

---

# NATIONAL BIODEFENSE STRATEGY

2018



*This page is intentionally blank*

## FOREWORD

It is a vital interest of the United States to manage the risk of biological incidents. In today’s interconnected world, biological incidents have the potential to cost thousands of American lives, cause significant anxiety, and greatly impact travel and trade.

Biological threats—whether naturally occurring, accidental, or deliberate in origin—are among the most serious threats facing the United States and the international community. Outbreaks of disease can cause catastrophic harm to the United States. They can cause death, sicken, and disable on a massive scale, and they can also inflict psychological trauma and economic and social disruption. Natural or accidental outbreaks, as well as deliberate attacks, can originate in one country and spread to many others, with potentially far-reaching international consequences. Advances in science promise better and faster cures, economic advances, a cleaner environment, and improved quality of life, but they also bring new security risks. In this rapidly changing landscape, the United States must be prepared to manage the risks posed by natural outbreaks of disease, accidents with high consequence pathogens, or adversaries who wish to do harm with biological agents.

Health security means taking care of the American people in the face of biological threats to our homeland and to our interests abroad. The significant infectious disease outbreaks of recent decades, including Severe Acute Respiratory Syndrome (SARS), pandemic influenza, Ebola virus disease, and Zika virus disease, have revealed the extent to which individual countries and international communities need to improve their preparedness and biosurveillance systems to detect and respond to the next health crisis. The health of the American people depends on our

ability to stem infectious disease outbreaks at their source, wherever and however they occur. America’s biodefense enterprise needs to be nimble enough to address emerging infectious disease threats, the risks associated with the accelerating pace of biotechnology, and threats posed by terrorist groups or adversaries seeking to use biological weapons.

The *National Biodefense Strategy* is aligned with the 2018 *National Security Strategy* of the United States. Pillar One of the 2018 *National Security Strategy* explicitly calls for protecting “the American people, the homeland, and the American way of life.” One component of this goal is achieved by detecting and containing biothreats at their source, supporting and promoting the responsible conduct of biomedical innovation, and improving emergency response. Pillar Two calls for “promot[ing] American prosperity,” which increasingly will depend on a vibrant life sciences and biotechnology enterprise.

This *National Biodefense Strategy* highlights the President’s commitment to protect the American people and our way of life, laying out a clear pathway and set of objectives to effectively counter threats from naturally occurring, accidental, and deliberate biological events. It is broader than a Federal Government strategy. It is a call to action for state, local, territorial, and tribal (SLTT) entities, other governments, practitioners, physicians, scientists, educators, and industry.

*This page is intentionally blank*

# TABLE OF CONTENTS

<b>FOREWORD</b> .....	i
<b>VISION</b> .....	1
<b>PURPOSE</b> .....	1
<b>THREATS AND CONSEQUENCES</b> .....	2
<b>BIOLOGICAL RISK MANAGEMENT</b> .....	2
<b>ASSUMPTIONS</b> .....	3
<b>GOVERNANCE</b> .....	4
<b>GOALS AND OBJECTIVES</b> .....	6
<b>CONCLUSION</b> .....	8
<b>ANNEX I: NATIONAL BIODEFENSE STRATEGY IMPLEMENTATION PLAN</b> .....	9
<b>ANNEX II: DEFINITIONS</b> .....	28
<b>ANNEX III: SCOPE, STATUTORY REQUIREMENTS, AND AGENCIES</b> .....	29

*This page is intentionally blank*

## VISION

The United States actively and effectively prevents, prepares for, responds to, recovers from, and mitigates risk from natural, accidental, or deliberate biological threats.

## PURPOSE

This *National Biodefense Strategy* 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 United States Government to protect the American people from biological threats. With National Security Presidential Memorandum (NSPM)-14, this strategy explains how the United States Government will manage 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.

The mission of the Federal Government during a biological incident is to save lives, reduce human suffering, protect property and the environment, control the spread of disease, and support community efforts to overcome the physical, emotional, environmental, and economic impacts. This federal mission is contingent upon the coordination with and the success of the community response. This strategy describes the goals and objectives that will guide the United States in assessing, preventing, detecting, preparing for, responding to, and recovering from a biological incident, consistent with its international obligations, including those identified in the World Health Organization's International Health Regulations (2005).

Enhancing the national biodefense enterprise will help protect the United States and its partners abroad from biological incidents, whether deliberate, naturally occurring, or accidental in origin. It will simultaneously build the U.S. innovation base for cutting edge medical countermeasures (MCMs), biosensors and diagnostics, and biosurveillance information technologies, and advance the biomedical industry.

## THREATS AND CONSEQUENCES

**Naturally Occurring Biological Threats.** Infectious disease threats do not respect borders. Urbanization, habitat encroachment, and increased and faster travel, coupled with weak health systems, increase the ability of infectious diseases to spread rapidly across the globe. Antimicrobial resistance, novel infectious diseases, and the resurgence and spread of once geographically limited infectious diseases can overwhelm response capacities and make outbreaks harder to control. An infectious disease outbreak—even in the most remote places of the world—could spread rapidly across oceans and continents, directly impacting the U.S. population and its health, security, and prosperity.

**Deliberate and Accidental Biological Threats.** The use of biological weapons or their proliferation by state or non-state actors presents a significant challenge to our national security, our population, our agriculture, and the environment. Multiple nations have pursued clandestine biological weapons programs and a number of terrorist groups have sought to acquire biological weapons. In many countries around the world, pathogens are stored in laboratories that lack appropriate biosecurity measures where they could be diverted by actors who wish to do harm. Similarly, some laboratories do not have appropriate biocontainment or biosafety protocols, which could lead to an outbreak through a laboratory acquired infection or if a pathogen is accidentally released into the environment. Biological material is ubiquitous and can self-propagate; pathogens are found all over the world—in the environment, animal reservoirs, humans, and laboratories. A natural outbreak can lead quickly to not only a public health crisis, but also a biosecurity vulnerability due to the thousands of clinical samples that are generated during an epidemic, which, if handled without appropriate biosecurity measures, could facilitate the development of a biological weapon.

## BIOLOGICAL RISK MANAGEMENT

Biological risk management requires understanding and assessing biological risks, and taking steps to prepare for, prevent, and respond to them, regardless of whether they originate in the United States or abroad. It also requires shared international recognition that the risk is global to empower effective, collective mitigation. In our interconnected world, it is not if, but when, the next biological incident will occur.

As the biological threat continues to evolve, so must our biodefense capabilities. If all countries could prevent, detect, and respond to infectious disease outbreaks at the local level, we can minimize the risk of global health emergencies, saving both lives and resources. Preventing acquisition of dangerous pathogens, equipment, and expertise for nefarious purposes, and maintaining the capability to rapidly control outbreaks in the event of a biological attack, are strategic interests of the United States. These must be strategic interests for partners around the

world as well. The United States cannot carry the burden alone. Finally, as we reap the benefits from biotechnologies, we must also understand and consider the risks they may pose. The United States will pursue an efficient and coordinated biodefense enterprise to protect the American people.

Domestic action alone is insufficient to protect America's health and security. The rapid globalization of science and technology and the interconnectedness of travel and trade necessitate



a strong biodefense enterprise that has global reach to effectively prevent, detect, and respond to biological incidents. The United States Government works at home and abroad to ensure that the United States and its partners are protected from natural, accidental, or deliberate biological threats. While the desired outcomes at home and abroad are the same, the conditions and avenues available to achieve these outcomes can be very different. Internationally, our efforts to protect the United States and our partners include direct investment in sustainable, context-appropriate capacity building that leads to self-reliance. We will work with multilateral organizations, partner nations, private donors, and civil society to control disease outbreaks at their source by supporting the development and implementation of biodefense and health security capabilities, policies, and standards.

The United States has long been an innovation leader. Whether augmenting our ability to provide health care and protect the environment, or expanding our capacity for energy and agricultural production towards global sustainability, continued research and development in life sciences is essential for a brighter future for the American people. To ensure that the United States is poised to meet the

evolving biological risk landscape, at a time when unparalleled advancement and innovation in the life sciences globally continue to transform our way of life, we are committed to promoting innovation throughout the national biodefense enterprise. We will promote innovative technologies and systems; encourage innovative technology communities and industry leaders to meet our targeted biodefense and health capacity needs; link stakeholders with new ideas, tools, and products; and pursue innovative approaches and partnerships to achieve, at home and abroad, the desired goals articulated in this *National Biodefense Strategy*.

