**Figure D-1: HHS/ASPR Resource Coordination Section (RCS) Request Process**

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

### ***Regional-level Resource Management***

At the regional (operational) level, the focus and priority of supply chain management is to monitor operational area resources (internal and external) and to establish resupply priorities, capabilities, and methods to meet requirements at the tactical level. HHS regional authorities, acting as a conduit of information, communicates these requirements and

priorities to HHS/ASPR SOC RC. Regional authorities coordinate through the IMT for visibility of capabilities and logistics resources at the tactical level. The IMT coordinates all procurement and contracting activities in advance with HHS/ASPR SOC RC to ensure that headquarters' contract services are accurate.

### ***National-level Resource Management***

At the national (strategic) level, the focus and priority of supply chain management is to ensure that adequate resources are acquired and to maintain constant visibility of one or more IMT operational area resources, to include resource available from strategic partners. The HHS/ASPR SOC RC must effectively and efficiently establish strategic partnerships with federal entities, commercial vendors, and distributors and create communications channels for critical information, such as logistics and infrastructure capabilities, at the strategic and operational levels.

HHS/ASPR SOC RC maintains situational awareness of logistic capabilities and requirements by hosting routine logistics conference calls and further coordinates with representatives from critical infrastructure and 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. CIKR entities have the primary responsibility of monitoring the overall status of the healthcare and public health supply chain during a response.

HHS may request that the Department of Defense (DOD), Department of Veterans Affairs (VA), or private sector industries provide medical equipment, durable medical equipment (DME), and supplies, including medical, diagnostic, and radiation-detecting devices, pharmaceuticals, and biologic products, in support of immediate medical response operations and for restocking healthcare facilities in an area affected by a major disaster or emergency. When a veterinary response is required, assets may be requested from the National Veterinary Stockpile, which is managed by the U.S. Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS).

### ***Stafford Act/National Emergency Declarations***

During an incident where a National Emergency or Stafford Act is declaration is made, health and medical resource management decisions may be elevated to the UCG to accommodate the escalated size and complexity of the response.

When resources are being requested by multiple SLTTs, a Supply Chain Task Force may be established within the UCG to collaborate with the National Response Coordination Center (NRCC) Resource Support Section (RSS) and SOC RC to provide an overall picture of the availability of materials and where the materials have been distributed. For example, during the Coronavirus disease 2019 (COVID-19) response, a Supply Chain Task Force evolved into a Supply Chain Control Tower (SCCT). The SCCT established a public-private partnership to understand available supplies. The SCCT developed a reporting structure from U.S. medical

distributors to provide visibility of their resource allocations, greatly improving UCG transparency of allocations to determine federal government allocation priorities.

Systems and databases may be created specifically for a national-level emergency to understand the scope of resource requests, availability, and allocations. As the incident decreases in size and complexity and federal departments and agencies reduce their presence, consider identifying the agency that will be responsible for continuing management of the system, if required.

Resource management and prioritization is difficult during an incident with a National Emergency Declaration when multiple regions are requesting identical resources simultaneously. To identify availability of resources and prioritize allocation of high-demand resources, a process to adjudicate resources is followed.

#### Resource Adjudication Process

Below are the general steps for a resource adjudication and decision process:

1. Identify resource needs.
  - a) Identify resource risks.
  - b) Analyze resource shortfalls.
  - c) Perform resource gap analysis.
  - d) Produce priority-based recommendations for resource usage.
2. Adjudicate resources.
  - a) Validate the need.
  - b) Identify whether the resource can be delivered to the requestor.
  - c) Identify whether the resource can be used right away.
  - d) Identify whether the amount being sent is enough to change an outcome.
3. Recommend allocation of resources.
4. Mobilize resources.

#### Resource Prioritization

During biological incidents, including those that escalate into nationwide incidents, a resource prioritization strategy is critical. An effective resource prioritization strategy must consider situations where supplies are limited and include an efficient plan for the rapid allocation and distribution of medical supplies, equipment, and other resources to locations with the most urgent need.

An example of how a short-term resource prioritization was managed during the COVID-19 response is described in Table D-1 below.

**Table D-1: Resource Prioritization**

1-24 Hours	25-48 hours	49-72 hours	73-96 hours
<ul style="list-style-type: none"> <li>• The NRCC identifies high demand and limited resources in need of national prioritization.</li> <li>• Members of the National Resource Prioritization Cell (NRPC) discuss the current data and modeling sources to understand what information analysis is available.</li> <li>• The Data Analysis Task Force extracts identified datasets to give to the NRPC.</li> </ul>	<ul style="list-style-type: none"> <li>• The NRPC determines the which information is most reliable and weighs variables to decide which information should be used to create recommendations for the cycle.</li> <li>• The NRPC provides the Data Analysis Task Force with a weighing of the variables.</li> </ul>	<ul style="list-style-type: none"> <li>• The NRPC drafts a prioritization table based on agreed-upon factors and weights.</li> <li>• The prioritization table is reviewed, and subject matter experts (SMEs) apply operational judgement to adjust prioritization recommendations.</li> <li>• The NRPC briefs the recommended prioritization to the NRCC.</li> </ul>	<ul style="list-style-type: none"> <li>• The NRPC finalizes the prioritization table and provides recommendations to the UCG.</li> <li>• The prioritization bulletin is provided to the private sector for use in determining distribution of their supplies.</li> <li>• The NRPC evaluates the effectiveness of the previous 96-hour process and makes any adjustments to continually improve the process.</li> </ul>

**ESF #8 Committees/Advisory Groups**

ESF #8, Public Health and Medical Services, Resource Allocation Committees/Advisory Groups, as informed by data working groups and supporting technical capabilities such as the Supply Chain Control Tower (SCCT) and the Healthcare Coalition Response Team (HCRT), formulate courses of actions (COAs) to address SLTT needs within the context of a resource constrained environment. Depending on the situational context of the incident and the specific nature of the SLTT request, multi-agency committees/advisory groups can be used to develop COAs for HHS/ASPR/Office of Operations and Resources (OOR) Deputy Assistant Secretary adjudication or senior executive-level discussion and decision, as required.

**Long-term Supply Chain Resilience**

Building resilience within and providing for the rapid restoration of supply chain systems is critical to any catastrophic incident response. Stabilizing the supply chain during a biological incident includes prioritizing and allocating critical supplies and equipment, together with SLTT partners and private sector entities. The Department of Homeland Security (DHS)/FEMA works closely with its public and private sector partners to enable this whole-of-community approach to respond to the pandemic and build a more resilient nation.

**Counterfeit MCMs**

During public health emergencies, especially when demand exceeds supply, logistics managers should be aware of counterfeit MCMs, such as PPE, hand sanitizers, and drug products. Concerns regarding potentially counterfeit PPE can be shared to an allegations team at the HHS/Food and Drug Administration (FDA) website: [Reporting Allegations of](#)

[Regulatory Misconduct](#).<sup>39</sup> The FDA works with manufacturers and other government partners, as appropriate.

## Allocation Process for Public Health Resource (placeholder)

### Defense Production Act (DPA)

The DPA is the primary source of Presidential authorities to expedite and expand critical supplies from the private sector for national defense, including emergency preparedness and response activities conducted pursuant to Title VI of the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. § 5195 et seq.]; protection and restoration of critical infrastructure operations; and efforts to counter terrorist activities within the United States.

#### DPA Authorities

##### *Priorities and Allocations Authorities (DPA Sec 101)*

This section describes priorities and allocations authorities (DPA Section 101) to require acceptance and priority treatment of contracts and orders and to allocate limited supplies of materials, services, and facilities that are available from the private sector.

**Table D-2: Priorities and Allocations Authorities**

Authority	Description
Priorities Authority	<p>Priority ratings could be included in contracts and orders both prior to and during a pandemic to ensure that needed resources to combat the outbreak are supplied in accordance with priorities established by the government.</p> <ul style="list-style-type: none"> <li>NOTE: Currently, DHS is not authorized to place priority-rated contracts and orders (“rated orders”) for “health resources” except for COVID-19-related items per Executive Order (EO) 13911. “Health resources” are defined in EO 13603 to mean “drugs, biological products, medical devices, materials, facilities, health supplies, services, and equipment required to diagnose, mitigate or prevent the impairment of, improve, treat, cure, or restore the physical or mental health conditions of the population.” Before DHS could place rated orders for health resources in support of a program to counter a pandemic, the program would have to be determined to be: (1) “necessary or appropriate to promote the national defense” (see Note under Allocations Authority below), and (2) priority-rating authority under the Health Resource Priorities and Allocations System would have to be requested from and provided by HHS.</li> </ul>

<sup>39</sup> <https://www.fda.gov/medical-devices/medical-device-safety/reporting-allegations-regulatory-misconduct>

Authority	Description
Allocations Authority	<p>The allocations authority could be used during a pandemic to control the distribution of over-taxed health resources.</p> <ul style="list-style-type: none"> <li>NOTE: In accordance with section 202 of EO 13603, the priorities and allocations authorities may be used only to support programs that have been determined in writing to be necessary or appropriate to promote the national defense. To be determined “as necessary or appropriate to promote the national defense,” a program to respond to a pandemic must involve military production or construction; emergency preparedness activities conducted pursuant to Title VI of the Stafford Act; critical infrastructure protection or restoration; or counterterrorism activities. DHS/FEMA is responsible for making this determination with respect to non-military programs.</li> </ul>

### *DPA Title III Authorities*

DPA Title III authorities can be used to create, maintain, protect, expand, or restore domestic industrial base capabilities essential for national defense.

**Table D-3: DPA Title III Authorities**

Authority	Description
Private Sector Investment	<p>In preparation for a pandemic, Title III authorities could be used to encourage private sector investment in additional drug production capabilities to enable greater output of vaccines and antivirals needed to combat a pandemic.</p> <ul style="list-style-type: none"> <li>NOTE: DOD has the only active Title III program, but HHS is also authorized to use Title III provisions under EO 13603. DHS/FEMA has no direct involvement in the Title III actions of other federal agencies.</li> </ul>
DPA Section 303e	<p>DPA Section 303(e) authorizes procurement and installation of additional equipment, facilities, processes, or improvements to plants, factories, and other industrial facilities owned by the federal government or by private persons. This authority could be used in connection with emergency preparedness activities conducted pursuant to the Stafford Act or for the protection or restoration of critical infrastructure operations involving drug production capabilities, hospitals, or other facilities involving production or delivery of health resources.</p>

### *DPA Title VII Authorities*

DPA Title VII contains several provisions with only a few, identified below, that would be useful for preparing for or responding to a pandemic or other biological incident.

**Table D-4: DPA Title VII Authorities**

Authority	Description
Voluntary Agreements (DPA Section 708)	<p>A “voluntary agreement” is an association of private interests approved by the federal government and made freely by two or more representatives of industry, business, financing, agriculture, labor, or other private interests to plan and coordinate actions in support of the national defense or federal government emergency preparedness and response activities. Participants in a voluntary agreement are granted relief from antitrust laws under the provisions of Section 708 of the DPA. A voluntary agreement among drug manufacturers could be used to plan and coordinate rapid production of new vaccines and antivirals. A voluntary agreement among medical providers and first responders could be used to plan and coordinate treatment and isolation of pandemic victims.</p> <ul style="list-style-type: none"> <li>NOTE: The sponsor of a voluntary agreement is required to keep DHS/FEMA informed about efforts to establish and conduct activities under a voluntary agreement, but the primary responsibilities for approving and monitoring voluntary agreements rests with the Attorney General and the Chairman of the Federal Trade Commission.</li> </ul>
Employment of Private Sector Experts (DPA Section 710) in Government Preparedness Planning and Response Activities	<p>The DPA Section 710 authorities could be used to: (1) engage private sector experts as unpaid government advisors to prepare for and respond to a pandemic, and (2) employ private sector experts as special government employees in the event of a pandemic to manage government response.</p> <ul style="list-style-type: none"> <li>NOTE: Unit sponsors of the National Defense Executive Reserve (NDER) are required to provide administrative records identifying their reservists to the NDER Program Manager in DHS/FEMA.</li> </ul>

***Examples of DHS/FEMA DPA Use During a Pandemic***

- Title I priority ratings were used by DHS/FEMA to procure more than 220 million respirators from 3M.
- FEMA used Title I allocation orders to prevent the export of scarce PPE and other critical health materials for domestic use pursuant to a temporary final rule administered by the Export Cargo Review Working Group.
- FEMA formed the “Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic” under Title VII to facilitate collaboration with the private sector during a pandemic.

**Federal Response Capability Inventory – Biological-Specific Assets, Resources, and Teams**

The purpose of this section is to identify resources, capabilities, and organizations that may be employed in response to a biological incident; it is not meant to assign responsibility to any one agency or organization. This section further defines organizational capabilities associated with a biological incident. There may be organizations identified who possess statutory or regulatory authorities to initiate a response prior to coordination with

DHS/FEMA. These federal organizations can provide an efficient, effective, and comprehensive response in coordination with all SLTT jurisdictions.

**Table D-5: Federal Response Resources and Capabilities**

Organization	Resource/ Capability Name	Description
USDA/Animal and Plant Health Inspection Service (APHIS)	Pet, service, or assistance animal technical assistance for rescue, shelter, and disposal of remains	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, USDA/APHIS coordinates with HHS, Environmental Protection Agency (EPA), DOD/U.S. Army Corps of Engineers (USACE), and/or DHS/FEMA to provide technical advice regarding disposal of animal carcasses.
USDA	Disaster Supplemental Nutrition Assistance Program (D-SNAP)	After an affected area has received a Presidential declaration of Major Disaster with Individual Assistance, commercial channels of food distribution have been restored, and families are able to purchase and prepare food at home, a state may request to operate D-SNAP. Once approved by USDA/Food and Nutrition Service (FNS), the state has the primary role for planning and operating D-SNAP. D-SNAP provides one month of benefits to eligible disaster survivors and can facilitate the issuance of supplemental SNAP benefits for ongoing households.
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 includes a system that consists of units that collect air samples in more than 30 cities and a network of local, state, and federal laboratories that analyze samples daily with a goal of providing warning of biological attacks within 12 to 36 hours of the release of selected agents. BioWatch operates 24 hours per day, 365 days per year.
DHS	Domestic Communications Strategy	The Domestic Communication Strategy is a guidebook that provides options for public information strategies, complementing existing federal plans and strategic guidance documents, that may be employed in a domestic terrorist attack or a credible threat to the homeland.
DHS	National Biodefense Analysis and Countermeasures Center (NBACC)	NBACC 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.

