

Position Paper: Bioterrorism Preparedness & Response

A Proposed Model for Bioterrorism Response: Initial Operations and Characterization



**Position Paper:
Bioterrorism Preparedness & Response**

A Proposed Model for Bioterrorism
Response: Initial Operations and
Characterization

A consensus pathway to implementing bioterrorism response and detection standards on a national scale to protect the people of the United States, our communities, counties, and tribal nations.

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EXECUTIVE SUMMARY

This paper presents the position of the InterAgency Board (IAB) on an approach to developing a national bioterrorism response capability. The IAB proposes a model for a biothreat response capability that brings together public safety jurisdictions, federal resources, processes, standards, and doctrine to support the creation of a network of locally owned and operated validated bioterrorism response teams. Under this model, responder organizations that meet eligibility requirements can apply to operate through contracts as approved bioterrorism response organizations within their own jurisdictions. These teams would be trained and equipped to meet a set of national standards and would work collaboratively with the Federal Bureau of Investigation (FBI) and the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) in bioterrorism incident responses.

The model described herein defines proposed equipment, training, and capability requirements and recommends establishing equipment and training standards. A model for funding this national program is also outlined. By implementing this model, all stakeholders in the biothreat response enterprise will be able to confidently make decisions on courses of action to assure public safety and consistently address threats or the perception of them.

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1. PURPOSE

This paper presents the position of the InterAgency Board (IAB) on an approach to developing a national bioterrorism response capability to address long-standing gaps in domestic bioterrorism preparedness and response. The IAB proposes a model that brings together public safety jurisdictions, federal resources, processes, standards, and doctrine to support the creation of a network of locally owned and operated validated bioterrorism response teams that constitute a national, rather than a federal, capability. Under this model, responder organizations that meet eligibility requirements can apply to operate through contracts as approved bioterrorism response organizations within their own jurisdictions. These teams would be trained and equipped to meet a set of national standards and would work collaboratively with the Federal Bureau of Investigation (FBI) and the Centers for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) in bioterrorism incident responses.

This paper defines the proposed equipment, training, and capability requirements for a validated biothreat response team, lists structured and validated activities that should occur during the incident characterization and initial response phases of a bioterrorism response, and recommends establishing equipment and training standards. By implementing this model, all stakeholders will be able to stand behind the information provided by initial response actions to assure public safety and consistently address threats or the perception of them.

The IAB and affiliated contributors from the first response community offer this position paper and proposed model with a deep and common sense of purpose, to protect the Nation from a long-standing vulnerability to bioterrorism and avert a catastrophic event that would devastate the American sense of safety and security and irrevocably damage the public trust in the U.S. emergency management enterprise. To date, no nationally recognized system has been instituted to provide a high level, consistent bioterrorism response. The model recommended herein will connect existing organizations in a national system of response capability that will standardize competency levels and raise them to a level sufficient to meet the potential threat.

2. HISTORICAL PERSPECTIVE

Since the introduction of domestic terrorism in the modern era, many disciplines and organizations in the United States have played critical roles in detecting and responding to incidents involving unconventional weapons. For decades, agencies and jurisdictions have maintained explosive and nuclear incident response capabilities to varying degrees. But with the 1995 Aum Shinrikyo attack in Tokyo, it became clear that the United States lacked a response

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capability against yet another threat—chemical and biological agents.¹ Initially, U.S. public policymakers turned to an existing capability—Hazardous Materials Response Teams (HMRTs)—as a primary response resource. This was a logical progression; HMRTs are a subset of public safety emergency response organizations, most commonly based in the fire service. The HMRT concept was developed in the 1980s following the Bhopal, India chemical release tragedy and the U.S. Superfund Amendments and Reauthorization Act (SARA).² These teams specialized in hazardous materials responses; they were qualified to use personal protective equipment, conduct decontamination, and possessed at least some chemical and radiological field detection capabilities. As new chemical, biological, radiological, and explosive threats evolved, the U.S. Government increased its focus on effective national preparedness,³ and many federal agencies proposed and funded potential solutions. Unfortunately, these efforts were not coordinated or consistent. While each found some success, communities and first responders nationwide remained vulnerable.