Through the *National Biodefense Strategy*, the United States will use all appropriate means to assess, understand, prevent, prepare for, respond to, and recover from biological incidents—whatever their origin—that threaten national or economic security. The *National Biodefense Strategy* recognizes that a collaborative, multi-sectoral, and trans-disciplinary approach to the national biodefense enterprise is necessary to counter biological threats effectively and efficiently.

## ASSUMPTIONS

The evolving biological threat landscape requires a comprehensive approach, and the United States recognizes the following principles:

- **Biological Threats are Persistent.** Pathogens have emerged and spread throughout history, and as new naturally occurring threats develop, the risk from them grows more acute as the world becomes more urbanized, travel increases, and habitats change. Separately, nation-states and terrorist groups have found value in pursuing biological weapons, and there can be no confidence that will change in the future. Advances in the life sciences will both reduce the technological hurdles to such weapons and expand the number of individuals with relevant skills to effectuate threats.
- **Biological Threats Originate from Multiple Sources.** The United States will include, within the scope of biodefense, not just countering deliberate biological threats, but also the threats that stem from naturally occurring and accidental outbreaks. This approach will allow the United States Government to fully utilize, integrate, and coordinate the biodefense enterprise and ensure the most efficient use of all biodefense assets.

- **Infectious Diseases Do Not Respect Borders.** An interconnected world increases the opportunity for pathogens to emerge and spread so that a disease threat anywhere is a disease threat everywhere. Infectious diseases travel without visas and cross borders indiscriminately; infected travelers may not manifest any symptoms. The United States Government will mitigate biological incidents both here in the United States and work with partners abroad because the United States cannot counter biological threats nationally without addressing them internationally. We will also seek to improve our ability to prevent the spread of infectious diseases to the United States through inbound travelers and goods. The Ebola outbreaks of 2014 and 2018 demonstrated that the United States Government must be prepared to act swiftly, and unilaterally if necessary, to respond to public health emergencies abroad if multilateral institutions and partners are not prepared to do so.
- **Multi-sectoral Cooperation is Critical for Prevention and Response.** This strategy calls for engagement and cooperation across all levels of government, to include SLTT governments, as well as internationally. It involves partnership with multiple sectors, including the medical; public, animal, and plant health; emergency response; scientific and technical; law enforcement; industrial; academic; diplomatic; defense and security; intelligence; and nonproliferation and counterproliferation sectors, among others. Engagement with non-governmental organizations (NGOs) and the private sector is critical to prevent the spread of disease and respond to the next outbreak before it becomes an epidemic.
- **A Multidisciplinary Approach Will Help Prevent Disease Emergence.** The health of people, animals, plants, and the environment are linked, and diseases affecting one component can soon affect others. At least 75 percent of infectious disease threats to human health are of animal origin. Threats to animals and plants can cause economic disruption and physical harm to health and well-being. A coordinated, multidisciplinary approach, representing the collaborative efforts across local, national, and global jurisdictions, is a best practice for understanding, communicating, and mitigating biological threats swiftly and efficiently. Such an approach is necessary to prevent and detect early inter-species cross-over of infectious diseases.
- **Science and Technology Will Continue to Advance Globally.** The ongoing revolution in the life sciences and biotechnology will continue at an ever-increasing rate, offering solutions to many of the challenges of ensuring the health, prosperity, and security of a growing global population. These technologies, no longer confined to sophisticated research laboratories, are being developed and utilized all over the world and the necessary expertise, materials, and equipment are available widely. Advances in science and technology bring revolutionary cures and progress, but they also have the potential to facilitate intentional misuse. The United States has a responsibility to ensure our technology, development, and assistance programs do not exacerbate this risk unintentionally.

## GOVERNANCE

The NSPM that accompanies the issuance of this *National Biodefense Strategy* creates a dedicated mechanism, housed within the U.S. Department of Health and Human Services, to coordinate federal biodefense activities and assess the effectiveness with which the *National Biodefense Strategy's* goals and objectives are being met. Led by the President of the United States and coordinated by the National Security Council staff in the Executive Office of the President, with day-

to-day coordination and execution by the Secretary of Health and Human Services, this mechanism will continually assess how effectively the objectives of the *National Biodefense Strategy* are being met.

The Assistant to the President for National Security Affairs will, in acting through the process described in NSPM-4, *Organization of the National Security Council, the Homeland Security Council, and Subcommittees*, serve as the lead for policy coordination and review, providing strategic input and policy oversight for federal biodefense efforts.

The Biodefense Steering Committee, chaired by the Secretary of Health and Human Services, and comprising the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Agriculture, the Secretary of Veterans Affairs, the Secretary of Homeland Security, and the Administrator of the Environmental Protection Agency, will be responsible for overseeing and coordinating the execution of the strategy and its implementation plan, and ensuring federal coordination with domestic and international government and non-governmental partners. The

Chair of the Biodefense Steering Committee, the Secretary of Health and Human Services, will serve as the federal lead for implementation of the strategy. The heads of other agencies with responsibilities or capabilities pertaining to biodefense shall participate in the Biodefense Steering Committee, as appropriate. This coordination and oversight mechanism also has a mandate to reach beyond the Federal Government to engage with SLTT, non-federal, and non-governmental stakeholders. Further, the recommendations and feedback stemming from this governance mechanism will be communicated back to departments and agencies in synchronization with the annual budget cycle. Recognizing that threats, actors, and biodefense-related science and technology are constantly evolving, the governance mechanisms will be adaptive, reviewing and recommending changes, as appropriate, in the *National Biodefense Strategy* and its implementation plan.

## GOALS AND OBJECTIVES

The *National Biodefense Strategy* has five goals with associated objectives for strengthening the biodefense enterprise, establishing a layered risk management approach to countering biological threats and incidents.

**GOAL 1: ENABLE RISK AWARENESS TO INFORM DECISION-MAKING ACROSS THE BIODEFENSE ENTERPRISE.**

The United States will build risk awareness at the strategic level, through analyses and research efforts to characterize deliberate, accidental, and natural biological risks; and at the operational level, through surveillance and detection activities to detect and identify biological threats and anticipate biological incidents.

**OBJECTIVES:**

**1.1:** Ensure decision-making is informed by intelligence, forecasting, and risk assessment.

**1.2:** Ensure that domestic and international biosurveillance and information-sharing systems are coordinated and are capable of timely bioincident prevention, detection, assessment, response, and recovery.

**GOAL 2: ENSURE BIODEFENSE ENTERPRISE CAPABILITIES TO PREVENT BIOINCIDENTS.** The United States will work to prevent the outbreak and spread of naturally occurring disease, and minimize the chances of laboratory accidents. The United States will also strengthen biosecurity to prevent hostile actors from obtaining or using biological material, equipment, and expertise for nefarious purposes, consistent with the United States Government’s approach to countering weapons of mass destruction (WMD) terrorism. Goal 2 will ensure we have the capabilities necessary to disrupt plots, degrade technical capabilities, and deter support for terrorists seeking to use WMD. This goal also recognizes the "dual use" natures of the life sciences and biotechnology, in which the same science and technology base that improves health, promotes innovation, and protects the environment, can also be misused to facilitate a biological attack. The United States seeks to prevent the misuse of science and technology while promoting and enhancing legitimate use and innovation.

**OBJECTIVES:**

**2.1:** Promote measures to prevent or reduce the spread of naturally occurring infectious diseases.

**2.3:** Deter, detect, degrade, disrupt, deny, or otherwise prevent nation-state and non-state actors’ attempts to pursue, acquire, or use biological weapons, related materials, or their means of delivery.

**2.2:** Strengthen global health security capacities to prevent local bioincidents from becoming epidemics.

**2.4:** Strengthen biosafety and biosecurity practices and oversight to mitigate risks of bioincidents.

**GOAL 3: ENSURE BIODEFENSE ENTERPRISE PREPAREDNESS TO REDUCE THE IMPACTS OF BIOINCIDENTS.** The United States will take measures to reduce the impacts of bioincidents, including maintaining a vibrant national science and technology base to support biodefense; ensuring a strong public health infrastructure; developing, updating, and exercising response capabilities; establishing risk communications; developing and effectively distributing and dispensing medical countermeasures; and preparing to collaborate across the country and internationally to support biodefense.