Organization	Resource/ Capability Name	Description
DHS	National Biosurveillance Integration Center (NBIC)	<p>The mission of NBIC is to enhance the capability of the federal government to:</p> <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	<p>DHS Surge Capacity Force is organized into four tiers for the purpose of prioritizing and providing for an informed selection of deployable human assets:</p> <ul style="list-style-type: none"> <li>• Tier 1 – Composed of DHS/FEMA Reservists with DHS/FEMA credentials.</li> <li>• Tier 2 – Composed of DHS/FEMA permanent full-time employees with DHS/FEMA credentials.</li> <li>• Tier 3 – Composed of DHS full-time federal employees.</li> <li>• Tier 4 – Composed of full-time or part-time federal employees from other federal departments and agencies.</li> </ul>
DHS/ Cybersecurity and Infrastructure Security Agency (CISA)	Stakeholder relationships with the 16 critical infrastructure partners and federal, SLTT, commercial, and international partners	<p>The CISA Stakeholder Engagement Division (SED) develops strategic and collaborative partnerships to broaden CISA influence, positions the agency as a thought-leader, and improves the coordination and integration of stakeholder relationships. SED manages CISA's customer relationship management platform, collects strategic stakeholder feedback and requirements, fosters collaboration and a culture of shared ownership of these relationships, and aligns and manages priorities and performance for stakeholder engagements. SED implements and communicates engagement priorities, governance, processes, standards of practice, performance management, and analytics to facilitate an enterprise stakeholder engagement approach.</p>
DHS/ Management Directorate/ Federal Protective Service (FPS)	Hazardous Response Program	<p>This program includes initial investigations of suspicious or threatening chemical, biological, radiological, nuclear, and high-yield explosive (CBRNE) incidents; CBRNE threat assessments; confirmations of unauthorized presence of CBRNE agents and materials; and emergency operations. The Hazardous Response Program also provides evacuation support during CBRNE incidents and CBRNE mutual aid response through agreement and training assistance. The program is compliant with Occupational Safety and Health Administration (OSHA) and National Fire Protection Association guidance and regulations.</p>

Organization	Resource/ Capability Name	Description
DHS/FEMA	Consequence Management Coordination Unit (CMCU)	In response to notification of a credible terrorist threat or actual incident, the Federal Bureau of Investigation (FBI) activates the Weapons of Mass Destruction Strategic Group (WMDSG). Within the FBI-led WMDSG, DHS/FEMA staffs and manages the CMCU, which may also be activated independently by FEMA for non-FBI-led incidents. This unit is also supported by federal technical capabilities, including, when appropriate, by the Department of Energy (DOE)/National Nuclear Security Administration (NNSA), HHS, DOD, and DHS. As the principal advisory unit for consequence management considerations within the FBI-led WMDSG, the CMCU provides recommended consequence management COAs that consider ongoing and evolving operations. The CMCU provides support to deconflict DOJ/FBI-led crisis response and DHS/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 DOJ/FBI concerning federal 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 chemical, biological, radiological, and nuclear (CBRN)-related scenarios and are the DHS/FEMA lead in the field to coordinate and integrate inter-jurisdictional response in support of affected SLTTs. N-IMATs provide initial situational awareness for federal decision makers and support the initial establishment of a Unified Command (UC). IMATs provide for multi-disciplinary needs of emergency management and may include members from the interagency community.
DHS/FEMA	Interagency Modeling and Atmospheric Assessment Center (IMAAC)	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, 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/ U.S. Coast Guard (USCG)	Marine Security Response Teams (MSRTs)	MSRTs constitute the USCG Counterterrorism Advanced Interdiction Force, which is capable of executing higher risk law enforcement missions against opposed/hostile maritime threats, including all CBRN threats. An MSRT is a quick response, ready assault force that conducts Short Notice Maritime Response operations. An MSRT is capable of interdicting, boarding vessels, and verifying CBRN and explosive threats and, when required, engaging in offensive operations against hostile threats.

Organization	Resource/ Capability Name	Description
DHS/USCG	National Strike Force (NSF)	The NSF supports On-Scene Coordinators (OSCs), 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 incidents. The NSF includes the National Strike Force Coordination Center; Atlantic, Gulf, and Pacific Strike Teams; Incident Management Assistance Team (IMAT); and Public Information Assist Team (PIAT).
Department of Commerce (DOC)/National Oceanographic and Atmospheric Administration (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. The 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.
DOD	Military Aeromedical Evacuation (AE)	Patient movement by DOD requires a request from a state or federal department and the activation of the patient movement and definitive care components of the NDMS. Patient movement regulated by the Global Patient Movement Requirements Center (GPMRC) is conducted on fixed-wing aircraft from an Aerial Port of Embarkation (APOE) to an Aerial Port of Debarkation (APOD). AE Patient movement functions are coordinated by the GPMRC, a unit of the U.S. Transportation Command at Scott Air Force Base in Illinois. The GPMRC collects casualty information from states and determines patient clearances for flight. DOD then matches patient needs with the aircraft, medical crew on board, and a destination facility (also known as “patient regulation”). 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 the GPMRC. Movement of patients with highly contagious diseases on DOD aircraft requires approval from the Secretary of Defense.

Organization	Resource/ Capability Name	Description
DOD	CBRN Response Enterprise	The CBRN Response Enterprise is composed of Active Duty and Reserve Component forces in a Title 10 (federalized) duty status and National Guard forces in a Title 32 (non-federalized) duty status that provide lifesaving capabilities for a national and regional CBRN response during major or catastrophic CBRN incidents. National Guard forces consist of Weapons of Mass Destruction-Civil Support Teams (WMD-CSTs), CBRNE Enhanced Response Force Packages (CERFPs), and Homeland Response Forces (HRFs) employed under state control. Under federal control, the Defense CBRN Response Force (DCRF) with Joint Task Force-Civil Support as its core and two Command and Control CBRN Response Elements (C2CREs) will provide direct support to the lead federal agency (LFA). In extremis, all CRE units may be federalized to a Title 10 status and allocated to U.S. Northern Command (USNORTHCOM) for command and control. WMD-CSTs are full-time National Guard units and provide 24/7 CWMD and CBRN detection, identification, and threat characterization for the Prevention and Response Missions in support of state, local, tribal, and federal responders in all 54 states and territories. All National Guard CRE forces support National Special Security Events (NSSEs) and other Special Event Assessment Rating (SEAR) events.
DOD/Defense Intelligence Agency (DIA)/National Center for Medical Intelligence (NCMI)	Collection, evaluation, and all-source analysis of worldwide health threats and issues	NCMI is the DOD-led activity that produces medical intelligence and prepares and coordinates integrated, all-source intelligence for DOD and other government and international organizations on foreign health threats and other medical issues to protect U.S. interests worldwide.
Department of the Interior (DOI)/U.S. Geological Survey (USGS)	Modeling for USGS threats to humans and animals	USGS 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 DOI/USGS expertise in the hydrologic, atmospheric, geologic, and ecologic processes that affect the transport and fate of agents in the environment.
DOI/USGS	National and international analysis of infection disease in various aquatic craniate animals	DOI/USGS-National conducts cause-of-death investigations and research in various freshwater and marine aquatic animals at multiple USGS science centers. USGS conducts research and diagnostics on high-consequence diseases within wild fish species, including diseases that can spill over into and result in economic impacts to U.S. aquaculture. USGS maintains aquatic high-containment lab space.

Organization	Resource/ Capability Name	Description
DOI/Fish and Wildlife Service (FWS) Wildlife Health Office	Wildlife health and disease surveillance and consequence management	<p>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 that support refuges, wetland management districts, and other service programs by:</p> <ul style="list-style-type: none"> <li>• Providing technical advice about wildlife disease and public health issues;</li> <li>• Providing guidance on adapting management strategies to prevent wildlife diseases;</li> <li>• Identifying health surveillance needs;</li> <li>• Conducting critical work on the issues linking wildlife, zoonotic diseases, and wildlife professionals;</li> <li>• Conducting research projects to determine best practices in disease prevention;</li> <li>• Providing veterinary services for field activities; and</li> <li>• Supporting emergency response efforts.</li> </ul>
DOI/USGS/ National Wildlife Health Center	Wildlife health and disease surveillance and consequence management	<p>Under ESF #11, Agriculture and Natural Resources, USGS and its National Wildlife Health Center serve as the federal lead on zoonotic and wildlife diseases. The center can assist in responding to highly contagious zoonotic diseases, biohazard incidents, or other emergencies involving wildlife by providing wildlife emergency response teams; risk assessment, mapping tools, and epidemiological modeling; 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 communications.</p>
DOI/National Park Service (NPS)/Wildlife Health Branch and Office of Public Health	Veterinary consultation and technical assistance	<p>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 DOI/NPS Office of Public Health and state and local health departments in zoonotic disease prevention and response. The DOI/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 assist in zoonotic and vector-borne disease surveillance and response in parks.</p>

Organization	Resource/ Capability Name	Description
DOJ/FBI	DOJ/FBI National Bioforensic Analysis Center (NBFAC)	Under the direction of the DOJ/FBI, the NBFAC conducts bio-forensic analysis of biological materials and associated evidence from a biocrime or terrorist attack to support investigations, attain a “biological fingerprint” to help investigators identify perpetrators, and determine the origin and method of attack. The 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 (typically DOJ/FBI).
DOJ/FBI	Hazardous Evidence Response Teams (HERTs)	These teams are DOJ/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 a FBI-led interagency crisis action team that supports information exchange and the deconfliction of law enforcement and counterterrorism operations to successfully resolve imminent WMD terrorist threats or incidents, to include biological threats or incidents, while simultaneously coordinating with federal agencies conducting consequence management activities to save lives and protect property and critical infrastructure.
DOJ/FBI	Critical Incident Response Group (CIRG)	The CIRG provides expertise in crisis management, hostage rescue, surveillance and aviation, hazardous devices mitigation, crisis negotiations, behavioral analysis, strategic information dissemination, and tactical operations, including a WMD device response.
DOJ/FBI	Hazardous Evidence Analysis Team (HEAT)	HEAT is composed of forensic examiners and crime scene specialists trained to perform cyber and traditional forensic analyses on CBRN materials in containment facilities.
DOJ/FBI	FBI Laboratory	The FBI Laboratory provides coordination of CBRN evidence collection during a deliberate incident, analysis of evidence for CBRN materials, and research, development, and validation of methodologies used for CBRN forensic investigations.
EPA	Consequence Management Advisory Division (CMAD)	CMAD 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, and waste treatment environmental cleanup and clearance. CMAD manages the EPA’s Airborne Spectral Photometric Environmental Collection Technology (ASPECT) fixed-wing aircraft, which provide chemical/radiological data, deploy and operate mobile and fixed chemical and biological laboratories, and manage the EPA Environmental Response Laboratory Network (ERLN).

Organization	Resource/ Capability Name	Description
EPA	CBRN Consequence Management Advisory Team (CMAT)	CMAT 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. CMAT manages the EPA's ASPECT fixed-wing aircraft, which provide chemical/radiological data and deploy and operate mobile and fixed chemical and biological laboratories.
EPA	Environmental Response Team (ERT)	This team provides scientific, engineering, 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. The ERT provides real-time data management and visualization via the Viper telemetry platform and provides fixed and mobile analytical services, including real-time air monitoring for chemicals with the EPA's mobile laboratories known as Trace Atmospheric Gas Analyzers.
EPA	Homeland Security Research Program	EPA's emergency response and homeland security research provides the science and technology needed to effectively respond to and recover from biological incidents and other disasters. SMEs in biological sampling, sample analysis, decontamination, fate and transport of agents, and waste management are available to provide support in decision making based on cutting-edge science.
EPA	National Criminal Enforcement Response Team	This EPA team provides technical, safety, and hazardous evidence collection and other forensic support to law enforcement in the instance of a WMD terrorist attack or environmental catastrophe.
EPA, DHS/USCG	Regional Response Team (RRT)	RRTs are co-chaired by the EPA and DHS/USCG. These teams are regional-level, multi-agency coordination entities comprising of 15 federal agencies and state and tribal representatives that provide technical assistance and resource support to the federal OSC during National Contingency Plan (NCP) and ESF #10 responses to oil and hazardous materials.
EPA, DHS/USCG	On-Scene Coordinators (OSCs)	OSCs coordinate the 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 decontamination of buildings and structures and management of waste. EPA generally provides the federal OSC for incidents in inland areas, while DHS/USCG provides the federal OSC for incidents in coastal areas.