The 9/11 terrorist attacks sharply heightened the Nation’s awareness of the devastating effect of terrorism and revealed the inadequacy of our domestic bioterrorism preparedness and response strategy. The Amerithrax attacks in October 2001 demonstrated further that biological weapons posed a serious threat to our nation and the world at large.⁴ These attacks drove substantial attention and funding to civilian biodefense—\$17 billion in grants and contracts.⁵

Yet today, the United States remains unprepared to respond to bioterrorism in many key areas. First responders often must address novel threats with which they are unfamiliar due to inadequate training and equipment, and limited time to plan and coordinate with new and unknown local, state, federal, and private-sector response partners who are equally unprepared for this new threat environment. In addition, it remains impossible to accurately determine the number of agencies involved, the funding provided, and the organizations that benefit, another indicator of the lack of coordination in improving bioterrorism response preparedness.

¹ Smithson, A.E. & Levy, L-A. (1999). Ataxia: The Chemical and Biological Terrorism Threat and the US Response, Report No. 35, October 2000. Washington, DC: Henry L. Stimson Center.

² Superfund Amendments and Reauthorization Act (SARA) of 1986, Pub. L. No. 99-499, 100 Stat. 1613 (1986).

³ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

⁴ Implementing Recommendations of the 9/11 Commission Act of 2007, Pub. L. No. 110-53, §1101, 121 Stat. 266, 375 (2007), codified at 6 U.S.C. §195b; *World at Risk, The Report of the Commission on the Prevention of WMD Proliferation and Terrorism*. New York: Vintage Books, 2008) p. xv; Guidance on Initial Responses to a Suspicious Letter/Container with a Potential Biological Threat, FBI–DHS–HHS/CDC Coordinated Document, November 2004.

⁵ Sell et al., Federal Agency Biodefense Funding, FY2013–FY2014, *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science*, 2013, 11(3): 196–216; Boddie et al., “Federal Funding for Health Security in FY2016”, *Health Security*, 2015, 13(3): 186–206.

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The Federal Government has attempted to improve bioterrorism response preparedness by expanding bioterrorism-related training and education. The U.S. Department of Justice, the Department of Defense (DOD), the Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and the Department of Homeland Security (DHS) have all produced educational programs for first responders. However, a lack of effective coordination among the various programs has resulted in limited and inconsistent improvements to response capabilities. For example, following the Aum Shinrikyo attack, federal agencies delivered presentations on detecting potential bioterror weapons, but did not address strategies or tactics for deploying technologies and integrating them into an emergency response. In many circumstances, federal grant programs called for a spectrum of competencies without requiring state and local jurisdictions, disciplines, and organizations to plan and execute joint exercises to improved coordinated responses. Organizations often were not aware of resources already available in their area.

Another approach to improving bioterrorism response preparedness has focused on establishing standards for biothreat detection. In 2007, the Stakeholder Panel on Agent Detection Assays (SPADA) was founded, funded by DHS and managed under contract with AOAC International, a not-for-profit voluntary consensus standards development organization. SPADA was charged with developing standards for “Public Health Actionable Assays” for the validation of automated biothreat detection systems and user interfaced (responder-operated) devices. The technology selected to execute these standards was polymerase chain reaction (PCR).⁶

Unfortunately, SPADA’s efforts failed to produce results that would support a validated biodetection capability for first responders. Several factors led to this outcome:

A declining market. Demand for biodetection devices for executive protection decreased as the public increasingly viewed bioattacks as less of a threat.

The perception by public health stakeholders that non-laboratory assays were inadequate. The public health community did not consider non-laboratory assays sufficient to order prophylaxis or isolation. DHS shifted funding away from evaluating and developing lateral flow assays after determining that users would prefer the more reliable PCR method.⁷

Unnecessarily high and expensive performance requirements. SPADA ultimately produced several standard method performance requirements (SMPRs) for biothreat detection, all but two of which are intended for “laboratory use for analysis of aerosol collection filters and/or liquids.”

⁶ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

⁷ Ibid.

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The two SMPRs that do exist for field screening of visible powders are both written for immunoassays. All the SMPRs have unnecessarily high performance requirements that can only be achieved with very significant expenditures of time and money. As of this date, no commercially available technology has been evaluated to determine whether it meets the full AOAC requirements for biothreat detection.

Voluntary compliance. Without the driver of mandatory compliance with standards, response agencies that purchased biodetection equipment during the early rounds of post-9/11 DHS grants were reluctant to focus more grant dollars on new equipment when doing so was not required and would not gain public health community acceptance.