**OBJECTIVES:**

<b>3.1:</b> Ensure a vibrant and innovative national science and technology base to support biodefense.	<b>3.6:</b> Enhance preparedness to limit the spread of disease through Community Mitigation Measures (CMMs).
<b>3.2:</b> Ensure a strong public and veterinary health infrastructure.	<b>3.7:</b> Enhance preparedness to support decontamination.
<b>3.3:</b> Develop, exercise, and update prevention, response, and recovery plans and capabilities.	<b>3.8:</b> Strengthen preparedness to operate and collaborate across the United States, including the U.S. territories.
<b>3.4:</b> Develop, exercise, and update risk communication plans and promote consistent messaging to inform key audiences, expedite desired response actions, and address public uncertainty and fear.	<b>3.9:</b> Strengthen international preparedness to support international response and recovery capabilities.
<b>3.5:</b> Enhance preparedness to save lives through MCMs.	

**GOAL 4: RAPIDLY RESPOND TO LIMIT THE IMPACTS OF BIOINCIDENTS.** The United States will respond rapidly to limit the impacts of bioincidents through information-sharing and networking; coordinated response operations and investigations; and effective public messaging.

**OBJECTIVES:**

<b>4.1:</b> Compile and share biothreat and bioincident information to enable appropriate decision-making and response operations across all levels of government and with non-governmental, private sector, and international entities, as appropriate.	<b>4.3:</b> Conduct operations and investigations, and use all available tools to hold perpetrators accountable.
<b>4.2:</b> Conduct federal response operations and activities in coordination with relevant non-federal actors to contain, control, and rapidly mitigate impacts of biothreats or bioincidents.	<b>4.4:</b> Execute risk-informed, accurate, timely, and actionable public messaging.

**GOAL 5: FACILITATE RECOVERY TO RESTORE THE COMMUNITY, THE ECONOMY, AND THE ENVIRONMENT AFTER A BIOINCIDENT.** The United States will take actions to restore critical infrastructure services and capability; coordinate recovery activities; provide recovery support and long-term mitigation; and minimize cascading effects elsewhere in the world.

**OBJECTIVES:**

<b>5.1:</b> Promote restoration of critical infrastructure capability and capacity to enable the resumption of vital U.S. activities.	<b>5.3:</b> Provide recovery support and conduct long-term mitigation actions to promote resilience.
<b>5.2:</b> Ensure coordination of recovery activities across federal and SLTT governments and, as appropriate, international, non-governmental, and private sector partners to enable effective and efficient recovery operations.	<b>5.4:</b> Reduce the cascading effects of international biological incidents on the global economy, health, and security.

## CONCLUSION

The risks from biological threats cannot be reduced to zero – but they can and must be managed. Wide-ranging threats require a comprehensive approach to minimizing the risks. Through this *National Biodefense Strategy*, the United States Government will optimize its own efforts, and harness the work of essential partners—inside government and outside, domestically and internationally—to understand, prevent, prepare for, respond to, and recover from the full range of biological threats that can harm the American people and our partners.

# ANNEX I

## NATIONAL BIODEFENSE STRATEGY IMPLEMENTATION PLAN

---

### GOAL 1: ENABLE RISK AWARENESS TO INFORM DECISION-MAKING ACROSS THE BIODEFENSE ENTERPRISE.

#### 1.1 Ensure decision-making is informed by intelligence, forecasting, and risk assessment.

##### 1.1.1 Enhance Intelligence and Analysis Activities.

- Provide timely intelligence analysis and information that identifies and assesses current and future biological threats posed by nation-state and non-state actors.
- Provide strategic warning for, and assess the potential impacts of, diseases with the potential to affect U.S. national security or interests abroad, including assessments of the potential cascading effects (e.g., economic, societal, and governmental impacts).
- Incorporate forecasting and modeling into intelligence products and processes, as appropriate.
- Routinely evaluate developments and advances in the life sciences, biotechnology, and related fields to identify emerging hazards and mitigation options.

##### 1.1.2 Conduct Research and Modeling Activities.

- Conduct research to characterize biological hazards, production methods, and dissemination methods that could be used in deliberate threats, when:
  - The results of that research are critical to informing risk assessments and plans to prevent or respond to deliberate bioincidents; and
  - The responsible department or agency utilizes a process to ensure that the research complies with treaties, laws, and policies and follows applicable nationally recognized guidance for best practices.
- Improve the ability to model and forecast the likelihood and impact of bioincidents, including accidental releases.

##### 1.1.3 Assess Risks and Capabilities.

- Conduct periodic national bioincident risk assessments to evaluate the risks, including relative risks, of deliberate, accidental, and naturally occurring bioincidents.
- Assess the security risks posed by the deliberate misuse of biotechnologies and life sciences research and training with dual-use potential.
- Assess the risks posed by research, such as with potential pandemic pathogens, where biosafety lapses could have very high consequences.
- Provide all levels of government with a common basis for understanding biological risks to support operational planning and preparedness actions.
- Develop risk-informed planning scenarios to facilitate capability and capacity assessments and identify gaps.

- Assess the potential impacts of bioincidents on critical infrastructure and supply chains, and how disruption of these systems might affect the ability to respond to bioincidents.

## **1.2 Ensure that domestic and international biosurveillance and information-sharing systems are coordinated and are capable of timely bioincident prevention, detection, assessment, response, and recovery.**

### **1.2.1 Enhance the Integration and Evaluation of Biosurveillance Systems.**

- Improve development, interoperability, integration, and evaluation processes for domestic biosurveillance systems, including opportunities to better-leverage multi-sectoral information.

### **1.2.2 Improve Information-sharing and Reporting.**

- Using a multi-sectoral approach, promote timely sharing of biosurveillance information among federal and SLTT biosurveillance programs and other federal programs designed to investigate biothreats and bioincidents.
- Coordinate and exchange relevant information between environmental biological detection systems and biosurveillance networks.
- Strengthen foreign governments' and international bodies' capability and commitment to identify, characterize, and report biothreats and bioincidents rapidly and transparently.
- Integrate international disease reporting data with domestic biosurveillance systems to enable early action that limits potential impact.
- Create biosurveillance and situational awareness reports tailored to inform decision-makers, the public, partner nations, and other audiences routinely and during a bioincident response.
- Ensure that the Federal Government, SLTT governments, partner nations, and the private sector have appropriate access to relevant information and analysis.
- As appropriate, ensure rapid downgrade of classified or otherwise sensitive intelligence information and write intelligence products for release, as appropriate, to enable sharing with those who need to act on it.

### **1.2.3 Develop and Deploy Enhanced Biosurveillance and Bioincident Characterization Capabilities.**

- Maintain and enhance public health, medical, animal, and plant surveillance systems for disease outbreaks that pose a risk to national security.
- Promote the sustainable development, maintenance, and improvement of SLTT, private sector, federal, regional, and international (United States Government and other national) surveillance systems and networks with reliable access to trained workforces and essential infrastructure for human, animal, and plant diseases.
- Identify and incorporate new technologies, data sources, analytic methods, and partnerships that include public, private sector, and non-traditional sources of data.
- Maintain and enhance biosurveillance capabilities for the identification of emerging biothreats, and monitor and assess short- and long-term post-bioincident health effects using traditional and non-traditional methods.
- Enhance capability to characterize bioincidents rapidly with respect to biohazards involved, populations and areas affected, and consequences (e.g., health, economic, societal, and environmental).

### **1.2.4 Develop and Deploy Enhanced Environmental Detection Systems, as Appropriate.**

- Monitor and evaluate the capability and effectiveness of systems for the environmental identification and detection of human, animal, and plant biohazards, and disease vectors.



- Develop improved environmental identification and detection systems, ensuring that they:
  - Are aligned with assessments of evolving and emerging biothreats; and
  - Can provide information that is timely, accurate, and relevant for response decisions.
- Assess options to ensure the effectiveness of environmental biodetection systems deployed by governmental or non-governmental entities.