Organization	Resource/ Capability Name	Description
EPA/USCG	National Response Team (NRT)	The NRT is a national-level multi-agency coordination entity comprising of 15 federal agencies that provides technical assistance and resource and policy support to the Federal OSC during NCP and ESF #10 responses to oil and hazardous materials incidents. The Chair of the NRT shall be the representative of EPA and the Vice Chair shall be the representative of the USCG, with the exception of periods of activation because of response action. During activation, the chair shall be the member agency providing the OSC/Remedial Project Manager (RPM).
HHS/ Administration for Children and Families (ACF)	Access and functional needs self-sufficiency technical assistance	ACF promotes the self-sufficiency of individuals, families, and those with access and functional needs prior to, during, and after disasters. Human Services Technical Assistance assets are employed in the field to provide these services.
HHS/ASPR	Aerial Ports of Embarkation (APOEs)	HHS NDMS teams provide critical care healthcare provider augmentation to federal transporters at APOEs to manage patients prior to flight.
HHS/ASPR	Recovery planning, mitigation, response, and recovery support to public health incidents	ASPR leads the nation and its communities preparing for, responding to, and recovering from the adverse health effects of public health emergencies and disasters. HHS/ASPR focuses on preparedness, planning, response, and recovery; provides federal support, including medical professionals through NDMS, to augment state and local capabilities during an emergency or disaster; and leads the federal Health and Social Services Recovery Support Function (RSF) of the <i>National Disaster Recovery Framework</i> (NDRF) to assist locally led recovery efforts in the restoration of the public health, healthcare, and social services networks of impacted communities.
HHS/Assistant Secretary for Public Affairs (ASPA)	External Affairs coordination during a public health emergency	HHS/ASPA assumes the lead in media response for public health, coordinated with and through the Joint Information Center (JIC). HHS/ASPA coordinates HHS Public Affairs planning, development, and implementation of emergency incident communications strategies and activities for the department.
HHS/ASPR	At-risk individuals, 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 with public health and medical emergency preparedness, response, and recovery activities to facilitate and promote community resilience and national health security.

Organization	Resource/ Capability Name	Description
HHS/ASPR/ Biomedical Advanced Research and Development Authority (BARDA)	Product development and funding of medications and tools needed in a response to a public health emergency	BARDA 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/Substance Abuse and Mental Health Services Administration (SAMHSA)	Crisis Counseling Assistance and Training Program	This is a state grant program administered by HHS/SAMHSA and funded by DHS/FEMA.
HHS/ASPR	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 rapid-response elements that supplement local medical care until other federal or contract resources can be mobilized or the situation is resolved.
HHS/ASPR	Disaster Mortuary Operational Response Team (DMORT)	DMORTs are teams of intermittent federal employees with particular fields of expertise who are activated in a disaster. DMORTs are directed by HHS/ASPR/Emergency Management and Medical Operations (EMMO)/NDMS. Teams are composed of funeral directors, medical examiners, coroners, pathologists, forensic anthropologists, medical records technicians and transcribers, fingerprint specialists, forensic odontologists, dental assistants, x-ray technicians, mental health specialists, computer professionals, administrative support staff, and security and investigative personnel.
HHS/ASPR	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 the decontamination of bodies when death results from the exposure to chemicals or radiation. The DMORT-WMD team 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 deaths occur in multiple locations.
HHS	Disaster Portable Morgue Unit (DPMU)	DPMUs are staged at locations on the east and west coasts of the United States for immediate deployment in support of DMORT operations. The DPMU is a collection of equipment and supplies that can be deployed to a disaster site. It contains a complete morgue with designated workstations for each processing element and prepackaged equipment and supplies.

Organization	Resource/ Capability Name	Description
HHS/ASPR	Incident Support Team (IST)	An IST is a scalable team that is employed every day at some operational level of intensity. Its organization is designed to be flexible and can expand as needed. An IST is the established structure through which information and potential threats are received and decisions, including the deployment of an IMT, are made. An IST operates within the principles of the Incident Command System (ICS) and National Incident Management System (NIMS). An IST effectively operates 24/7 but can reach its full capacity with associated liaisons within 4 hours.
ASPR/SNS	Federal Medical Station (FMS)	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 shelters for the general population during an incident.
HHS/ASPR	Incident Management Team (IMT)	The IMT and the IMT-Forward act as the HHS agents on scene at emergency sites under the direction of the HHS SOC. The IMT directs and coordinates the activities of all HHS personnel deployed to the emergency site and assists SLTTs and other federal agencies, as applicable.
HHS/ASPR	Joint Patient Assessment and Tracking System (JPATS) Strike Team	JPATS Strike Teams are two-person teams that are deployed to APOEs, patient reception areas/casualty collection points, and destination locations to track patients through the system.
HHS/ASPR	National Disaster Medical System (NDMS)	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 affected areas to medical care locations remote from the affected areas, and (3) provide definitive medical care at NDMS civilian member hospitals.
HHS/Centers for Disease Control and Prevention (CDC)	National Electronic Disease Surveillance System (NEDSS)	This system facilitates the electronic transfer of 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 (NNDSS).
HHS/National Institutes of Health (NIH)		HHS/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/NIH	National Institute of Environmental Health Sciences (NIEHS) Worker Training Program (WTP)	The NIEHS WTP provides grants to nonprofit organizations, including labor-based health and safety organizations and academic institutions, so that they can deliver training to a variety of workers who may face a hazardous work environment. Training is provided to workers across many occupational sectors relevant to response and recovery, such as environmental cleanup workers, first responders, and healthcare employees.

Organization	Resource/ Capability Name	Description
HHS	National Public Health Information Coalition	HHS leverages a network of state and local health public health communicators to exchange information and increase the likelihood of consistent messaging and communications activities between federal and state or local governments regarding an emergency and its impact on health.
HHS	National Veterinary Response Team (NVRT)	NVRTs are cadres of individuals within the NDMS who have professional expertise in areas of veterinary medicine, public health, and research. They are the primary federal resource for the treatment of injured or ill animals affected by disasters.
HHS/ASPR	Regional Emergency Coordinators (RECs)	RECs are the primary representatives of HHS/ASPR throughout the country at the regional level that coordinate preparedness and response activities for public health and medical emergencies.
HHS	Secretary's Operations Center (SOC)	The HHS SOC operates 24/7/365 and its mission is to serve as the focal point for the synthesis of critical public health and medical information on behalf of the federal government.
HHS (and Private Sector)	Certified Bio-Containment Units for Highly Infectious Diseases (Category A)	These units are located at Emory University (Atlanta, GA), Nebraska Medical Center (Omaha, NE), NIH (Bethesda, MD), and St. Patrick Hospital (Missoula, MT).
HHS/CDC	CDC Emergency Operations Center (CDC EOC)	The HHS/CDC EOC brings together highly trained experts and state-of-the-art technology to coordinate resources, information, and crisis and emergency risk communications to detect and respond to public health threats. The HHS/CDC EOC manages the deployment of HHS/CDC staff and oversees the procurement and management of all equipment and supplies that HHS/CDC responders may need during their deployment. When activated for a response, the HHS/CDC EOC can accommodate up to 230 personnel per 8-hour shift to handle situations ranging from local incidents to worldwide incidents.
HHS/CDC	Epidemic Information Exchange (Epi-X)	Epi-X is the HHS/CDC's secure, web-based communications network that serves as a powerful communications exchange between HHS/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 and at the HHS/CDC, through the HHS/CDC's Center of Surveillance, Epidemiology, and Laboratory Services, and are dispatched to investigate possible epidemics due to both natural and artificial causes, e.g., <i>Bacillus anthracis</i> , hantavirus, West Nile virus, and the Ebola virus.

Organization	Resource/ Capability Name	Description
HHS/CDC	Health Alert Network (HAN)	HAN is the CDC’s primary method of sharing cleared information about urgent public health incidents with public information officers, federal and SLTT public health practitioners, clinicians, and public health laboratories.
CDC/National Institute for Occupational Safety and Health (NIOSH)	Occupational safety and health research and technical assistance	CDC/NIOSH conducts research and makes recommendations to prevent worker injury and illness. CDC/NIOSH can deploy a multi-discipline team to provide guidance and technical assistance on responder and worker safety and health.
HHS/CDC	National Notifiable Disease Surveillance System (NNDSS)	The NNDSS is a nationwide collaboration that enables all levels of public health entities—SLTT, federal, and international—to share notifiable disease-related health information. Public health entities use this information to monitor, control, and prevent the occurrence and spread of state-reportable and nationally notifiable infectious and noninfectious diseases and conditions. The NNDSS is a multi-faceted program that includes a surveillance system for the collection, analysis, and sharing of health data. It also includes policies, laws, electronic messaging standards, people, partners, information systems, processes, and resources at the SLTT and federal levels.
HHS/CDC	Public Health Information Network (PHIN)	HHS/CDC’s PHIN is a national initiative to increase the capacity of public health agencies to electronically exchange data and information across organizations and jurisdictions (e.g., from clinical care facilities to public health agencies, between and among public health agencies, and from public health agencies 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 Team	This survey instrument gives local and state entities a tool to register responders and other persons exposed to the chemical, biological, or nuclear agents of a disaster. The survey instrument is a two-page form that can be distributed on paper or electronically. It can be implemented quickly to collect information rapidly and identify and locate victims and people displaced or affected by a disaster.
HHS/ASPR	Strategic National Stockpile (SNS) Push Packages	SNS Push Packages are caches 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 incident. A cache is packed in cargo containers that can be delivered anywhere in the United States within 12 hours of the federal decision to deploy.

Organization	Resource/ Capability Name	Description
HHS/ASPR	Strategic National Stockpile (SNS); Managed Inventory (MI)	If an incident requires additional pharmaceuticals and/or medical supplies, follow-on MI supplies are shipped to arrive within 24 to 36 hours. If an agent is well defined, the Vendor Managed Inventory (VMI) can be tailored to provide pharmaceuticals, supplies, and/or products specific to the suspected or confirmed agent. In this case, the VMI could act as the first option for immediate response from the SNS program.
HHS/FDA	Medical Product Regulation	In part, HHS/FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. HHS/FDA is responsible for advancing public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get accurate, science-based information to use medical products (for example diagnostics and vaccines), including in the context of a public health emergency. HHS/FDA also plays a significant role in the national counterterrorism capability by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.
HHS/FDA	Regulated Products/ Commodity Response Teams	These teams aid state and local health authorities, or in the absence of state and local health investigators, assume primary responsibility for the evaluation and recovery of food service establishments and pharmacies.
HHS/FDA/Office of Counterterrorism and Emerging Threats (OCET)	Medical Countermeasures Initiative (MCMi)	This office coordinates HHS/FDA MCM development, availability, preparedness, and response. This office leads an HHS/FDA-wide initiative to coordinate MCM development, preparedness, and response. HHS/FDA ensures that 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	Deployment Stratification for USPHS	The Public Health Emergency Response Strike Team (PHERST) deploys within 8 hours in support of an immediate need for community stabilization related to unexpected events, threats to public health, or severe impacts to life, health, and/or property.
HHS/USPHS	USPHS Regular Active-Duty Force	Deploys within 36 hours of being put on alert status. Officers offer clinical and public health augmentation expertise to communities experiencing threats to public health, or severe impact to life, health, and/or property. Combines expertise and skills from previous USPHS force structure (i.e., Rapid Deployment Forces (RDF), Capital Area Provider Teams (CAP), Applied Public Health Team (APH), Regional Incident Support Team (RIST), National Incident Support Team (NIST), Mental Health, Services Access, and Tier 3 responders) into 5 individual teams team, rotating on-call months.

Organization	Resource/ Capability Name	Description
HHS/USPHS	USPHS Ready Reserve Force	This force deploys within 5 days of being activated for service. Officers offer clinical and public health expertise to communities experiencing adverse events, threats to public health, or severe impacts to life, health, and/or property. This asset also allows the Readiness and Deployment branch greater flexibility with reducing agency requests and supporting communities until they are truly ready to transition to recovery operations.
General Services Administration (GSA)	Public Buildings Service	GSA provides facility space as requested.
United States Postal Service (USPS)	United States Postal Inspection Service (USPIS)	The USPIS conducts biological surveillance for pathogens shipped through the mail.
Department of Veterans 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 are likely to arrive and be triaged, received, and transported to NDMS partner hospitals for inpatient medical care.
VA	Disaster Emergency Medical Personnel System	VA'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 for supporting a mission after a Presidential Disaster Declaration under ESF #8.

Table D-6 provides a consolidated listing of the Integrated Consortium of Laboratory Networks (ICLN), their governing organization, and a description of their role. ICLN, led by DHS/OHS, 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: DOD, USDA, DOE, HHS, DHS, DOI, DOJ, Department of State (DOS), and the EPA. 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 (NAHLN), National Plant Diagnostic Network, and the Veterinary Laboratory Investigation and Response Network.

**Table D-6: Integrated Consortium of Laboratory Networks (ICLN) Capabilities**

Organization	Resource/Capability Name	Description
DOD/DOD Laboratory Network (DLN)	DOD CBRN and infectious disease analytics and recommendations	The DLN provides a capability that allows DOD laboratories, programs, and activities with analytic or response capabilities to coordinate execution, develop consensus, and make recommendations governing detection, identification, characterization, and diagnosis and the 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 global and homeland defense missions.
EPA/ Environmental Response Laboratory Network (ERLN)	Routine and urgent analysis of environmental samples	The ERLN supports the capability to perform routine and emergency analysis of environmental samples. The ERLN is integrated into the ICLN organization. The ERLN integrates the capabilities of existing public sector laboratories with those of accredited private sector labs to support the environmental response.
Food and Drug Administration (FDA)/ Veterinary Laboratory Investigation and Response Network (Vet-LIRN)	Testing of animal food, drug, and diagnostic samples	Vet-LIRN is managed by the HHS/FDA Center for Veterinary Medicine. The primary objective of Vet-LIRN is to promote human and animal health by partnering with over 40 state and university veterinary diagnostic laboratories. Vet-LIRN laboratories help HHS/FDA investigate potential adverse events affecting national animal food and drug supplies by conducting testing of animal foods, animal drugs, or animal diagnostic samples. Vet-LIRN laboratories develop chemistry and microbiology testing methods, maintain preparedness by optimizing and harmonizing testing methods, assist with case investigations related to adverse event reports, and participate in network proficiency exercises. Since 2017, Vet-LIRN has tracked antimicrobial resistance in bacterial pathogens from animals, particularly companion animals, in a successful application of the One Health paradigm. <sup>40</sup>
HHS/CDC/ Laboratory Response Network (LRN)	Public and non-public health chemical, biological, and infectious disease laboratory support	The LRN and its partners maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies.
USDA/FDA/ Food Emergency Response Network (FERN)	Ability to organize national SLTT food testing into one network	FERN integrates national food-testing laboratories at the federal and SLTT levels into a network that can respond to emergencies involving biological, chemical, or radiological contamination of food. The FERN structure is organized to ensure federal and state interagency participation and cooperation in the formation, development, and operation of the network.