Perhaps the most important outcome of SPADA’s efforts was the emergence of a common understanding regarding what is required to provide a national bioterrorism response capability. This common understanding garnered multi-lateral agreement among previously opposed stakeholders and serves as a roadmap for implementing this model. On September 12, 2008, a Town Hall Meeting Assembly adopted five articles that served as a position document delivered to DHS. The SPADA summary report is provided in Appendix A.

The findings of the Town Hall meeting, along with the body of all SPADA meeting deliberations, were consolidated into an overarching description of needs called the “SPADA Onion” (Figure 1). The SPADA Onion identifies five key capability elements of response, including but not limited to the assay; it was also incorporated in a key 2011 DHS Framework document.⁸

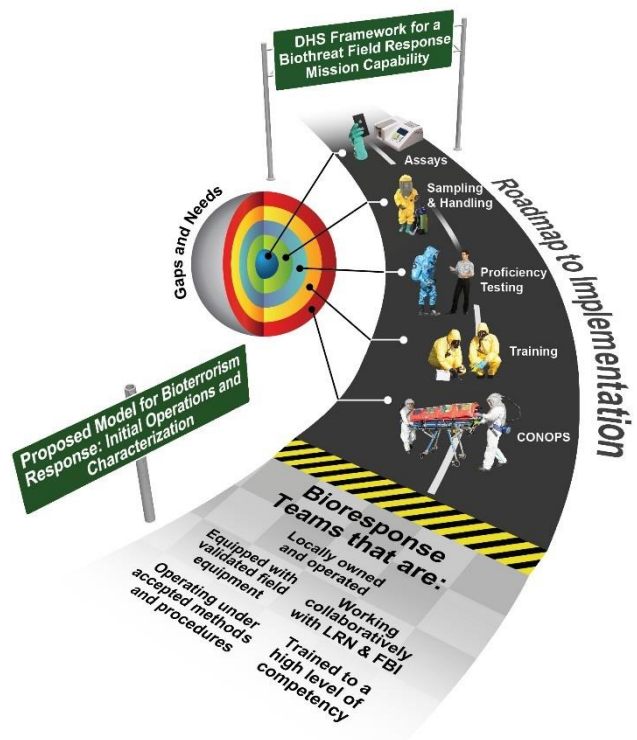


Figure 1. Components of a mission capability for biothreat field response ("SPADA Onion")

⁸ Department of Homeland Security. (2011). *Framework for a Biothreat Field Response Mission Capability*, April 2011, p. 5.

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3. BIOTERRORISM RESPONSE GAPS

The historical perspective reveals gaps in organization, equipment, training, and coordination.

Lack of coordination between response agencies, public health, and the medical community. Various jurisdictions and organizations throughout the United States apply their expertise, training, and resources to identifying and addressing known or perceived threats.⁹ But a siloed approach is inefficient—it does not leverage all the skills and resources available across the nation. For example, following the 2001 anthrax attacks, fire departments and law enforcement agencies rushed to obtain detection technologies to fill a perceived gap without knowing the range of public health laboratory resources available to them.

At the same time, many state and local public health departments were refining their skills in laboratory sample analysis without linking to the response community. Many organizations have developed training, plans, and methods without guidance, coordination, or collaboration between the laboratories and response communities. The growing availability of a wide array of untested biodetection products with varying levels of performance efficacy and scientific accuracy may also have exacerbated this isolation.

Lack of validated and standardized biodetection products that support both short-term and long-term decision making. Also in the immediate post-9/11 period, a robust debate arose between the first responder and public health/medical communities regarding first responders' capability to identify biological threat agents and determine how to treat human exposures. In a bioterrorism response, first responders must determine the risk to guide decisions on appropriate short-term tactical actions to protect the public and preserve potential crime scenes. These actions include properly collecting samples for definitive analysis by a qualified laboratory. However, there are currently no validated field biodetection products that first responders can use to effectively support short-term, tactical decision making without complicating the long-term health/medical response and without unnecessarily employing limited and expensive responder or laboratory resources.¹⁰ At the same time, not all public health laboratories can analyze samples rapidly enough to meet the needs of first responders and community leaders.