#### **1.2.5 Enhance Biosurveillance Laboratory Operations.**

- Promote the sustainable development, maintenance, and improvement of SLTT, private sector, federal, regional, and international (United States Government and partner nation) laboratory networks, with reliable access to trained workforces and essential infrastructure, for human, animal, and plant diseases.
- Promote interoperability of laboratory reporting systems at all levels of government.
- Strengthen capabilities and address appropriate needs for sharing—under both routine and crisis conditions—timely information (e.g., data and results), samples, and reagents among sectors including research; human, animal, and plant health; emergency services; and law enforcement.
- Address impediments to the timely sharing of information, samples, and reagents among countries and international organizations under both routine and crisis conditions.

## **GOAL 2:**

### **ENSURE BIODEFENSE ENTERPRISE CAPABILITIES TO PREVENT BIOINCIDENTS.**

#### **2.1 Promote measures to prevent or reduce the spread of naturally occurring infectious diseases.**

##### **2.1.1 Strengthen Infection Prevention Measures Domestically and Internationally.**

- Using a multidisciplinary approach, strengthen medical, public health, animal health, and plant health capacities to improve infection prevention and control.
- Strengthen vaccination and other health intervention activities.

##### **2.1.2 Reduce the Emergence and Spread of Antimicrobial-resistant Pathogens Domestically and Internationally.**

- Strengthen awareness of drug-resistant pathogens and their associated diseases, and improve stewardship of medically important drugs.
- Strengthen understanding of the drivers of drug resistance and improve the development and adoption of effective mitigation measures.
- Promote the use of preventive and therapeutic options other than antimicrobial drugs.
- Accelerate basic and applied research and development of new antimicrobials, novel preventatives and therapeutics, vaccines, and diagnostic tests.

##### **2.1.3 Strengthen Multidisciplinary Efforts to Control Vector-borne Disease Domestically and Internationally.**

- Identify the risk of the vectors transmitting disease to humans, animals, and plants.
- Develop and disseminate, as appropriate, measures that will safely limit the exposure of humans, animals, and plants to disease vectors and the ability of vectors to transmit disease to humans and animals.
- Address resistance of vectors to vector control or mitigation measures.

##### **2.1.4 Limit Trans-border Introductions and Domestic Spread of Biohazards, Including Those Responsible for Food-borne Illness.**

- Identify, locate, and destroy or contain contaminated/infected plant, animal, and food prior to entry into the United States, and within the United States, that:
  - Contain biohazards that could give rise to bioincidents, including food-borne illness; or
  - Harbor economically and environmentally significant pests.
- Improve capabilities and protocols for screening, isolation, and quarantine of humans, plants, and animals to reduce disease spread.
- Develop programs and policies to encourage plant and animal producers to report suspected or actual biohazards and encourage full compliance with response guidance to limit the spread of plant or animal diseases and reduce their impact on the overall industry.

##### **2.1.5 Strengthen Animal Disease Detection and Prevention Capacity.**

- Strengthen capacity to detect and prevent the spread of animal and zoonotic diseases.
- Support the development and deployment of diagnostics and countermeasures for use in animals as well as the development of disease-resistant animals.

- Strengthen international partnerships regarding awareness, detection and control, and eradication of animal diseases before they reach the United States.

#### **2.1.6 Strengthen Plant Disease Prevention Capacity.**

- Strengthen the capacity to prevent establishment and spread of plant pests.
- Support the development and deployment of new disease-resistant crops.
- Strengthen international partnerships regarding detection and management of plant diseases before they reach the United States.

#### **2.1.7 Strengthen the Resilience of the Water Sector to Prevent or Contain Water-borne Disease Outbreaks.**

- Identify water system vulnerabilities that increase the risk of drinking water contamination, and promote the development of engineering controls and best practices to reduce the risk.
- Develop plans and procedures to reduce the spread of contaminants in a compromised water system and reduce public exposure to contaminated water.
- Improve the ability to detect biohazardous agents in source and finished drinking water.

## **2.2 Strengthen global health security capacities to prevent local bioincidents from becoming epidemics.**

#### **2.2.1 Promote Global Health Security.**

- Promote the development and implementation of national legal frameworks adequate to support and enable the implementation of the World Health Organization's International Health Regulations (2005) and the World Organisation for Animal Health reporting requirements.
- Promote transparent, independent, and objective assessments of country capacity to prevent, detect, and respond to bioincidents.
- Strengthen timely surveillance and monitoring for core syndromes and confirmed reportable infections as outlined by international bodies to ensure quick identification and reporting of bioincidents.

#### **2.2.2 Strengthen Country Capacity to Prevent, Detect, and Respond to Bioincidents.**

- Promote a prepared public health and animal health workforce appropriate for the population.
- Strengthen capacity and promote policies and best practices to minimize transmission of disease between humans and animals.
- Promote incident management systems capable of activating an emergency operations system in response to public health emergencies.
- Promote the development of a system for specimen referral and effective diagnostics to ensure timely testing of biological specimens, and work to remove barriers to the sharing of samples among countries and international organizations.
- Promote national laboratory systems capable of timely receipt and testing of biological specimens from all jurisdictions in a country.

## **2.3 Deter, detect, degrade, disrupt, deny, or otherwise prevent nation-state and non-state actors' attempts to pursue, acquire, or use biological weapons, related materials, or their means of delivery.**

### **2.3.1 Deter Nation-state and Non-state Actors.**

- Ensure accountability by increasing and communicating the political, economic, and other consequences for actors that develop, acquire, produce, or use biological weapons, or assist in such efforts.
- Ensure domestic and international capabilities to identify, investigate, and attribute development or use of biological weapons in order to hold accountable those who are responsible.
- Demonstrate reduced vulnerability through enhanced U.S. and partner-nation capacity to prevent, respond to, and recover from bioincidents.
- Reinforce the obligations in the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological and Toxin Weapons and on their Destruction (BWC) (1975) and United Nations (U.N.) Security Council Resolution 1540, as well as other standards and norms against nation-state or non-state development, acquisition, or use of biological weapons, related materials, or means of delivery.

### **2.3.2 Detect, Degrade, or Deny Acquisition, Development, or Transfer of Biological Weapons.**

- Strengthen nations' commitment and support their efforts to implement their obligations under the BWC and U.N. Security Council Resolution 1540 to establish and enforce appropriate and effective laws prohibiting and preventing the acquisition, development, or transfer of biological weapon-related materials, equipment, and means of delivery for purposes proscribed by these instruments.
- Strengthen domestic and international capabilities to identify, deny, and disrupt biological weapon-related transfers, and to identify and disrupt adversary proliferation networks.
- Deny the acquisition of pathogenic material, equipment, knowledge, or expertise for illicit purposes, and promote appropriate measures to impede misuse of life sciences and biotechnology, while facilitating legitimate use and innovation.

### **2.3.3 Prevent, Disrupt, Degrade, or Deny Use of Biological Weapons.**

- Identify and locate threat actors and proliferation networks, and preempt or disrupt deliberate biothreats and bioincidents.
- Ensure robust capabilities to interdict, disable, destroy, render safe, and attribute responsibility for biological weapons and weapons-related equipment, material, means of delivery, and facilities.
- Strengthen the engagement of the law enforcement and security communities with other stakeholders to facilitate recognition and mitigation of situations involving deliberate biothreats and bioincidents.

### **2.3.4 Develop, Exercise, and Update Prevention and Disruption Plans and Capabilities.**

- Ensure prevention and disruption capabilities and plans are developed, routinely exercised, evaluated, and updated, as appropriate.

## **2.4 Strengthen biosafety and biosecurity practices and oversight to mitigate risks of bioincidents.**

### **2.4.1 Strengthen Biosafety and Biosecurity.**

- Maintain and continuously improve biosafety, biosecurity, and oversight programs and practices for laboratories and other facilities, and for the end-to-end management of samples and specimens (e.g., collection, transport, inactivation, disposal, and waste management).

- Promote appropriate national and facility-specific biosafety, biosecurity (including cybersecurity), and oversight programs, policies, practices, and legislation in partner nations while facilitating legitimate research and innovation.
- Coordinate and conduct basic and applied biosafety and biosecurity research to provide an evidence base for improving safety and security practices.
- Encourage facilities working with biohazards to engage in pre-incident response planning, training, and exercises, including with local responders, to minimize impacts from accidental releases.