<sup>40</sup> For more information on Vet-LIRN, see <http://www.fda.gov/AnimalVeterinary/ScienceResearch/ucm247334.htm>.

Organization	Resource/Capability Name	Description
USDA/ National Plant Diagnostic Network (NPDN)	Ability to detect pests and pathogens associated with a biological incident	The 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 has invested in diagnostic laboratory infrastructure and training, developed an extensive network of first detectors through education and outreach, and enhanced communications among public agencies and stakeholders responsible for responding to and mitigating new outbreaks.
USDA/NAHLN	Animal health diagnostics and biological threat detection for animal agriculture	The NAHLN is a 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 animal agriculture, thus protecting animal health, public health, and the national food supply. 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).

## Training

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

This appendix provides training resources and services available through both public and governmental websites that can promote a better understanding of hazards that could commonly result from the type of biological incidents covered in this document. 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.

The following is a list of websites that provide 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 falls under FBI Biosecurity and Awareness Training, which is managed by the FBI WMD Directorate's Chemical Biological Countermeasures Unit (CBCU). The FBI Biosecurity and Awareness Training is designed to prevent the misuse of biological knowledge and materials. For more information on training opportunities and resources, contact the FBI WMD Directorate at [WMDD.Training@fbi.gov](mailto:WMDD.Training@fbi.gov).

The National Institute of Environmental Health Sciences (NIEHS) Worker Training Program (WTP) and its grantee partners work with community organizations to provide health and safety training as well as to advance racial equity and support for underserved communities by providing training to and increasing job opportunities for people.

# Appendix U: Outstanding Policy Issues

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## Purpose

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

## Mass Care and Human Services

This *Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plan (FIOP)* is considered a “living” document and contains information that is subject to change over time. This plan, along with its supporting documents, will undergo a review as required. The following areas are identified as requiring additional development and refinement:

- Identify and address 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 arise during a biological incident due to the unique characteristics of a disease outbreak. Existing resources for the physical and emotional well-being of impacted populations are likely to be exceeded rapidly. The Unified Coordination Group (UCG) may consider additional support through the Substance Abuse and Medical Health Services Administration (SAMHSA) Disaster Technical Assistance Center; subject matter expert (SME) support to the Department of Health and Human Services (HHS)/Office of the Assistant Secretary for Preparedness and Response (ASPR) Secretary’s Operations Center (SOC) from the ASPR Technical Resource Guide; or expansion of Emergency Support Function (ESF) support by the Federal Resource Coordinator/UCG.
- Augment mass care capabilities to reduce the burden on healthcare facilities (including 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 need to coordinate efforts closely with the 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 when 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 U.S. Public Health Service (USPHS), service access teams, and Individual Assistance-Technical Assistance Contract (IA-TAC) staff;

delivery service organizations; and non-governmental organizations (NGOs), such as the American Red Cross, The Salvation Army, and Voluntary Organizations Active in Disasters (VOADs). ESF #6 (Mass Care, Emergency Assistance, Temporary Housing, and Human Services), ESF #7 (Logistics), and ESF #8 (Public Health and Medical Services) should be followed for guidance on coordinating meals, home healthcare, medical countermeasures (MCMs), and other assistance.

- Animal care, treatment, sheltering, and placement are managed according to SLTT jurisdictional plans and supported by ESF #6, ESF #8, and ESF #11 as well as national NGOs.
- Support resources are required (at shelters and 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 PPE and MCMs**

There are several ways to prioritize receipt of personal protective equipment (PPE) and MCMs; however, having a method for classifying 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 many challenges based on the agent, the magnitude of the outbreak, and resource availability. Additional policy decisions 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; use HHS/Department of Labor (DOL) decision protocols to assess occupational risk and develop/update recommendations for the protection of the workforce; or defer to interagency coordination between HHS, HHS/Centers for Disease Control and Prevention (CDC), and DOL to modify existing agency recommendations. A combination of all three options is also a possibility. In a UCG setting, Department of Homeland Security (DHS)/FEMA and HHS coordinate and prioritize all resources. For specific resource allocation challenges, the National Security Council (NSC) can provide guidance to the UCG.

### ***Coordinate and Support Continuity of Critical Infrastructure Capabilities to Maintain Continuity of National Essential Functions***

Per Presidential Policy Directive 40 (PPD-40), National Essential Functions (NEFs) are the core functions that are necessary to lead and sustain the nation during a catastrophic emergency. NEFs and primary mission-essential functions (PMEFs) can be utilized as criteria to help identify and prioritize critical infrastructure. The need for the government to be able to perform essential functions and deliver services to the nation is built upon the foundation

of infrastructure and that relationship needs to be addressed as part of the critical infrastructure framework.

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 public. Methods to assure continued operational capabilities may include coordination among Sector Risk Management Agencies (SRMAs), Sector Coordinating Councils (SCCs), the Continuity Advisory Group, and Government Coordinating Councils; assessments and support through related ESFs; and coordination through a combination of ESFs, the National Incident Coordination Center (NICC), and SRMAs/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; personnel shortages are further impacted as staff becomes part of the affected population. Recovery measures to facilitate the salvaging of critical infrastructure may be in Annex E (Infrastructure Systems Recovery Support Function Operation) of the *Response and Recovery Federal Interagency Operational Plan* (FIOP). Otherwise, such measures may be developed or initiated via identification of Level 1 and 2 critical infrastructure and key resources (CIKR) in affected areas by the DHS Homeland Infrastructure Threat and Risk Analysis Center and the Office of Cyber and Infrastructure Analysis; implementation of CIKR and other support plans via HHS and SLTT coordination; or collaboration between SLTTs and the Environmental Protection Agency (EPA) to develop and implement plans.

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

### **Provision of Support to Public Health and Medical Surge Needs and Conservation of Public and Private Healthcare/Pharmaceutical Supply Chains**

There is limited capability between interagency partners to provide support for public health and medical surge needs as well as to 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 force workers may be called upon to assist 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 members and non-clinical volunteers, National Disaster Medical System (NDMS) teams, Field Medical Stations (FMSs), DHS Surge Capacity Force, federal clinical personnel, other

ESF #6 and ESF #8 resources, and Department of Defense (DOD) personnel, if available. Maintaining or surging existing supply chains for medical (and veterinary) materiel, including medications, supplies, and equipment, could be accomplished using foreign aid or the Defense Production Act (DPA) but there could be delays in receiving products. A work group could be formed to review policy implications (e.g., sending federal teams into potentially harmful environments) and resource shortages for meeting objectives.

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

Since the issuance of Executive Order (EO) 13527, Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack (Dec. 30, 2009), the federal government 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, detailed timelines for resource movement, and the logistics required to move MCMs. In each of the 10 largest U.S. cities that participated in the Urban Area Security Initiative, there now exists 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 of required doses for each POD are now known. By far the greatest of the limitations in these plans is the ability to staff PODs in time to disseminate MCMs within the window in which they are 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 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**

Previous experience with the handling of contaminated waste generated by patients with the 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 that 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 (e.g., waste classification, waste minimization, segregation, storage) should 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 should primarily focus on the safety of the people who handle or package—or otherwise risk contact with—contaminated materials. Plans should pre-identify whether waste is inactivated on-site or is transported to a final treatment and disposal site.

Although infectious waste is not regulated under the Resource Conservation and Recovery Act (RCRA), the waste generated may contain other materials which could be classified as RCRA Hazardous Waste. Such waste should be managed according to the appropriate RCRA regulations.

In the past, waste management facilities have refused to accept waste from biological incidents, even fully inactivated waste demonstrated to contain no infectious agents. Community pressure has a significant influence on these decisions, therefore early communication with community groups to explain the decontamination process as well as how waste is tested to determine that it has been successfully decontaminated is advised.

Waste generated from assessment and cleanup activities should be incinerated, autoclaved, or chemically disinfected to be sure infectious agents are inactivated. Complex aqueous matrices, such as contaminated wastewater or decontamination effluents, may have significant oxidant demand, requiring additional chemical disinfectant. Porous materials present challenges to waste treatment processes. Waste disposal for agent-contaminated wastes generated from the decontamination activities may be problematic. Disposal of aqueous waste, even if chemically treated, via discharge to sanitary sewer may require consultation with the respective authorities. On-site treatment (e.g., autoclaving) prior to transport for off-site disposal may ease the requirements for special transportation permits. Landfills willing to take these wastes may be limited due to state requirements. It may be prohibitively expensive or impractical to dispose of infectious wastes through incineration due to a limited number of medical/infectious waste incinerators nationally. Assuming that agent-contaminated wastewater is accepted by local wastewater facilities, even if pre-treated, it may be difficult to dispose of resulting sludge.

Although testing may be desired to satisfy waste acceptance criteria specified by state regulators and/or a treatment/disposal facility, there are very limited options for measuring biological agents in common waste matrices, and other approaches (e.g., proof of compliance with minimum operating conditions of on-site treatment equipment) could be used to specify waste acceptance criteria. All waste disposal options, and waste acceptance criteria, should be investigated as early in the response process as possible.

Transportation of potentially contaminated wastes from the site to a treatment/disposal facility may present challenges as well. First, agreements must be reached between the offeror and acceptor before transport, followed by timely public notification of transport and disposal activities. The DOT/PHMSA regulates movement of hazardous materials across all modes of transportation through Hazardous Materials Regulations (HMRs), which are designed to minimize risks to life, property, and the environment during the transportation of hazardous materials. HMRs provide clear regulations for classification, packaging, and communications 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). Any waste contaminated with biological agents would likely be considered a Category A infectious

substance for transportation purposes. See *Managing Solid Waste Contaminated with a Category A Infectious Substance* (June 2022) at <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2022-06/Cat%20A%20Waste%20Planning%20Guidance%20-%20Final%20-%202022-06.pdf>.

EPA has developed an online tool to help communities and facilities develop pre-incident waste management plans. This tool can be found at <https://wasteplan.epa.gov/>.

EPA has developed I-WASTE, a web-based tool that contains links to waste transportation guidance, treatment and disposal facilities, state regulatory offices, packaging guidance, and guidance to minimize the potential for contaminating the treatment or disposal facility. Access to this decision support tool requires pre-registration ([www2.ergweb.com/bdrtool/login.asp](http://www2.ergweb.com/bdrtool/login.asp)).

Consideration must be given on how to handle, process, and address the disposition of contaminated/infected human remains from a biological incident as well as contaminated/infected animal carcasses.

The current language of the Decontamination Standards and Clearance Goals needs to be reevaluated and possibly condensed during the next iteration of the BIA update.

The next iteration of the BIA update should be condensed regarding HMRs while including considerations for the housing of exposed or infected populations.

Consider including in the next iteration of the BIA the need to export any samples or waste during a domestic response that would be associated with the Department of Commerce (DOC)/Bureau of Industry and Security role due to export licensing.

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

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 comprising of the highest ranking local federal officials in metropolitan areas; FEB officers are elected annually and serve on a voluntary basis. The OPM has oversight of FEBs and can work with DHS/FEMA to assist with the awareness and interagency communications of federal PODs in FEB areas.

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# Appendix V: Authorities and Other References

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## Primary Authorities<sup>41</sup>

This appendix identifies and describes authorities applicable to this *Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plan (FIOP)*. Authorities are divided into two categories: Public Health and Medical Authorities (key authorities) and Other Authorities and References. They include Presidential Policy Directive (PPD)-8 (National Preparedness), National Security Presidential Memorandum (NSPM)-36 (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 Public Health Service Act (PHSA), and numerous federal criminal statutes. Certain federal agencies are authorized to respond directly to specific biological incidents.

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

Federal agencies may take appropriate independent emergency actions within the limits of their own statutory and/or regulatory authorities to protect the public, mitigate immediate hazards, and gather information concerning the emergency to avoid delay. Key authorities applicable to this appendix are listed in the following sections.

## Public Health and Medical Authorities and References

The authorities that guide the structure, development, and implementation of the Response and Recovery FIOP and this annex are statutes, Executive Orders (EOs), regulations, Presidential directives, memoranda of understanding (MOUs), and memoranda of agreement (MOAs). Congress has provided the broad statutory authority necessary for this plan, and the President has issued EOs and Presidential directives to supply policy direction

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<sup>41</sup> Federal laws prohibit discrimination in federally conducted programs and activities as well as programs and activities receiving federal aid to ensure that actions, both intentional and unintentional, do not exclude anyone based on race, color, national origin (including individuals with limited English proficiency), disability, sex, religion, economic status, or familial status in the preparation, response, or recovery phases of emergency and disaster management. <https://www.dhs.gov/civil-rights-emergencies-and-disasters>

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>42</sup> (OSH Act) was passed to prevent workers from being killed or seriously harmed at work. This law created the Department of Labor (DOL)/Occupational Safety and Health Administration (OSHA), which sets and enforces protective workplace safety and health standards. DOL/OSHA also provides information, training, and assistance to employers and workers. 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. DOL/OSHA's primary role is to provide oversight and guidance for federal department and agency 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 DOL/OSHA is operating in a technical assistance and support mode, FEMA's established standards remain in effect and DOL/OSHA retains its ability to enforce the standards under its legal authority. Although some states operate their own DOL/OSHA-approved occupational safety and health programs (state plans), DOL/OSHA federal offices provide coordination, technical assistance, support services, and oversight in all 50 states, U.S. territories, and the District of Columbia.

EO 12196 extends the protections provided to federal employees under the OSH Act to private sector employees. Generally, federal employer responsibilities under the EO and OSH Act apply no matter where the federal employee is located (including outside the continental U.S.). The EO and OSH Act do not cover uniformed military personnel, U.S. Coast Guard (USCG) personnel, members of the Department of Commerce (DOC)/National Oceanic and Atmospheric Administration (NOAA) Commission Corps, the U.S. Public Health Service (USPHS) 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)

The PHSA<sup>43</sup> forms the foundation of the HHS legal authority for responding to Public Health Emergencies (PHEs). 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* (NRF), to direct the PHS and other components of the department to respond to a PHE, 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

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<sup>42</sup> Occupational Safety and Health Act of 1970, Pub. Law 91-596 (as amended by 29 U.S.C. §§ 651-678).

<sup>43</sup> Public Health Service Act of 1944, Pub. Law 78-410 (as amended by 42 U.S.C. §§ 201 et seq.).

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, and certain classes of people involved in the administration of a program to deliver covered treatments to patients and their employees.

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

Under Section 319 of PHS Act, 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 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.C. § 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 as 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 PHS Act 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 PHE, 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 PHS Act, 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 42 CFR 70 and 71, the HHS/Centers for Disease Control (CDC) is authorized to detain, medically examine, and release persons arriving in the United States and traveling between states who are suspected of carrying 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>44</sup> (FD&C Act) is the foundation for the HHS/Food and Drug Administration (FDA) authority and responsibility for protecting and promoting 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 national food supply. During a biological incident, medical products regulated by the HHS/FDA may need to be used to mitigate health impacts with certain flexibilities. For example, under Section 564 of the FD&C Act, the HHS/FDA Commissioner may authorize the use of certain unapproved drug, device, or biological products (e.g., 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 that circumstances exist to justify the use of EUA for unapproved drugs, devices, or biological products or for unapproved uses of approved drugs, devices, or biological products.

In addition, the HHS/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 serious or life-threatening diseases or conditions caused by a chemical, biological, radiological, or nuclear [CBRN] threat agent or emerging infectious disease when, among other criteria, there are no adequate, approved, and available alternatives to the product). An EUA no longer remains in effect when the HHS EUA declaration that supports it is terminated (e.g., because the emergency or threat circumstances have ceased to exist), when it is revoked by HHS/FDA (e.g., to protect the public health or safety because it is determined that the criteria for issuance are no longer met), or when revocation is appropriate to protect public health or safety.

Once a Secretarial determination is made, the Commissioner of the HHS/FDA may issue an EUA for specific 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).

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<sup>44</sup> Federal Food, Drug, and Cosmetic Act, Pub. Law 75-717 (as amended at 21 U.S.C. §§ 301-399f).

Public Law 115-92 (H.R.4374), enacted December 12, 2017, amended Section 564 of the FD&C Act to allow for emergency uses of medical products for threats in addition to CBRN agents, to include other agents that may cause or are associated with an imminently life-threatening and specific risk to U.S. military forces. Public Law 115-92 also authorized the Department of Defense (DOD) to request, and FDA to provide, assistance to expedite development and FDA product review to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel.

### **Project BioShield Act**

In 2004, the Project BioShield Act<sup>45</sup> amended the PHSA and the FD&C Act to provide flexible authorities to expedite and enhance the research, development, procurement, and stockpiling of MCM for CBRN threat agents and authorized funding for procurement of those MCMs. The Act also provides HHS with a broader ability to quickly authorize use of certain MCMs during emergencies. The authorities enacted under the Project BioShield Act were further clarified and expanded under the Pandemic and All-Hazards Preparedness Act (PAHPA) (Pub. Law 109-417) and the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) (Pub. Law 113-5).

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

The PAHPA of 2006 amended the PHSA and designates the Secretary of HHS to lead all federal public health and medical responses to public health emergencies and incidents. It also established within HHS a new Assistant Secretary for Preparedness and Response (ASPR) and provides new authorities for several programs, including the advanced development and acquisition of MCMs. PAHPA places the NDMS under the purview of HHS and calls 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 PHSA to reauthorize funding for public health and medical preparedness programs (e.g., the Hospital Preparedness Program and Public Health Emergency Preparedness Cooperative Agreement) and for the purchase of MCMs. The legislation increases the flexibility of Project BioShield as well as state health departments in dedicating staff resources to meet critical community needs in a disaster. Also, PAHPRA enhances the authority of the HHS/FDA to support stakeholder preparedness for rapid MCM responses in advance of a PHE by amending the authority to permit issuance of EUAs in advance of an emergency when there is a significant for potential for a public health emergency. PHEs and PAHPRA also provide additional MCM EUAs under the FD&C Act to

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<sup>45</sup> Project BioShield Act of 2004, Pub. Law 108-276 (as amended at 21 U.S.C. § 360bbb-3; 42 U.S.C § 247d-6a, 247d-6b).

facilitate the use of approved MCM products, such as the authority for HHS/FDA to issue emergency dispensing orders without having to issue an EUA.

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

The 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) amended the PHS Act and authorizes new public health and medical preparedness programs for regional healthcare preparedness and military and civilian partnerships and reauthorizes funding and enhances authorities for the Hospital Preparedness Program, Public Health Emergency Preparedness Cooperative Agreement program, and other public health and medical preparedness programs. PAHPAIA also authorizes uses for the PHEF when the Secretary declares a PHE or determines that there is a significant potential for a PHE and authorizes advanced funding for buying MCMs under the Project BioShield Act as well as to support advanced research and development of potential MCMs.

PAHPAIA also amends the FD&C Act to enhance the authority of the HHS/FDA to support rapid responses to public health emergencies.

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

The Public Readiness and Emergency Preparedness Act<sup>46</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 MCMs 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 each of these groups; and the federal 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 MCMs covered by the declaration.

### **Social Security Act (Section 1135: Authority to Waive Requirements during National Emergencies)**

The Social Security Act 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

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<sup>46</sup> Public Readiness and Emergency Preparedness Act (PREP Act), Pub. Law 109-148 (42 U.S.C. §§ 247d-6d, 247d-6e).

under the PHSA. Waivers may be requested by affected healthcare 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 the determination of termination of a PHE under the PHSA. 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 (EMTALA) 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>47</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>48</sup>

## National Emergencies Act

Several federal statutes provide “springing” authorities that may only be triggered by a declaration of a national emergency by the President. The NEA<sup>49</sup> establishes procedures and requirements for the Presidential invocation of national emergency authorities, such as the authority to impose export controls under other federal statutes.

## 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 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.

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<sup>47</sup> <https://www.cms.gov/files/document/alternativecaresitefactsheetpdf>.

<sup>48</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>49</sup> National Emergencies Act, Pub. Law 94-412, 90 Stat. 1255, enacted September 14, 1976, codified at 50 U.S.C. § 1601-1651.

## **Coronavirus Aid, Relief, and Economic Security Act (CARES Act)**

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) was signed into law on March 27, 2020, to aid response efforts and ease the economic impact of Coronavirus disease 2019 (COVID-19). In addition to the COVID-19 response efforts, the CARES Act includes authorities intended to enhance FDA abilities to identify, prevent, and mitigate possible medical product shortages by, among other things, enhancing FDA visibility into supply chains. Medical product shortages can occur for many reasons, including manufacturing and quality problems, delays, and discontinuations. Medical product manufacturers provide FDA with most of the shortage information the agency receives, and the agency works closely with manufacturers to prevent or reduce the impact of shortages.

## **Other Authorities and References**

### **National Biodefense Strategy**

The National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security brings together and puts in place for the first time, a single coordinated effort to orchestrate the full range of activity that is carried out across the federal government to protect the American people from biological threats. With NSPM-15, this strategy explains how the federal government manages its activities more effectively to assess, prevent, detect, prepare for, respond to, and recover from biological threats, coordinating its biodefense efforts with those of international partners, industry, academia, non-governmental entities, and the private sector.

### **National Security Memorandum-1 (NSM-1): United States Global Leadership to Strengthen the International COVID-19 Response and to Advance Global Health Security and Biological Preparedness**

The COVID-19 pandemic is a grave reminder that biological threats, whether naturally occurring, accidental, or deliberate, can have significant and potentially existential consequences for humanity. This memorandum reaffirms EO 13747 of November 4, 2016, which made clear that these threats pose global challenges that require global solutions. United States international engagement to combat COVID-19 and advance global health security and biopreparedness is thus an urgent priority—to save lives, promote economic recovery, and develop resilience against future biological catastrophes. The federal government treats epidemic and pandemic preparedness, health security, and global health as top national security priorities and works with other nations to combat COVID-19, seeking to create a world that is safe and secure from biological threats.

### **National Security Memorandum-2 (NSM-2): Organization of the National Security Council System**

NSM-2, Renewing the National Security Council System, issued by President Biden on February 4, 2021, describes the national security policy development and decision-making

system for the President as well as the role and membership of the National Security Council (NSC) and their subordinate committees, including the Principals Committee (PC), the Deputies Committee (DC), and the management of the development and implementation of national security policies by multiple interagency policy committees (IPCs). NSM-2 is one in a series of Presidential memoranda that communicate Presidential decisions about the national security policies of the United States.

### **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 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, PPD-44 provides a process for the identification of a lead federal agency (LFA) and senior response official to lead coordination of the federal incident response. Given DHS/FEMA's experience and important role in assisting the American people during crises, PPD-44 states that DHS/FEMA may assist the lead agency in coordinating a federal incident response. PPD-44 does not change the way that SLTT officials respond to incidents and does not alter the way that DHS/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 (ESF) 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 (e.g., 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 SLTT 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 communities and build a more resilient nation.

## **Response and Recovery Federal Interagency Operational Plan (FIOP)**

The *Response and Recovery Federal Interagency Operational Plan* (FIOP) guides federal departments and agencies (hereafter “federal agencies”) in executing the Response and Recovery Mission Areas of the National Preparedness Goal to achieve Unity of Effort through coordination and communication following an incident for which an interagency response is required. Response and recovery are two of the five mission areas of the National Preparedness Goal. Although these are distinct mission areas, the importance of coordination and integration of their activities has become apparent in managing incidents, stimulating the production of a single response and recovery FIOP.

## **National Security Memorandum 15 (NSM-15): Support for National Biodefense**

NSM-15 launched the National Biodefense Strategy and Implementation Plan for Countering Biological Threats, Enhancing Pandemic Preparedness, and Achieving Global Health Security (the Strategy), a whole-of-government effort across 20 federal agencies to detect, prevent, prepare for, respond to, and recover from biological incidents, in partnership with our international, state, local, tribal, territorial, and private sector partners. NSM-15 supports execution of the Strategy by strengthening the coordination of biodefense efforts across government by centralizing oversight of policy coordination at the White House to ensure accountability for implementing the Strategy and in so doing to bring together the strengths of all federal agencies; directing departments and agencies to prioritize biodefense and implementation of the Strategy in their annual budgets; directing the Intelligence Community to closely monitor the evolving biothreat landscape and provide critical and potentially time-sensitive information needed to address naturally occurring, accidental, and deliberate biothreats; ensuring that the federal government continuously adapts to the evolving threat landscape by exercising annual biodefense emergency response plans, reviewing ongoing responses, and adjusting federal priorities on a regular basis to account for lessons learned.

## **Homeland Security Presidential Directive 5 (HSPD-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 (NIMS). This management system provides a consistent nationwide approach to prevent, protect against, mitigate, 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 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. The DHS Secretary coordinates federal resources that are used in the response to or

recovery from terrorist attacks,<sup>50</sup> 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 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 and at the discretion of the Secretary of Homeland Security as to how they execute their HSPD-5 responsibilities.

### **National Security Memorandum 16 (NSM-16): Defense of U.S. Agriculture and Food**

NSM-16 establishes a national policy to strengthen the security and resilience of U.S. food and agriculture. For additional details, refer to the *Food and Agricultural Incident Annex* (FAIA).

### **Homeland Security Presidential Directive-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 (WMD). It acknowledges that always having sufficient resources on hand in 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 involves a focused development of agent-specific MCMs and Tier II concerns the development of a flexible capability for new MCMs. HSPD-18 provides that DHS shall develop and update at least every 2 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. 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 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

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<sup>50</sup>This does not include activities that may interfere with those of the Attorney General or the DOJ/FBI Director, as described in HSPD-5, paragraph 8, and other applicable Presidential policy directives and memoranda.

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.

### **EO 13527: Medical Countermeasures Following a Biological Attack**

EO 13527 serves as the framework for the federal government to plan and prepare for the timely provision of MCMs 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.

### **EO 13887: Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health**

EO 13887 aims to expand domestic capacity to rapidly respond to emerging influenza viruses and to advance the development of influenza MCMs.

### **Animal Health Protection Act**

The Animal Health Protection Act authorizes the Secretary of Agriculture to restrict the importation, entry, or further movement in the United States, or to order the destruction or removal, of animals (including livestock) and related conveyances and facilities for reasons of livestock pest or disease control or humane treatment. It authorizes related activities regarding exportation, interstate movement, cooperative agreements, enforcement and penalties, seizure, quarantine, and disease and pest eradication.