#### **2.4.2 Support and Promote the Responsible Conduct of the Life Science and Biotechnology Enterprise.**

- Support and promote a culture of global biosafety, biosecurity, ethical, and responsible conduct in the life sciences.
- Promote effective global oversight of:
  - Dual-use research, to prevent misuse; and
  - Research for which biosafety lapses could have very high consequences, such as with potential pandemic pathogens.
- Encourage engagement among the health, scientific, biotechnology, enthusiast, and security communities in the United States, and with international partners, to reduce the risk of misuse.
- Promote the development and implementation of relevant national and international policies, guidance, training, and other resources across the health, scientific, biotechnology, enthusiast, and security communities to reduce the risk of misuse.

## **GOAL 3:**

### **ENSURE BIODEFENSE ENTERPRISE PREPAREDNESS TO REDUCE THE IMPACTS OF BIOINCIDENTS.**

#### **3.1 Ensure a vibrant and innovative national science and technology base to support biodefense.**

##### **3.1.1 Enable U.S.-led Innovation for Biodefense Through Robust Scientific, Technical, and Industrial Bases.**

- Support investments and U.S. leadership in emerging technologies.
- Maintain laboratory capabilities required for biodefense preparedness and response, including:
  - Assured United States Government access to laboratory infrastructure, including a trained workforce capable of supporting United States Government biodefense programs and decision-making; and
  - A secure and dedicated United States Government laboratory capability for conducting forensic analysis of biological agents and traditional forensic examinations of contaminated evidence up to the highest biosafety levels.
- Strengthen U.S. processes to prevent industrial espionage and other actions that would weaken the U.S. biodefense enterprise.

##### **3.1.2 Integrate Research and Development (R&D) into Federal Planning.**

- Identify and facilitate sharing of tools, practices, policies, and incentives across interagency response R&D efforts.
- Establish capabilities to conduct rapid-response, real-time R&D during bioincidents to inform ongoing response measures and to understand phenomena that only occur during bioincidents.
- Establish procedures for prioritizing, funding, and coordinating R&D efforts during bioincidents.

#### **3.2 Ensure a strong public and veterinary health infrastructure.**

##### **3.2.1 Ensure Public and Veterinary Health Critical Capacities.**

- Establish capability to provide surge staffing, resources, and supplies to SLTT public and veterinary health departments.
- Advance and sustain a highly-skilled public and veterinary health workforce.

##### **3.2.2 Modernize Public and Veterinary Health Laboratories.**

- Ensure core public and veterinary health laboratories have access to modern and updated diagnostic tests, methods, equipment, and technologies.

#### **3.3 Develop, exercise, and update prevention, response, and recovery plans and capabilities.**

##### **3.3.1 Develop and Exercise Policies, Plans, Guidelines, and Recommendations to Support Prevention, Response, and Recovery Activities.**

- Establish policies, plans, guidelines, and recommendations with multi-sectoral input (and

international stakeholder input, as appropriate) to inform appropriate and timely federal and SLTT response actions to biothreats and bioincidents.

- Develop plans that implement or support surge capabilities across response sectors in coordination with SLTT entities, health care coalitions, foreign governments, international organizations, NGOs, and private sector partners, to include the following:
  - Medical surge response, including to augment specialized clinical care, behavioral and mental health care, transition to crisis standards of care, and provision of mass care and mass fatality management;
  - Clinical guidance to assist with appropriate triage and medical management of illnesses;
  - Transport and reception system and capabilities for crossing borders and U.S. jurisdictions with highly infectious disease patients and materials related to incident response
  - Augmenting provision of human services, including shelters, housing, and commodity distribution;
  - Implementing enhanced surveillance and public health measures for disease control;
  - Clinical, environmental, food testing, and forensic surge laboratory operations;
  - Controlling, responding to, and recovering from animal and plant disease;
  - Engineering response for managing water, land, waste, and air systems; and
  - Routinely conducting and evaluating biothreat and bioincident response exercises for all incident management phases of the response at the federal and SLTT levels.

### **3.3.2 Ensure that Emergency Funding Mechanisms Exist to Support Urgent Responses to Bioincidents.**

- Establish, as appropriate, dedicated funding processes and mechanisms to respond to an actual or imminent bioincident.
- Establish processes to access funds in a timely manner.

### **3.3.3 Support the Effective Deployment of the MCM Stockpiles.**

- Conduct pre-incident planning for distribution and dispensing of the MCM stockpiles to ensure such activities can be accomplished in a timely manner, are informed by appropriate guidance, and can be supported operationally by federal and SLTT agencies during a bioincident.
- Ensure plans consider the provision of MCMs to personnel performing mission-essential functions to help ensure that mission-essential functions continue to be performed after a bioincident.
- Ensure the safety, security (including cybersecurity), and reliability of supply chains to provide necessary MCMs and other materiel support during bioincidents.
- Ensure the capability to monitor the safety and effectiveness of deployed MCMs.
- Integrate the access and functional needs of at-risk individuals in planning for MCM distribution and dispensing.
- Ensure that operational plans, clinical guidance, regulatory mechanisms, and operational capacity are in place to administer stockpiled MCMs effectively.

### **3.3.4 Support the Provision of Health Care and the Conduct of Clinical Research During Bioincidents.**

- Establish procedures and guidelines for the use of MCMs, including personal protective equipment (PPE), and infection control strategies.
- Ensure plans address the needs of all populations, including at-risk individuals.
- Establish and identify medical centers capable of providing specialized care, including at the initial stages of bioincidents.
- Strengthen healthcare system preparedness to enhance hospital and health care facilities' ability to maintain health care operations and provide necessary care during bioincidents.

- Identify existing mechanisms to protect health care workers from financial liability during federally-led responses.
- Establish capabilities to conduct clinical research at the onset of a bioincident to inform optimal clinical care strategies for current and future bioincidents and to support MCM development.
- Establish and pre-position protocols for the conduct of ethical, efficient, and interpretable clinical trials to test promising investigational MCMs during domestic or international bioincidents.
- Establish mechanisms for the collection and sharing of clinical samples to support development of diagnostic tests.
- Establish a regional aid system that will improve national healthcare readiness and medical surge for bioincidents.

### **3.3.5 Support the Continuity of Operations.**

- Further refine, exercise, and evaluate Continuity of Operations plans (including the mitigation of impacts on critical infrastructure located within and outside the United States) to ensure continuation of National Essential Functions during and after bioincidents.

### **3.3.6 Support Provision of Essential Services and Long-term Recovery.**

- Protect the continuity of critical infrastructure, and restore infrastructure and services disrupted by the bioincident.
- Restore critical infrastructure to minimize cascading effects.
- Provide an environment in which essential businesses can continue to operate.
- Support or restore transportation pathways and infrastructure to facilitate supply chains and movement of people.
- Facilitate movement/delivery of supplies critical to response and recovery.

## **3.4 Develop, exercise, and update risk communication plans and promote consistent messaging to inform key audiences, expedite desired response actions, and address public uncertainty and fear.**

### **3.4.1 Improve Federal Messaging Coordination for Biothreats and Bioincidents.**

- Develop a government-wide strategy that institutionalizes the use of risk communication principles to provide clear, consistent, and coordinated information.
- Train spokespersons for federal departments and agencies on risk communications.
- Clarify roles of lead agencies for risk communication messaging to key sectors (e.g., public health, medical, animal, plant, and the environment).

### **3.4.2 Develop and Exercise Communications Plans.**

- Develop and test messaging strategies, platforms, and materials for all sectors and stakeholders to synchronize messaging, address public fear and uncertainty, encourage appropriate response actions, and empower the public during biothreats and bioincidents.
- Develop messaging for non-English speaking populations and in formats that accommodate the access and functional needs of all individuals.
- Establish a national “brand” where stakeholders may routinely seek information on biodefense activities and response actions.
- Routinely exercise communication strategies during pre-incident planning to prepare for real-time biothreat and bioincident response communications.



### **3.4.3 Enhance Messaging Partnerships.**

- Identify a cadre of academic and private sector experts who would be encouraged to interact with traditional and social media and provide accurate information on biothreats and bioincidents.
- Strengthen pre-incident relationships between government communication specialists and the media who specialize in bioincidents and related topics.
- Strengthen pre-incident relationships with private sector social media and other non-traditional media partners capable of broadly disseminating information.

## **3.5 Enhance preparedness to save lives through MCMs.**

### **3.5.1 Improve Diagnostic Capabilities.**

- Advance diagnostic capabilities, including for plants and animal diseases, to enable timely and accurate biohazard and disease detection.
- Maintain a core capability to develop, produce, and refine diagnostic tests rapidly to meet outbreak response needs.
- Develop instructions for public health and medical stakeholders regarding the use of Food and Drug Administration (FDA)-authorized or -cleared diagnostic tests, if available.
- Enhance capability to rapidly characterize bioincidents to help inform ongoing or future response to biothreats and bioincidents.
- Establish standardized Material Transfer Agreements for sample sharing.

### **3.5.2 Enhance MCM Development, Sustainment, and Availability.**

- Use risk and intelligence assessments, epidemiologic analysis, and anticipated operational capacities to inform the life cycle of research, development, evaluation, manufacturing, acquisition, stockpiling, and sustainment of MCMs for humans and animals.
- Support and strengthen mechanisms to comprehensively evaluate and make changes, as needed, across the portfolio of MCMs.
- Prioritize the development and procurement of MCMs with the highest potential to reduce severe morbidity and mortality.
- Prioritize the development of modular platform and innovative technologies to support timely development, production, and availability of MCMs for bioincidents.
- Identify additional incentive mechanisms to engage MCM developers and stimulate private sector investment and innovation across the range of the MCM technology base.
- Improve or develop affordable, flexible, and multi-functional PPE for responders, health professionals, and the general population.
- Establish manufacturing surge capacity for MCMs, including diagnostic tests and PPE.

## **3.6 Enhance preparedness to limit the spread of disease through CMMs.**

### **3.6.1 Enhance Development of and Capabilities for Implementing CMMs.**

- Develop and assess the effectiveness of CMMs to mitigate the impact of bioincidents.
- Establish and promote best practices for implementing CMMs during bioincidents.

## **3.7 Enhance preparedness to support decontamination.**

### **3.7.1 Conduct Research and Develop Verified Technologies.**

- Conduct research to understand the persistence and potential for secondary transmission of biological contaminants in a variety of environments and the ability of various disinfection

technologies to inactivate or remove biological contaminants.

- Develop and verify technologies for all phases of environmental cleanup that address various types of infrastructure, equipment, and environments.
- Develop readily available and scalable technologies and software tools to support water and wastewater infrastructure decontamination and the treatment of contaminated water.

#### **3.7.2 Develop and Exercise Decontamination Plans.**

- Develop and verify plans for all phases of environmental cleanup for facilities, equipment, and the environment through drills and exercises that incorporate relevant partners and stakeholders.
- Establish pre-incident decontamination and waste management recommendations for:
  - Impacted community members, patients, and response personnel;
  - Contaminated drinking water;
  - Waste collection, handling, and packaging methods suitable for waste transport (including interstate transport), temporary storage, off-site treatment, and disposal;
  - Handling and disposition of human remains;
  - Disposition of animal remains; and
  - Environmental decontamination practices, as warranted.

### **3.8 Strengthen preparedness to operate and collaborate across the United States, including U.S. territories.**

#### **3.8.1 Establish Collaborative and Resource Sharing Policies and Operational Frameworks.**

- Establish mechanisms to facilitate rapid deployment of federal and SLTT response personnel and response resources across jurisdictional boundaries.
- Establish and augment mechanisms by which the Federal Government can use assistance from non-federal and foreign sources with medical products, qualified public health, medical, or other personnel, or other resources during a bioincident.
- Establish protocols for timely sharing of samples, specimens, and related clinical information among federal departments and agencies and across public health, animal health, and environmental jurisdictions in the United States and U.S. territories.

### **3.9 Strengthen international preparedness to support international response and recovery capabilities.**

#### **3.9.1 Strengthen Foreign Governments and International Organizations' Commitment to, Preparedness for, and Capacity to Respond to Bioincidents.**

- Promote global health security as a leadership priority and a national responsibility to accelerate bioincident detection, response, and recovery capacity-building.
- Support health emergency response teams of qualified personnel to respond rapidly to international health emergencies.
- Support workforce preparedness in emergency management principles, exercised on an Emergency Operation Center platform.
- Promote multi-sectoral and trans-disciplinary collaboration across diverse stakeholders to facilitate rapid and comprehensive response to bioincidents.
- Improve international access to and promote use of: best practices, model procedures, reporting templates, and training materials to facilitate rapid identification and notification of, and response to, potential biothreats or bioincidents.
- Promote and enhance mechanisms for sharing specimens, samples, and information.

- Ensure that international mechanisms are prepared fully for the unique challenges of responding to deliberate biotreats and bioincidents.
- Support transparent, independent, and objective assessments of the international community's capacity to respond to bioincidents.
- Coordinate with partner countries to develop and implement multi-sectoral plans to address identified gaps in health security and ensure adherence to standards outlined in the International Health Regulations (2005) and by the World Organisation for Animal Health.
- Support country and regional development and sustainment of public and veterinary core capacities and standards.

### **3.9.2 Enhance International Preparedness through MCMs.**

- Promote increased global capacities for research, development, evaluation, manufacturing, acquisition, stockpiling, deployment, and distribution of MCMs, including through collaborative arrangements.
- Address legal, regulatory, administrative, and financing barriers for international sharing of MCMs, other medical products, and qualified personnel.
- Ensure that international coordination and planning for bioincidents include consideration of the constraints to the ability of the United States to provide MCMs to other countries to address international bioincidents.
- Expand the international deployment and utilization of FDA-authorized or -cleared diagnostic tests.
- Develop appropriate plans and agreements to facilitate the rapid international deployment and distribution of MCMs under the appropriate regulatory mechanisms, or for the rapid development, including clinical trials, of investigational MCMs during a crisis.
- Strengthen international protocols for the conduct of clinical trials in a crisis.

### **3.9.3 Enhance International Preparedness Through CMMs.**

- Promote the implementation of CMMs that can prevent transmission of communicable disease (e.g., voluntary isolation, hand washing with soap, covering mouth when coughing or sneezing, voluntary home quarantine).
- Support international partners in developing the authority to invoke and the capacity to implement threat-appropriate travel and border health measures, such as travel warnings and restrictions.
- Enhance engagement with community leaders to promote understanding of CMMs.
- Strengthen whole of society approaches through promoting multi-sectoral civil society, government, and private sector partnerships to improve incident reporting, and early action and response, and to mitigate the impact within communities by expanding coordination and response networks.

### **3.9.4 Further Develop, Exercise, and Update United States Government Plans for Responding to and Recovering from International Bioincidents.**

- Develop bioincident response plans for response and recovery at the international level with key international stakeholders as well as key SLTT, non-governmental, and private sector partners.
- Ensure that international coordination and planning for bioincidents consider the constraints to the ability of the United States to provide response capabilities to address international bioincidents.
- Prepare and exercise plans for repatriation of personnel and materiel during a bioincident.

## **GOAL 4:**

### **RAPIDLY RESPOND TO LIMIT THE IMPACTS OF BIOINCIDENTS.**

#### **4.1 Compile and share biothreat and bioincident information to enable appropriate decision-making and response operations across all levels of government and with non-governmental, private sector, and international entities, as appropriate.**

##### **4.1.1 Ensure Access to Timely, Accurate, and Useful Information.**

- Coordinate and exchange biothreat and bioincident information and analysis across multi-sectoral stakeholders nationally and internationally.

##### **4.1.2 Coordinate Federal Decision-making to Augment and Support Response Operations.**

- Coordinate and communicate decision-making during biothreat and bioincident prevention, response, and recovery operations.
- Rapidly identify and resolve at the federal level any resource and policy issues related to ongoing response and recovery activities, both nationally and internationally.
- Utilize intelligence, biosurveillance, diplomacy, healthcare capacity and capability data, and modeling capabilities to maintain situational awareness and support decision-making across sectors and between local, national, and international organizations and partners throughout the response.
- Notify, share information, and coordinate with international organizations and partners in accordance with the International Health Regulations (2005) and World Organization for Animal Health reporting requirements, and relevant frameworks throughout the bioincident response.

##### **4.1.3 Enhance Situational Awareness Through Real-time, Incident Information Sharing.**

- Rapidly share modeling, detection, healthcare capacity and capability data, and diagnostic information with appropriate stakeholders to monitor the bioincident continually and support multi-sectoral decision-making throughout the response.
- Utilize all sources of data, as appropriate, including social media and intelligence feeds, electronic medical records/health information exchanges, and new data analytic technologies, such as artificial intelligence, to further support incident awareness.
- Provide timely information to domestic and international stakeholders regarding utilization of border measures, prioritization of MCM dispensing, epidemiological control measures, and re-occupation of decontaminated areas.