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

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), commonly referred to as the Superfund Act, was enacted to provide response authorities to actual or potential releases of (1) hazardous substances or (2) pollutants or contaminants that may present an imminent and substantial danger to public health or welfare.<sup>51</sup>

CERCLA's implementing regulation is the National Oil and Hazardous Substances Pollution Contingency Plan (40 CFR 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 DHS/USCG with the authority to gather information, collect samples, and take action to contain and mitigate the threat. EPA and/or DHS/USCG environmental assessments, decontamination/cleanup, and waste management activities may be conducted under CERCLA or, if there is a Stafford Act declaration, under an ESF #10 (Oil and Hazardous Materials Response) mission assignment.

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<sup>51</sup> Subject to certain limitations. See 42 U.S.C. § 9604(a)(3).

## 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 national reliance on land disposal of hazardous waste. U.S. regulations under RCRA<sup>52</sup> 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 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, packaged as regulated medical waste, or handled as a special Category A infectious 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 are likely to be involved in a biological incident response.

*Managing Solid Waste Contaminated with a Category A Infectious Substances* addresses planning for Category A waste management activities, including considerations for developing, evaluating, and revising organizational or jurisdictional plans and protocols. Overarching planning considerations and governmental roles and responsibilities as they relate to Category A waste are also addressed. This document contains information for and describes the responsibilities of those who generate, treat, or inactivate, transport, and dispose of Category A waste. Also included is a section on worker health and safety that discusses protecting employees involved in waste management activities from initial generation to final disposition. The guidance is supplemented by several appendices that provide additional resources, assist with decision making, and address questions and answers about Category A waste.

## Homeland Security Act of 2002

The Homeland Security Act of 2002<sup>53</sup> created DHS as an executive department of the federal government. The Act consolidated component agencies, including DHS/FEMA, into the Department. The Secretary of Homeland Security is the head of DHS and has direction, authority, and control over it. The functions of all officers, employees, and organizational units of DHS are vested in the Secretary. The mission of DHS includes preventing terrorist attacks within the United States, reducing American vulnerability to terrorism, and minimizing the damage of and recovering from attacks that occur.

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<sup>52</sup> <http://www.epa.gov/rcra>.

<sup>53</sup> Homeland Security Act of 2002, Pub. Law 107-296 (codified as amended at 6 U.S.C. §§ 101-629).

## Post-Katrina Emergency Management Reform Act

The PKEMRA<sup>54</sup> clarified and modified the Homeland Security Act with respect to organizational structure, authorities, and responsibilities of DHS/FEMA and the DHS/FEMA Administrator. Enacted as part of the DHS Appropriations Act of 2007, PKEMRA was intended to address various shortcomings identified in the preparation for and response to Hurricane Katrina. The Act enhanced DHS/FEMA responsibilities and its autonomy within DHS. Per PKEMRA, DHS/FEMA's responsibility is to lead and support the nation in a risk-based, comprehensive emergency management system of preparedness, protection, mitigation, response, and recovery. Under the act, the DHS/FEMA Administrator reports directly to the Secretary of Homeland Security. DHS/FEMA is a distinct entity within DHS, and the Secretary of Homeland Security can no longer substantially or significantly reduce the authorities, responsibilities, or functions of DHS/FEMA—or the capability to perform them—unless authorized by subsequent legislation. The Act further directed the transfer to DHS/FEMA of many of the functions of DHS's former Preparedness Directorate.

## Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act)

The Stafford Act<sup>55</sup> authorizes the programs and processes by which the federal government provides disaster and emergency assistance to SLTT governments, 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 tribe, the President may declare a major disaster or emergency if an incident is beyond the combined response capabilities of SLTT governments. Among other things, such a declaration allows federal assistance to be mobilized and directed in support of SLTT response efforts. Under the Stafford Act (42 U.S.C. § 5191(b)), the President can also declare an emergency without a gubernatorial request if the 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 support, where necessary, to save lives, prevent human suffering, or mitigate severe damage and to notify the state of that activity.

## 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

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<sup>54</sup> Post-Katrina Emergency Management Reform Act (PKEMRA) of 2006, Pub. Law 109-295.

<sup>55</sup> Robert T. Stafford Disaster Relief and Emergency Assistance Act, Pub. Law 93-288 (as amended primarily at 42 U.S.C. §§ 5121-5207).

determines that the requested support cannot otherwise be provided by contract more conveniently or cheaply through a commercial enterprise.

## Defense Production Act

The Defense Production Act<sup>56</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 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 to Title VI of the Stafford Act, efforts to protect and restore critical infrastructure; and efforts to prevent, reduce vulnerability to, minimize damage from, and recover from acts of terrorism within the United States. Presidential DPA authorities are delegated to the heads of various federal departments via EOs 13603, 13909, 13910, and 13911.<sup>57</sup> The DPA, however, does not necessarily increase the production of critical resources if those production lines are already operating at maximum capacity and the demand for such resources are high, resulting in significant national shortages.

The DPA provides multiple types of authorities that could, potentially, be used to combat a pandemic, as follows: DPA Title I: Priorities and Allocations Authorities, DPA Title III: Financial Incentive Authority, the Installation of Government Equipment, and DPA Title VII: Voluntary Agreements between the U.S. Government and two or more representatives of industry.

## 9/11 Commission Act of 2007

The Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Commission Act) established within DHS the 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 incidents 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 incidents 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. The NBIC has identified the following agencies as NBIS partners: U.S. Department of Agriculture (USDA), DOC, DOD, Department of Energy (DOE), HHS, Department of the Interior (DOI), Department of Justice (DOJ), Department of State (DOS), Department of Transportation (DOT), Department of Veterans Affairs (VA), U.S. Postal Service (USPS), and EPA as well as SLTT agencies who are provided access to information and analysis and are allowed to contribute data.

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<sup>56</sup> Defense Production Act of 1950, as amended (50 U.S.C. § 4501 et seq.).

<sup>57</sup> Executive Order 13603 of March 16, 2012: National Defense Resources Preparedness.

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# Appendix W: Glossary

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**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.

**Assumption:** Provides a supposition about the current situation or future course of events that is presumed to be true based on an assessment of available facts.

**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. Government program to detect the aerosolized presence of select pathogens in the air in 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 agents 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:** A 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, in the environment, or on or in clothes, bedding, toys, surgical instruments or dressings, or other inanimate articles or substances, including water, milk, and food.

**Critical Consideration:** Elements of information that provide necessary context to help explain the limitations that may constrain or restrain the execution of a plan.

**Critical Workforce:** Public and private sector workers who conduct a range of operations and services that are essential to continuity of public health and safety, infrastructure viability, as well as economic and national security.

**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 identification of a biological pathogen of concern.

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

**Disease Surveillance:** An epidemiological practice by which the spread of disease is monitored in people and animals to establish patterns of progression. The main role of disease surveillance is to predict, observe, and minimize the harm caused by outbreak, epidemic, and pandemic situations as well as increase knowledge about which factors contribute to such circumstances.

**Disinformation:** False information deliberately and often covertly spread (as by the planting of rumors) to influence public opinion or obscure the truth (e.g., Ivermectin can prevent and treat COVID, dietary supplements can prevent COVID).

**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 their investigation.

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

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

**Fact:** Statement of information known to be true and necessary for the development of a plan.

**First Receiver:** Employees at a hospital engaged in decontamination and treatment of victims who have been contaminated by a hazardous substance 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, 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.

**Malinformation:**<sup>58</sup> Based on fact, but used out of context to mislead, harm, or manipulate (e.g., Russia and China have promoted their vaccines by focusing on the deaths during the Pfizer trials [but out of context] and highlighted any positive stories about their vaccines).

**Misinformation:** Information that is false, inaccurate, or misleading according to the best available evidence at the time (e.g., vaccines don't work as well for protection as getting COVID).

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

**Multi-Agency Coordination Centers (MACCs):** 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 the Department of Homeland Security (DHS) established to enhance the Nation's capability for integrating 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 (NPIs):** Items such as ventilators, devices, personal protective equipment (PPE) such as face masks and gloves, and public health interventions (e.g., contact and transmission interventions, social distancing, community shielding) to prevent and mitigate the health effects of biological agents, some of which may be HHS/Food and Drug Administration (FDA)-regulated and some of which may not.

**Outbreak:** An increase in a disease in a certain geographic area over a certain period and above an expected baseline. (An outbreak may require just one case for smallpox, for example, but, for other diseases, 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, fungi) or infectious agents (e.g., prions) that cause disease in human beings.

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

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<sup>58</sup> <https://www.cisa.gov/mdm>.

**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 presenting symptoms. These individuals are physically separated and their movements 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.

**RO:** Pronounced “R naught,” RO is a mathematical term that indicates how contagious an infectious disease is. It is also referred to as the reproduction number. As an infection is transmitted to new people, it reproduces itself.

**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, which are 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.

# Appendix Y: Acronyms and Abbreviations

**Table Y-1: Acronyms and Abbreviations**

Acronym	Term
ACF	Administration of Children and Families
ACS	Alternate Care Sites
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	Administration for Strategic 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, and nuclear
CBRNE	chemical, biological, radiological, nuclear, and high-yield explosives
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CIKR	critical infrastructure and key resources
CMCU	Consequence Management Coordination Unit
COCA	Clinician Outreach and Communication Activity
COG	Continuity of Government
COM	Chief of Mission
COOP	Continuity of Operations
CWMD	Countering Weapons of Mass Destruction Office
CVB	Center for Veterinary Biologics
DEST	Domestic Emergency Support Team
DME	durable medical equipment
DHS	Department of Homeland Security
DLN	Department of Defense Laboratory Network
DMAT	Disaster Medical Assistance Team
DMORT	Disaster Mortuary Operational Response Team
DOC	Department of Commerce

Acronym	Term
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
DSCA	Defense Support of Civil Authorities
D-SNAP	Disaster Supplemental Nutrition Assistance Program
ECC	Environmental Clearance Committee
EIS	Epidemic Intelligence Service
EO	Executive Order
EOC	Emergency Operations Center
EMMO	Emergency Management and Medical Operations
EPA	Environmental Protection Agency
Epi-X	Epidemic Information Exchange
ERLN	Environmental Response Laboratory Network
ESF	Emergency Support Function
ETA	Employment Training Administration
EUA	Emergency Use Authorization
FAA	Federal Aviation Administration
FBI	Federal Bureau of Investigation
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
HCW	healthcare worker
HHS	Department of Health and Human Services
HHS SOC	Health and Human Services Secretary's Operation Center
HIPAA	Health Insurance Portability and Accountability Act
HIPPS	Department of Health and Human Services International Policy Group for Personnel Sharing

Acronym	Term
HPR	Homeland Preparedness and Response
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
IPC	Interagency Policy Committee
IHS	Indian Health Service
IMAAC	Interagency Modeling and Atmospheric Assessment Center
IMT	Incident Management Team
JIC	Joint Information Center
JOC	Joint Operations Center
JTTF	Joint Terrorism Task Force
LRN	Laboratory Response Network
MaHIM	Medical and Health Incident Management
MCMs	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
NFP	National Focal Point
NGO	non-governmental 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

Acronym	Term
NPDN	National Plant Diagnostic Network
NPHIC	National Public Health Information Coalition
NHTSA	National Highway Traffic Safety Administration
NPI	non-pharmaceutical intervention
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
OHS	Office of Health Security
OFDA	Office for Foreign Disaster Assistance
OPM	Office of Personnel Management
OPP	Office of Policy and Planning
OSC	On-Scene Coordinator (ESF-10) On-Scene Coordinator (FBI)
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 Declaration
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
PKEMRA	Post-Katrina Emergency Management Reform Act
POD	point of distribution
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
RSS	Resource Support Sections

Acronym	Term
SAMHSA	Substance Abuse and Medical Health Services Administration
SCC	Sector Coordinating Council
SCCT	Supply Chain Control Tower
SLTT	state, local, tribal, and/or territorial
SNS	Strategic National Stockpile
SOC	Secretary's Operation Center
SRMA	Sector Risk Management 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
USGS	U.S. Geological Survey
USPHS	U.S. Public Health Service
USNORTHCOM	U.S. Northern Command
VA	Department of Veterans Affairs
VMI	Vendor-Managed Inventory
WFRC	Western Fisheries Research Center
VOAD	Voluntary Organizations Active in Disasters
WHO	World Health Organization
WMD	Weapons of Mass Destruction
WMD-CT	Weapons of Mass Destruction Counterterrorism
WMDSG	Weapons of Mass Destruction Strategic Group

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# Attachment 1: Branch 1 Plan: Intentional Biological Incidents

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## Situation

This branch plan addresses the unique nature of intentional biological threats and incidents.

## Purpose

This branch plan provides supplemental information to the *Biological Incident Annex (BIA) to the Response and Recovery Federal Interagency Operational Plan (FIOP)*. Federal interagency partners can respond in a lead role or in support of state, local, tribal, and territorial (SLTT) governments to save lives; protect property, critical infrastructure, the workforce, and the environment; and meet basic human needs when there is a threat of or an actual intentional incident involving biological agents.

## Scope

This branch plan applies to all federal responses to intentional biological threats and incidents, regardless of size, or complexity, biological agent, or toxin<sup>59</sup> unless otherwise noted, including but not limited to covert incidents where the need for immediate federal and state coordination is obvious, resource pre-positioning is not possible, and the exact nature of resource and asset requirements is not known.

## Facts

The following facts pertain to intentional biological threats and incidents:

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

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<sup>59</sup> The Branch 1 Plan (Intentional Biological Incidents) provides guidance on the law enforcement response to biological agents and biotoxins, including viruses, bacteria, fungi, and prions, that have the potential to pose a severe threat to public health and safety, to animal and plant health, to animal or plant products, or to national security.

- 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 PPE, and medical monitoring, medical examination, and fit-testing programs are in place.