#### **4.2 Conduct federal response operations and activities in coordination with relevant non-federal actors to contain, control, and to rapidly mitigate impacts of biothreats or bioincidents.**

##### **4.2.1 Ensure Appropriate Oversight and Coordination.**

- Identify a lead federal department or agency to provide overall coordination for the United States Government response to a national or international bioincident and to ensure coordination of response at the national/international interface level.

- Provide federal bioincident coordination to improve incident management across sectors and with all key stakeholders.
- Coordinate support to international bioincident response operations through the Department of State, including Chiefs of Mission, to prevent the spread of bioincidents.
- Identify mechanisms for access to budgetary resources to support the rapid response to a large-scale bioincident.
- When necessary, integrate coordinated federal activities into SLTT response efforts.
- Coordinate domestic assistance from international entities and from the private sector.
- Plan to use the *Defense Production Act of 1950*, as amended (2009) (50 U.S.C. 2061-2071) to obtain and facilitate distribution of resources that are urgently needed to respond to biological threats and incidents.

#### 4.2.2 Deploy MCMs and Implement CMMs.

- Rapidly identify potentially exposed populations to begin triage, preventive healthcare activities, and treatment.
- Ensure that access and functional needs of at-risk individuals are integrated into rapid deployment.
- Implement CMMs and other multidisciplinary bioincident control measures, to include addressing service animal and wildlife concerns, animal vaccination, and agricultural depopulation.
- Deploy MCMs and support SLTT and medical supply distribution systems in the dispensing of MCMs, PPE, and medical equipment, under the appropriate regulatory mechanisms.
- Monitor the safety and effectiveness of deployed MCMs.
- Supplement, as necessary, the capabilities of affected jurisdictions to rapidly deploy MCMs following a bioincident, via a rapid response capability.
- Ensure provision of MCMs, as appropriate, to personnel performing or supporting mission-essential functions following a bioincident.
- Ensure resources to maintain or develop clinical guidance and utilization policies to prepare for MCM deployment in crisis situations.
- Assess deficiencies in the health care system in the United States and U.S. territories to address these threats and coordinate *in extremis*.

#### 4.2.3 Conduct Real-time Research.

- Conduct real-time research during response to characterize emerging biothreat agents and develop response tools in order to improve response and recovery capacity, capability, and future preparedness.
- Rapidly identify and disseminate guidelines and clinical approaches during a bioincident for the purpose of decreasing transmission, morbidity, and mortality; and rapidly identify and disseminate analogous approaches for animals and plants.
- Conduct real-time clinical research to evaluate promising investigational MCMs, and identify potential novel diagnostics, treatments, and vaccines.
- Establish processes to accelerate protocol development, clinical sites identification, and institutional review board and regulatory review.

#### **4.2.4 Implement or Support Response Operations.**

- Deliver and distribute response equipment and supplies, including healthcare resources and trained personnel, and provide for the availability of security capabilities to support response operations domestically and internationally.
- Facilitate implementation of crisis standards of care as needed and return to conventional care, as appropriate.
- Provide available federal medical, public health, and veterinary surge capacity and capabilities in a timely, coordinated manner to implement or support public and animal health, behavioral, and medical and veterinary services, including by augmenting SLTT capabilities.
- Provide mass fatality management including mortuary affairs, as appropriate.
- Augment transportation and reception systems and provide capabilities to support movement of highly infectious disease patients and response-generated materials across borders and U.S. jurisdictions.
- Provide oversight and assistance for carcass management services, as appropriate.
- Conduct decontamination operations and the management of waste and contaminated materials in a manner that is protective of human, animal, and plant health, the environment, and the economy.
- Ensure the health and safety of federal, SLTT, private sector, and NGO responders involved in response operations.

#### **4.2.5 Preserve the Continuity of Operations.**

- Maintain comprehensive and effective continuity of operations, including appropriate devolution, to ensure the preservation of the United States Government's structure under the U.S. Constitution and the continuing performance of National Essential Functions under all conditions.
- Secure, protect, and restore, as needed, critical infrastructure assets that have the potential to impact or be impacted by the spread of the bioincident.
- Secure and protect critical information and communications systems necessary for biodefense.

### **4.3 Conduct operations and investigations, and use all available tools to hold perpetrators accountable.**

#### **4.3.1 Conduct Incident Operations and Investigations.**

- Utilize secure advanced communications capabilities between specialized response assets, technical experts, and senior decision-makers.
- Strengthen federal and SLTT law enforcement, medical, public health, animal, and plant health stakeholder capacity and capabilities to conduct joint criminal-epidemiologic investigations for suspect and confirmed intentional biotreats or bioincidents.
- Rapidly assess interdicted biological materials contained within a weapon or dispersal device, disable it, and contain the materials to prevent further dissemination.
- Transport biological weapons, materials, and means of delivery to an appropriate location for further characterization.
- Draw from national and international tools, including applicable laws and agreements, where appropriate and consistent with prosecutorial discretion, to hold perpetrators of intentional bioincidents accountable.

#### **4.3.2 Forensics and Attribution.**

- Utilize forensic tools and investigation capabilities to conduct forensic examinations to support attribution of a biothreat or a bioincident.
- Use applicable protocols and memoranda of agreement to facilitate transport of potentially bio-contaminated evidence and classified materials to appropriate, pre-designated facilities for analysis.

#### **4.3.3 Support International Investigations.**

- Provide appropriate technical and logistical support to investigations of alleged biological weapons, materials, and means of delivery under international auspices.

### **4.4 Execute risk-informed, accurate, timely, and actionable public messaging.**

#### **4.4.1 Deliver Public Messaging to Facilitate Public Understanding and Decision-making During a Bioincident.**

- Provide timely, regular, coordinated, and consistent risk communication, including information on response and recovery procedures and personal protective measures, across a range of media for the public.
- Provide mechanisms for stakeholders and members of the public to ask questions and provide comments and feedback.
- Use accessible communication strategies to maximize participation in appropriate response measures that address the needs for messaging in multiple formats and languages to accommodate the access and functional needs of the entire population.
- Identify and combat misinformation, including information regarding movement restrictions and re-entry of health workers and other incident responders.

## **GOAL 5:**

### **FACILITATE RECOVERY TO RESTORE THE COMMUNITY, THE ECONOMY, AND THE ENVIRONMENT AFTER A BIOINCIDENT.**

#### **5.1 Promote restoration of critical infrastructure capability and capacity to enable the resumption of vital U.S. activities.**

##### **5.1.1 Restore Capability and Capacity.**

- Ensure that safety measures are in place to enable and help restore health, social, and economic activity.
- Address the loss of critical infrastructure capability and capacity as quickly as possible to limit cascading effects by working with owners and operators, SLTT entities, and international partners, as appropriate.
- Support restoration of critical infrastructure in addition to continued performance of National Essential Functions through recovery of the federal, military, local first responders, and other critical workforces.
- Facilitate health monitoring and surveillance for emergency responders, health care providers, federal personnel, and the public, including through the provision of post-exposure evaluations and medical monitoring.

#### **5.2 Ensure coordination of recovery activities across federal and SLTT governments and, as appropriate, international, non-governmental, and private sector partners to enable effective and efficient recovery operations.**

##### **5.2.1 Coordinate and Oversee.**

- Coordinate recovery planning and information-sharing among federal, SLTT, non-government, and health care coalition partners.
- Support SLTT officials in decision-making and implementation of services such as relocation, alternative housing, and re-occupancy strategies, and access to health and social services.
- Support SLTT officials in decision-making regarding re-habitation and re-introduction of wildlife, livestock, service animals, and pets in the environment, homes, or commercial market.
- Conduct impact assessments, develop recovery strategies, and implement operational capabilities.
- Restore public confidence in community and environmental safety through frequent strategic communications via various media and other messaging partners.

#### **5.3 Provide recovery support and conduct long-term mitigation actions to promote resilience.**

##### **5.3.1 Conduct Recovery and Mitigation Activities.**

- Support SLTT officials in decision-making about long-term recovery operations, including remediation of remaining contaminated areas, long-term environmental monitoring, and assessing and communicating the appropriateness for re-occupancy of impacted areas.