## Planning Assumptions

The following planning assumptions pertain to intentional biological threats and/or incidents and are supplemental to the assumptions listed in the base annex of this BIA:

- **Incident Cause:** All suspected criminal incidents involving a biological agent are treated as an intentional biological incidents and all potential terrorist acts are treated as acts of terrorism until determined otherwise by the Attorney General, acting through the Department of Justice (DOJ)/Federal Bureau of Investigations (FBI) Director.
- **Method of Incident Detection:** There are many methods for detecting a biological incident such as (1) provision of intelligence information, (2) criminal and epidemiological investigations, (3) environmental monitoring (e.g., Department of Homeland Security [DHS] Countering Weapons of Mass Destruction Office [CWMD] BioWatch program), (4) electronic disease reporting and syndromic surveillance by public health authorities (e.g., Department of Health and Human Services (HHS)/Centers for Disease Control and Prevention (CDC) and SLTT health departments), and (5) animal/veterinary disease reporting. Depending upon the specific agent and associated symptoms, a delay could occur before public health and medical authorities detect a biological incident.
- **Response Timeline:** Federal assistance is mobilized as rapidly as possible, but there may be a significant delay for personnel to arrive on scene.
- **Federal and SLTT Government Response Delays:**
  - Full information about the biological agent is not immediately available and can take hours, days, or months to become known.
  - Availability and deployment vary depending on asset status, political decisions, and infrastructure availability.
  - Adequate federal and state resources (e.g., personnel, equipment, commodities, and materiel) capable of safe and efficient operations require several hours for activation, staging, and deployment prior to the commencement of tactical operations.
- **Exposed Population:** The incident requires a national effort to identify potential victims and refer them for medical follow-up, as appropriate.

- **Contamination Control:** Depending on the agent, contamination may spread to uncontaminated areas from movement through the contaminated zones.
- **Law Enforcement:** In all suspected intentional biological threats and incidents, DOJ/FBI leads and coordinates law enforcement and criminal investigative response and related intelligence activities to resolve the threat, including locally through the DOJ/FBI Joint Operations Center (JOC). Operational coordination with the DOJ/FBI On-Scene Commander (OSC) is critical to risk-informed operations and decisions during response, recovery, and prevention operations. At the national level, the DOJ/FBI-led Weapons of Mass Destruction Strategic Group (WMDSG) connects to the DOJ/FBI JOC.

## Critical Considerations

- **Immediate public information:** Public information must be accessible to older adults (who may not have smartphones), individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities), and individuals who are limited English proficient. There is an immediate need to inform the public on the situation and what protective actions to take.<sup>60</sup>
- **Simultaneous operational mission requirements:** Multiple interagency missions (e.g., counterterrorism, defense, continuity, response, and recovery) 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, must be shared comprehensively and immediately with the DOJ/FBI Joint Terrorism Task Forces (JTTFs) 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, benefits from operational coordination and information sharing with the Prevention Mission. Response efforts, therefore, requires timely threat reporting from the Prevention Mission to inform decisions or operations.

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<sup>60</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 messaging 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.

- **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 is key for triggering a federal prevention operation.
- **Locations as crime scenes:** The location of a biological threat and/or incident suspected or known to be intentional is 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 DOJ/FBI JOC to establish joint priorities to save lives, protect property, and conduct prevention activities.
- **Intentional incidents:** A biological threat and/or incident suspected or known to be intentional could take many forms. Mission area planning should account for a full range of possible incident scenarios. Incident scenarios may involve one or more, but are not limited to, the following characteristics:
  - *Non-contagious biological agent and biologically derived toxins:* Not all biological agents and biologically derived toxins are transmissible between humans or from animals to humans. In these circumstances, the cases of disease may be limited to those immediately exposed during the release; however, exposures could occur after 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 Mission Area operations 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 reach beyond international borders. It is critical that public health officials 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 bioterrorism attack may be temporally and geographically dispersed within a city or within a state, without a 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, Prevention and Response Mission operations may occur concurrently and possibly in different phases (see below) for different attacks/threats.
- *Indeterminate location(s)*: The location of a bioterrorism attack provides value to determining the methods of operation employed 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 officials, emergency management officials, and law enforcement and/or counterterrorism officials should coordinate with each other and share information to identify possible locations associated with the attack. Law enforcement and public health authorities may also be conducting joint criminal-epidemiological (Crim-Epi) investigations that can identify possible locations associated with the attack. While all biological threats and incidents are evaluated to determine if they may be an act of terrorism or otherwise criminal, the intentional release of a biological agent may be indistinguishable from a naturally occurring incident. As a result, all suspected criminal incidents involving a biological agent are treated as an intentional biological incident and all potential acts of terrorism are treated as acts of terrorism until determined otherwise by the Attorney General, acting through the DOJ/FBI Director. This results in response, Recovery, and Prevention<sup>61</sup> Missions occurring concurrently to save lives, protect property, and resolve threats.

If a biological incident is treated as intentional, such as a suspected or known to be intentional 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 Crim-Epi investigations to determine the cause. Numerous examples demonstrate the complexity of bioterrorism threats and the need for integrated Prevention, Response, and Recovery operations.

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

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<sup>61</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.

## Mission

### End State

In addition to the criteria described in the base annex, 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; and
- Intentional biological threats and incidents are attributed to perpetrators and they are held accountable.

### Execution

In response to an intentional biological incident, immediate priority must be given to saving lives and minimizing serious injury. Among other things, this requires clear, coordinated, and unified public messaging to address protective measures, such as the administration of medical countermeasures (MCMs) and other protective actions, including self-decontamination and/or sheltering-in-place when appropriate. Among other things, depending on the nature of the incident, the effective administration of MCMs, the immediate removal of contaminated clothing, showering, and staying indoors have the greatest impact on the health of affected populations in the first 24–48 hours. Immediate response actions must focus on the following:

- Characterizing the incident.
- Stopping the spread of disease.
- Promoting public health and safety measures to save lives and minimize serious injury to people and their animals as well as damage to the environment.
- Public messaging—accessible to individuals with disabilities (e.g., those who are deaf or hard of hearing, those who are blind or have low vision, individuals with cognitive or intellectual disabilities) and individuals who are limited English proficient—that conveys actionable and timely information to the whole community, including information on actions being taken and assistance being made available by SLTT authorities.
- Identifying those responsible for the attack.
- In accordance with applicable policy, public health and other authorities should address any fear/anxiety or other public concerns that may arise from misinformation, disinformation, or malinformation.

The notification and lead and supporting federal agencies implementing the response and recovery efforts differ depending on whether incidents are naturally occurring, intentional, or accidental.

## Recognition of an Intentional Biological Incident

The DOJ/FBI and its SLTT law enforcement partners maintain constant vigilance regarding threats of terrorism, including bioterrorism incidents. The public health community and emergency management officials should work closely with law enforcement regarding the positioning of resources and appropriate capabilities when indications of an intentional biological threat or incident emerge. Threat information is provided through a variety of sources, including open sources, the private sector, SLTT partners, federal agencies, the intelligence community, and foreign governments. Important informational or decisional points for each of the various phases of response, which may lead to the determination that a biological threat and/or incident suspected or known to be intentional has occurred, are addressed in the sections below. The activities described below align with Line of Effort (LOE) #1, *Detect, Prevent, and Characterize the Threat*, which was discussed in Appendix C of this BIA.

### *Key Information Channels*

- Report of a BioWatch Actionable Result (BAR) by the local BioWatch jurisdiction.
- Determination of a suspected or confirmed biological incident through the DOJ/FBI 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 suggesting a suspicious pattern that may indicate an intentional act.
- National Security Council (NSC) staff may activate the Biological Incident Notification and Assessment (BINA) Protocol to develop a common understanding of an evolving threat or incident.

### *Notification of an Intentional Biological Incident*

Law enforcement personnel may be confronted with several 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 several communications channels.

### Key Federal Decisions

- Hold a TCE, led by the DOJ/FBI. No other authority can serve as the lead agency in holding a TCE other than the DOJ/FBI.
- DOJ/FBI determines whether a law enforcement investigation and/or counterterrorism operation should be initiated, possibly in conjunction with a public health epidemiological investigation, as appropriate.

- 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 (2) hours** of a BAR confirmation or as early as possible based upon other forms of intentional biological incident detection, as described previously.
- Provide notification to the World Health Organization (WHO) via the U.S. International Health Regulations (IHR) National Focal Point (NFP). Per our obligations under IHR 2005, this must occur within 24 hours of federal confirmation of an IHR reportable event and requires coordination and communications between SLTTs and the federal technical agency to compile reportable event information.<sup>62</sup>
- Once the notification of a potential intentional incident is received, the DOJ/FBI JTTF conducts a law enforcement investigation into the situation. All possible incidents are immediately evaluated to determine if a weapon of mass destruction (WMD) is involved and if there are possible links to terrorism.

### *Conduct a Law Enforcement Investigation and/or Joint Crim-Epi Investigations*

Where appropriate, law enforcement and public health authorities also conduct joint Crim-Epi investigations. However, the occurrence of an intentional biological incident may result in an emergency that may overwhelm SLTT capabilities and require a whole community approach. An intentional biological incident may cause mass casualties, displacement of people, and other obstacles to response efforts. DHS/FEMA does not need to 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 is conducted in concert with and at the request of state and local authorities that retain leadership of response operations.

#### Key Federal Decisions

- Determination by the DOJ/FBI to conduct a law enforcement and/or counterterrorism response in accordance with applicable Presidential and national policies.
- Determination by the DOJ/FBI or a request by another department and agency to activate the Weapons of Mass Destruction Strategy Group (WMDSG).
- Determination by the DOJ/FBI regarding the composition of and whether to deploy the Domestic Emergency Support Team (DEST).
- Determination by DHS/FEMA regarding the staffing levels for the WMDSG Consequence Management Coordination Unit (CMCU), the DHS/FEMA home team, and any forward deployed DHS/FEMA assets.
- Determination by the DOJ/FBI and HHS/CDC whether to conduct a joint Crim-Epi investigation.

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<sup>62</sup> Coordination with the Attorney General should be performed before the release of information to the World Health Organization during a bioterrorism incident.

## Key Federal Roles and Responsibilities

As noted above, during intentional biological threats and incidents, law enforcement and public health authorities (e.g., DOJ/FBI, HHS/CDC) may conduct joint Crim-Epi investigations to identify threat actors, attribute a threat or incident to threat actors, and hold threat actors accountable. Generally, law enforcement and public health may exchange information once they confirm the existence of a criminal act or an outbreak. For an effective response to a biological threat to occur, however, public health and law enforcement need to share information prior to a confirmation that an intentional incident has occurred. The timely exchange of information in the early stages of a response is critical to containing the outbreak and apprehending perpetrators.

Joint Crim-Epi investigations seek to maximize the efficiency and effectiveness of the investigation through the exchange of real-time investigative information in an effort to: (1) protect public health and safety; (2) identify the disease causing agent; (3) identify the source and perpetrators of the attack; (4) apprehend and prosecute perpetrators or otherwise hold perpetrators accountable; (5) determine the modes of spread or transmission of the biological agent; (6) determine where and when exposure to the biological agent may have occurred; (7) identify who may have been exposed; (8) protect law enforcement personnel; (9) prevent subsequent follow-on attacks; and (10) ensure that the need for rapid collection and testing to save lives is given high priority. Supporting activities include:

- Gathering evidence with specially trained law enforcement teams to handle the collection of evidence in contaminated environments;
- Maintaining the chain of custody of biological samples, which could be contaminated;
- Obtaining original documents and conducting witness interviews;
- Evaluating evidence, including having biological samples sent to laboratories within the Laboratory Response Network (LRN) and the National Bioforensic Analysis Center (NBFAC) for confirmatory analyses; and
- Apprehending suspects, including in what may be a contaminated environment.

When a joint investigation is initiated, law enforcement and public health officials are empowered to share information, including public health information, throughout the course of the joint operations, in accordance with applicable law and regulations. Information sharing between law enforcement and public health authorities must also consider the need to protect sensitive law enforcement information for the investigative and prosecutorial processes, the unauthorized disclosure of which could result in the destruction of evidence or jeopardize the safety of confidential informants or classified sources by allowing the suspects to directly identify law enforcement's sources. Consistent with the foregoing, the critical information in the following sections should be shared.

### Critical Information Requirements: Public Health Information to Be Shared with Law Enforcement

- Times and locations where exposures may have occurred (may be based on agent-specific characteristics or other investigational findings)
- Names of case-patients (including dates of birth) for all confirmed, probable, and exposed cases
- Positive laboratory results for a biological threat agent from an approved laboratory
- Case definition (epidemiological picture of the outbreak)
- Risk factors that may be associated with exposure (e.g., demographics, occupation, other activities)
- Hypotheses generated by the epidemiological investigation
- Notification of when public health authorities are planning to conduct interviews with case-patients or contacts
- National or international health alerts that may be related to the current biological threat
- Laboratory results used to characterize the specific biological agent (e.g., strain, genetic sequencing, antimicrobial resistance)
- Identification of any unusual cases (e.g., past case-patients, coroner reports)
- Any other investigative information that may be relevant to the biological threat (e.g., requests for or theft of antibiotics, identification of a laboratory in someone's home)

### Critical Information Requirements: Law Enforcement Information to Be Shared with Public Health Authorities, as Applicable

- Law enforcement investigative information (e.g., interviews scheduled, planned search warrants) that may assist public health officials with the identification of the agent and determination of the source of the outbreak
- Information regarding any known group or sector (e.g., government or financial, entertainment, religious/ethnic groups) that may be targeted for an attack
- Other law enforcement cases that may have ties to the existing biological threat investigation
- Pre-incident indicators (e.g., videotaping, sketching maps, break-ins, perimeter breaches at facilities) that may be related to the biological threat incident
- Information developed by law enforcement regarding the biological agent used, mechanism for delivery/dissemination, and dates, times, and locations of exposures
- Information regarding any medical equipment, chemicals, biotoxins, biological agents, or laboratory supplies stolen, developed, or uncovered that may be related to the biological threat
- Intelligence information regarding the characteristics of the biological agent (e.g., strain, antimicrobial resistance)

### ***Transition from Law Enforcement and/or Counterterrorism Response to Consequence Management***

Prevention operations take place concurrently with known or suspected intentional threats and with response operations. In some circumstances, these operations may occur simultaneously during recovery. The transition from law enforcement and/or counterterrorism operations to consequence management operations in response to an intentional biological incident is determined by the unique aspects, complexity, and magnitude of each situation. For example, the timeline required to neutralize criminal elements may vary greatly, and crime scene operations in hazardous or contaminated environments may be taking place while consequence management operations are taking place. Prevention operations are also focused on preventing follow-on attacks and conducting investigative activities to attribute the incident to perpetrators and to hold them accountable. At some point, the active criminal investigation at the crime scene transitions response efforts from law enforcement and/or counterterrorism activities to primarily consequence management operations. The DOJ/FBI, in conjunction with DHS/FEMA and public health authorities, uses ongoing established coordination mechanisms and shares critical information to provide situational awareness to facilitate the gradual stand-down of law enforcement and/or counterterrorism operations at crime scenes.

#### Key Federal Decisions

- Determination by the DOJ/FBI to demobilize the DEST.
- Determination by the DOJ/FBI to stand-down the WMDSG.
- Determination on the stand-down of DHS/FEMA to transition to long-term recovery operations.
- Determination by DOJ/FBI and HHS/CDC whether to continue the joint Crim-Epi investigation.

The full range of a federal response is far more robust than described in this branch plan. It includes many factors that require the involvement of several federal, SLTT, private, and non-governmental entities, which may or may not include law enforcement, and continues 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 threat or incident, several support and operational coordination elements are employed. These elements, combined with the assets, resources, and teams identified in the Federal Response Capability Inventory located in Annex D, 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 rapidly deployable interagency team that supports the DOJ/FBI. As part of its mission, the DEST supports the DOJ/FBI On-Scene Commander (OSC) and other officials (e.g., the National Assets Commander) and supports the integration of law enforcement and counterterrorism operations with consequence management operations that may be taking place simultaneously. Based upon the threat and requirements, DOJ/FBI determines the composition of the DEST and maintains operational control throughout its activation. The DEST can provide the DOJ/FBI with expert advice and guidance that can inform prevention operations and may include a ready roster from DHS/FEMA, DOJ/FBI, Department of Defense (DOD), HHS/Assistant Secretary for Preparedness and Response (ASPR), Department of Energy (DOE), Environmental Protection Agency (EPA), and others, as appropriate. The DHS/FEMA Administrator, in support of the DOJ/FBI, is responsible for policies and planning governing the use of the DEST Team and for facilitating approval for its deployment, in accordance with agreed-upon policies and procedures.

## Weapons of Mass Destruction Strategic Group

The WMDSG is a DOJ/FBI-led interagency crisis action team. When facing a credible WMD threat or incident, the DOJ/FBI-led WMDSG is activated within the DOJ/FBI Strategic Information and Operations Center (SIOC). The DOJ/FBI-led WMDSG supports information exchange and deconfliction of law enforcement and/or counterterrorism operations to prevent imminent threats, while simultaneously coordinating with the efforts of federal agencies responsible for public health and other consequence management activities to save lives and protect property and critical infrastructure. Through its collection of interagency representatives and subject matter experts (SMEs), the DOJ/FBI-led WMDSG facilitates the integration and sharing of real-time investigative information, intelligence, and technical analysis; facilitates the identification and use of interagency assets; and enhances the synchronization and deconfliction of prevention, response, and recovery operations. The DOJ/FBI-led WMDSG can include SMEs from different departments and agencies depending on the nature of the threat and its modality (e.g., representatives from HHS/ASPR and HHS/CDC during biological threats, from DOE/National Nuclear Security Administration [NNSA] for radiological and nuclear threats, and from EPA during chemical threats). The DOJ/FBI-led WMDSG, with its collaborative environment and through the dissemination of its products, including the WMD Threat Profile, contributes to risk-informed decision making at all levels of the response, including, when appropriate, with SLTT, public health, private sector, and international partners. The DOJ/FBI-led WMDSG connects with other DOJ/FBI command posts (e.g., the DOJ/FBI Critical Incident Response Group [CIRG] National Assets Command Post regarding all technical information represented by and collected from the WMD device) within the DOJ/FBI SIOC and with the operations centers of other federal agencies. It also connects to DOJ/FBI Field Offices and appropriate local/regional partners through DOJ/FBI JOCs.

## Consequence Management Coordination Unit

FEMA staffs and manages the WMDSG Consequence Management Coordination Unit (CMCU), which has reach-back to the DHS/FEMA home team. The CMCU is the principal advisory unit for consequence management considerations within the WMDSG and provides strategic recommended and integrated consequence management courses of action (COAs) that consider ongoing and evolving law enforcement and/or counterterrorism operations. The CMCU links operational coordination and information sharing to the response and protection activities of DHS and Sector-Specific Agencies (SSAs). The CMCU is supported by federal technical capabilities provided through DOE/NNSA, HHS, DOD, and DHS. CMCU responsibilities include the following:

- Coordination of the identification of potential risks for impacted populations.
- Identification of potential preparatory consequence management actions to reduce risks to life and property by lessening the impact of the incident.
- Positioning the response community to be able to respond should the incident 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 Plan (FIOP) serve as the default posture for achieving BIA response and recovery objectives. This base annex provides an overview of this default posture. It is noted that, for an intentional biological incident, response, recovery, and prevention activities are interdependent and often concurrent. Decisions made and priorities set early in the response 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 BIA base 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 the response to a biological incident.

The DOJ/FBI and its federal and SLTT law enforcement partners maintain constant vigilance regarding threats of terrorism, including biological threats and incidents. Public health and emergency management officials should share information with each other and with law enforcement officials to report suspicious activities and other indicators/tripwires for a suspected intentional biological threat or incident and should work closely regarding the potential pre-positioning of resources and appropriate capabilities in the event a biological incident takes place.

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

Phases 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 or other preventative actions that may take place during Phase 1c, such as the alerting, activation, staging, and deployment of resources.

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 investigations and intelligence.

Suspected intentional biological threats and incidents are immediately evaluated to determine whether the threat or incident is credible through the DOJ/FBI TCE process, which may, if the DOJ/FBI determines that it is appropriate, include other stakeholders (e.g., the private sector, SLTT partners, federal departments and agencies, the intelligence community, 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, non-governmental organization (NGO), 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.

**Error! Reference source not found.** Figure Branch 1-1 is an example of an operational construct that could be used in Phases 1 through 3.

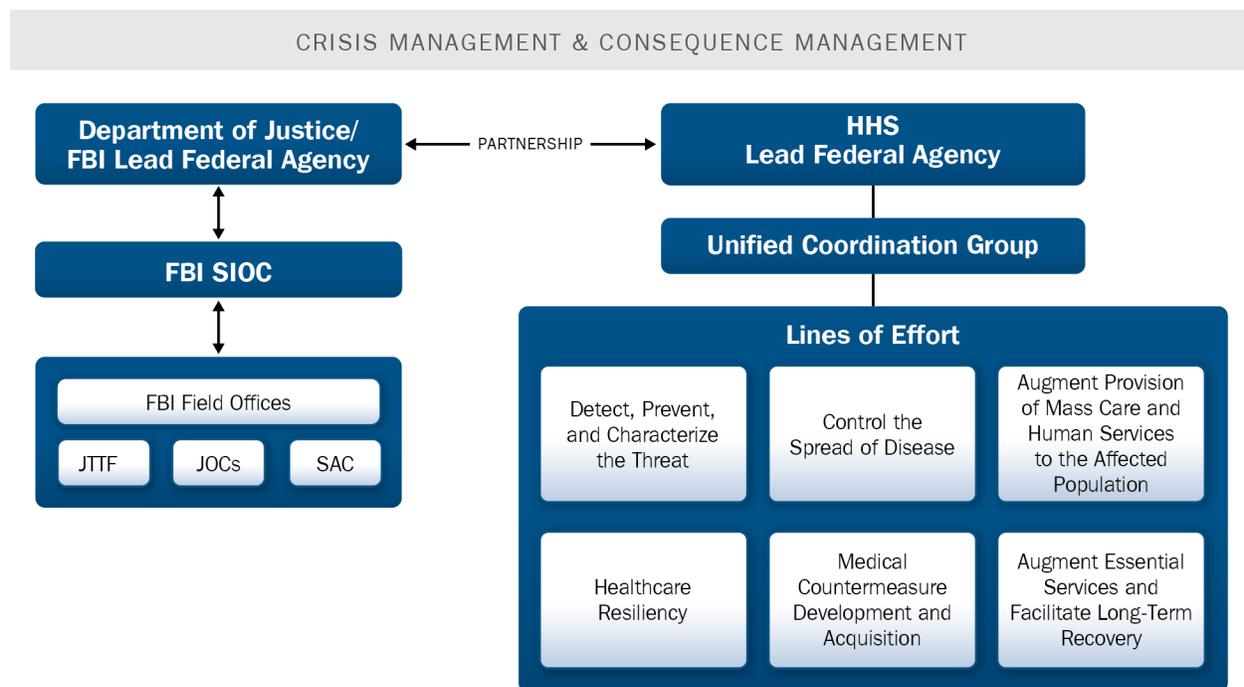
Phase 1c begins with the determination of a credible threat. After the threat has been deemed credible, DOJ/FBI determines COAs, such as how to best to collect and analyze the evidence, including but not limited to biological environmental samples. Led by the DOJ/FBI, the interagency WMDSG is activated and provides a mechanism for information sharing to support strategic and risk-informed decision making and the coordination of deconfliction of crisis management and consequence management operations during a biological threat and/or incident suspected or known to be intentional.

Phases 1b and 1c (Elevated Threat and Credible Threat) involve the activation and potential deployment and employment of preventative capabilities, including to detect illicit biological materials and WMD at the point of manufacture, transportation, and use (or threatened use). This may also involve the detection and identification of the nature of material through adjudication or resolution of the detection alarm. DOJ, acting through the FBI, is the LFA for the operational law enforcement response. HHS serves as the LFA for the public health and medical response and provides advice and guidance to support DOJ/FBI crisis management activities relevant to the biological materials and WMD. Preparatory consequence management activities, including to pre-position consequence management assets and

resources to minimize loss of life and serious public health consequences, must be coordinated with DOJ/FBI through established coordination mechanisms (e.g., DOJ/FBI-led WMDSG).

While DOJ/FBI leads the crisis management activities in Phase 2 (e.g., conducting ongoing investigative and intelligence activities), in a large-scale biological incident, HHS may establish a Unified Coordination Group (UCG) for consequence management activities. Federal departments and agencies with the same core capabilities identified for naturally occurring/accidental biological incidents can participate in these activities through the UCG for intentional incidents. Delivery of public health and medical services and materials (e.g., Strategic National Stockpile [SNS]) and the implementation of a Recovery Support Strategy for affected populations are the focus for consequence management.

As depicted below, crisis management operations constitute time-sensitive law enforcement and/or counterterrorism actions to prevent an intentional criminal and/or terrorist threat or incident, including biological incidents. Consequence management operations constitute efforts to protect public health and safety, restore government services, and provide emergency relief to governments, businesses, and individuals affected by the consequences of a terrorist incident, including biological incidents.



**Figure Branch 1-1: Example of UCG Construct for an Intentional Biological Incident**

## Phase 2a (Initial Response)

Formal unified coordination begins with Phase 2, but, during credible biological threats and incidents, may begin earlier in Phase 1c. Phase 2 also typically begins with the implementation of initial response activities following the identification of a credible threat, although coordinated preparatory consequence management activities, including the pre-positioning of assets and resources, could have taken place during Phase 1c. As appropriate, Phase 2a is dominated by efforts to provide coordinated, consistent, and unified public messaging that is credible and provides clear, timely, and actionable information that is accessible to and culturally and linguistically appropriate for all affected populations, adhering to the principles of risk communications, even in areas unaffected by the incident, and including information regarding the threat, hazard, or incident as well as the actions being taken and the assistance that is available. In addition, law enforcement and/or counterterrorism operations are actively underway in Phase 2, depending on the circumstances and joint Crim-Epi investigations.

The Prevention Mission works 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 includes 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 and to defeat the device, which may already have been found, in accordance with applicable Presidential polices, memoranda, and frameworks. Finally, the White House Director of Communications coordinates risk communications strategies by implementing the Domestic Communications Strategy using primarily ESF #8 (Public Health and Medical) and ESF #15 (Public Information and Warning).<sup>63</sup>

## Phase 2b (Employment)

Prevention operations are well underway. This phase also includes the initial employment of federal response-related resources (e.g., personnel, PPE, MCMs) to supplement and support SLTT health authority activities and to protect public health and safety. It also includes stabilization and delivery of recovery support.

## Phase 2c (Intermediate/Sustained Response)

Crim-Epi investigations may be well underway. As response operations transition to recovery, law enforcement and/or counterterrorism operations also continue, assuming the threat has not been fully neutralized, in order to prevent follow on attacks. In addition, the overall incident response begins to enter sustained, long-term operations. The delivery of Stafford Act programs (if there is a Stafford Act declaration), the delivery of public health services and materiel (e.g., SNS), and the completion of a Recovery Support Strategy also occur as does

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<sup>63</sup> In the instance of a criminal investigation/act or suspected threat of terrorism or actual act of terrorism, DOJ/FBI shall be consulted before releasing potentially sensitive law enforcement information.

the provision of accessible interim housing/sheltering solutions (for those populations affected by contaminated biological agents) and the re-establishment of businesses.

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# Attachment 2: Biologically Derived Toxins Addendum to the BIA (Placeholder)

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