- Support provision of long-term medical and behavioral health services to affected populations, including for emergency responders.
- Support effective and timely risk communication to promote public awareness of recovery operations.
- Provide necessary support and augmentation of SLTT civilian capabilities to maintain and sustain public safety protection assurances.
- Assist recovery of private entities that cannot operate because of a bioincident, as funding and authorities permit.
- Support partner countries in decision-making about long-term recovery operations.
- Support SLTT officials and private-sector responders involved in determining how to integrate mitigation considerations into long-term recovery operations.
- Coordinate the activities of the Federal Government in support of SLTT officials to assess, restore, and initiate necessary interventions to re-establish critical capabilities in health and social services.

## **5.4 Reduce the cascading effects of international biological incidents on the global economy, health, and security.**

### **5.4.1 Reduce International Economic, Health, and Security Impact.**

- Promote the provision of recovery support and related activities to mitigate the second order impacts of a bioincident.
- Assess impacts—such as severe disruptions of health services, economic and social activity and the decline of essential governmental services—caused by an international bioincident.
- Support activities to strengthen host governments’ ability to deliver critically needed services and to retain democracy and governance.
- Support households, communities, and agriculture markets to recover from the food safety impacts of the bioincident.

## ANNEX II

### DEFINITIONS

The terminology used throughout the strategy is consistent with the following definitions:

**Biodefense:** Actions to counter biological threats, reduce risks, and prepare for, respond to, and recover from bioincidents.

**Biodefense enterprise:** Stakeholders with a role in the prevention, preparedness for, detection, response, and recovery from bioincidents (e.g., federal and SLTT governments, non-governmental and private sector entities, and international partners).

**Biological hazard (biohazard):** A biological agent or biologically active substance—excluding toxic chemical substances that are considered solely as chemical weapons agents, regardless of origin (e.g., naturally occurring or bioengineered)—that represents an actual or potential danger to humans, animals, plants, or the environment.

**Biological incident (bioincident):**

- Any act of biological warfare or terrorism;
- A crime involving a biohazard consistent with the scope of this strategy; or
- Any natural or accidental occurrence in which a biohazard harms humans, animals, plants, or the environment consistent with the scope of this strategy.

**Biological threat (biothreat):** An entity involved with, or a situation involving, a biohazard that can potentially cause a bioincident.

**Biosurveillance:** The process of gathering, integrating, interpreting, and communicating essential information and indications related to all-hazard threats or disease activity affecting human, animal, plant, and environmental health to achieve early detection and provide early warning, contribute to overall situational awareness of the health aspects of the incident, and to enable better decision-making at all levels.

**Bioweapons-related:** Materials, equipment, information, or technology covered by relevant

multilateral treaties and arrangements, or included on national or international control lists, which could be misused for the design, development, production, or use of biological weapons and their means of delivery.

**Clinical Guidance:** Recommendations that define prevention, triage, and medical management of individuals who are at-risk or affected by biothreats.

**Community Mitigation Measures (CMMs):** Behaviors or actions that people and communities can take to help slow the spread of a biological hazard, to include threat-appropriate travel and border health measures.

**Delivery system:** Any apparatus, equipment, device, or means of delivery used or intended to be used to deliver or disseminate biological material.

**Dual-use:** Intended for legitimate purposes but having the potential for both benevolent and malevolent applications.

**Healthcare coalition:** A collaborative network of healthcare organizations and their respective public and private sector emergency response partners, including, but not limited to, hospitals, emergency medical services, and emergency management and public health agencies, that serves as a multiagency coordinating group to assist with preparedness, detection, response, recovery, and mitigation activities related to healthcare service delivery during bioincidents.

**Medical Countermeasures (MCMs):** Pharmaceutical products, such as vaccines, antimicrobials, and antitoxins, and non-pharmaceutical products, such as ventilators, diagnostic tests, PPE, and patient decontamination materials, that may be used to prevent, mitigate, or treat the adverse health effects from a bioincident.

## ANNEX III

### SCOPE, STATUTORY REQUIREMENTS, AND AGENCIES

#### SCOPE

The *National Biodefense Strategy* addresses biothreats and bioincidents that have the potential to cause significant harm (as measured by injury or death, or damage to property, the environment, or the economy) to the United States or to U.S. interests; or that otherwise affect U.S. national security.

The *National Biodefense Strategy* is intended to inform the policy development process and is not a budget document. The commitment of federal resources to support activities associated with this

document will be determined through the annual budget process, which will be informed by this strategy.

#### STATUTORY REQUIREMENTS

Section 1086 of the *National Defense Authorization Act for Fiscal Year 2017* (Pub. L. No. 114-328; enacted December 23, 2016), codified at 6 U.S.C. 104, provides:

**SEC. 1086. NATIONAL BIODEFENSE STRATEGY.**

(a) **STRATEGY AND IMPLEMENTATION PLAN REQUIRED.**—The Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Agriculture shall jointly develop a national biodefense strategy and associated implementation plan, which shall include a review and assessment of biodefense policies, practices, programs and initiatives. Such Secretaries shall review and, as appropriate, revise the strategy biennially.

(b) **ELEMENTS.** The strategy and associated implementation plan required under subsection (a) shall include each of the following:

(1) An inventory and assessment of all existing strategies, plans, policies, laws, and interagency agreements related to biodefense, including prevention, deterrence, preparedness, detection, response, attribution, recovery, and mitigation.

(2) A description of the biological threats, including biological warfare, bioterrorism,

naturally occurring infectious diseases, and accidental exposures.

(3) A description of the current programs, efforts, or activities of the United States Government with respect to preventing the acquisition, proliferation, and use of a biological weapon, preventing an accidental or naturally occurring biological outbreak, and mitigating the effects of a biological epidemic.

(4) A description of the roles and responsibilities of the Executive Agencies, including internal and external coordination procedures, in identifying and sharing information related to, warning of, and protection against, acts of terrorism using biological agents and weapons and accidental or naturally occurring biological outbreaks.

(5) An articulation of related or required interagency capabilities and whole-of-Government activities required to support the national biodefense strategy.

(6) Recommendations for strengthening and improving the current biodefense

capabilities, authorities, and command structures of the United States Government.

(7) Recommendations for improving and formalizing interagency coordination and support mechanisms with respect to providing a robust national biodefense.

(8) Any other matters the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Agriculture determine necessary.

(c) SUBMITTAL TO CONGRESS.—Not later than 275 days after the date of the enactment of this Act, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Agriculture shall submit to the appropriate congressional committees the strategy and associated implementation plan required by subsection (a). The strategy and implementation plan shall be submitted in unclassified form, but may include a classified annex.

(d) BRIEFINGS. Not later than March 1, 2017, and annually thereafter until March 1, 2019, the Secretary of Defense, the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Secretary of Agriculture shall provide to the Committee on Armed Services of the House of Representatives, the Committee on Energy and Commerce of the House of Representatives, the Committee on Homeland Security of the House

of Representatives, and the Committee on Agriculture of the House of Representatives a joint briefing on the strategy developed under subsection (a) and the status of the implementation of such strategy.

(e) GAO REVIEW.—Not later than 180 days after the date of the submittal of the strategy and implementation plan under subsection (c), the Comptroller General of the United States shall conduct a review of the strategy and implementation plan to analyze gaps and resources mapped against the requirements of the National Biodefense Strategy and existing United States biodefense policy documents.

(f) APPROPRIATE CONGRESSIONAL COMMITTEES DEFINED. In this section, the term “appropriate congressional committees” means the following:

- (1) The congressional defense committees.
- (2) The Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.
- (3) The Committee on Homeland Security of the House of Representatives and the Committee on Homeland Security and Governmental Affairs of the Senate.
- (4) The Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

## AGENCIES

Consistent with the requirements of the *National Defense Authorization Act for Fiscal Year 2017*, the primary drafters for the *National Biodefense Strategy* are the Departments of Defense, Health and Human Services, Homeland Security, and Agriculture. In addition, the National Security Council Staff coordinated the review and finalization of the *National Biodefense Strategy* with the Departments of State, Treasury, Justice, Interior, Commerce, Labor, Transportation, Energy, and Veterans Affairs, the Environmental Protection Agency, the Office of Management and Budget, the Office of the Director of National Intelligence, the Office of Science and Technology Policy, the U.S. Agency for International Development, and the Federal Bureau of Investigation.