For purposes of clarification, the term “short-term, tactical decision making” is used to provide a clear distinction from public health decision making. Threat detection methods for short-term, tactical decision making need not necessarily meet the same standards as those for public health

⁹ Guidance on Initial Responses to a Suspicious Letter/Container with a Potential Biological Threat, FBI-DHS-HHS/CDC Coordinated Document, November 2004.

¹⁰ Guidance on Initial Responses to a Suspicious Letter/Container with a Potential Biological Threat, FBI-DHS-HHS/CDC Coordinated Document, November 2004.

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decision making. Nonetheless, early decisions and communication, even regarding false positives and false negatives, can have reverberating, long-term impacts on community perceptions of safety, public policy, and rule-making, and on public support and trust.

Rapid detection of biothreat agents is paramount for several reasons:

- To determine whether a threat is credible and characterize the risk.
- To effectively address public fears.
- To support short-term remediation decisions affecting infrastructure, population, commerce, and transportation.
- To identify potential criminal activity
- To support real-time response measures, including protective actions, summoning of resources, initiation of investigations, and identification and protection of crime scenes for prosecutorial purposes.

The position of the public health and medical communities was that field identification and recommendations were only medically appropriate and safe when analyses were conducted under medical laboratory performance standards. Rapidly implementing response measures is hampered by conflicting scientific and legal measures and the ongoing debate between jurisdictions, organizations, agencies, and individuals regarding the best way to interpret and communicate findings to leaders and communities. While both approaches have positive impacts, they are obviously inherently incompatible.

There is value in finding the nexus between the need of first responders to support immediate emergency decision making and the need of health/medical providers to analyze threats and take effective long-term actions to protect the health of the community. Maintaining community trust in first responders' ability to ensure public safety requires consistency and accuracy from decision makers and communicators. The challenge is addressing both the short- and long-term goals effectively and consistently.

Lack of training and joint planning and exercises. Validated technologies and capabilities must be present in all bioterrorism incident-related activities to aid in credible risk evaluation and decision making. This requires ongoing and consistent funding for technology, training/skill development, exercising, and inter-disciplinary planning. With the collaboration of various federal funding entities, implementation of this model would help standardize procedures, but as funding decreases, so might the impetus for collaboration. The model provides for measurable performance standards so that community leaders and residents can judge the model's effectiveness. This model provides a framework for bioterrorism emergency response;

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effectively implementing it requires the willingness of impacted organizations to cooperate and collaborate.¹¹

4. KEY CONCEPTS OF THE BIOTERRORISM RESPONSE MODEL

This bioterrorism response model seeks to deter the use of and enhance effective response to biological agent threats by creating a national program for public safety jurisdictions that leverages federal funding and coordinates public health laboratories, federal law enforcement, and National Guard resources. This will be accomplished by bringing together all required process elements, including standards and doctrine, as they pertain to bioterrorism. The result will be a bioterrorism response capability that can be replicated in jurisdictions nationwide. Implementing this model will enable all stakeholders to stand behind the information provided by initial response actions to assure public safety and consistently address threats or the perception of them.

This approach is similar to the present “Securing the Cities” initiative operated by the DHS Domestic Nuclear Detection Office,¹² which serves as a precedent or model for legislation. In this bioterrorism response model, responder organizations—principally HMRTs operated by state, local, or tribal governments—that meet eligibility requirements can apply to operate under contract as validated bioterrorism response teams within their own jurisdictions. Under these contracts, organizations will receive training and certification from a nationally approved and administered program. Training could be delivered locally by National Guard Weapons of Mass Destruction Civil Support Teams (WMD-CSTs), state laboratories operating as members of the CDC Laboratory Response Network (LRN), FBI, Weapons of Mass Destruction coordinators, and other approved in-state trainers. Training will include testing for demonstrated competency and an annual recertification process.

Participating organizations will also receive federally issued, approved, biological detection devices that meet or exceed consensus performance standards in field testing. In this bioterrorism response model, approved field testing equipment will be maintained within each designated team. Such equipment will be issued by, and remain the property of, the managing federal entity, which will also facilitate periodic performance verification and upgrades when new and improved equipment becomes available.

¹¹ Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent, Section 6, E2770-10, ASTM International, October 2010.

¹² Securing the Cities Act of 2015, Report 114-295, Committee on Homeland Security, U.S. House of Representatives, 114th Congress, October 20, 2015.

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In this proposed model, public safety response is defined as the emergency dispatch and deployment of public safety resources to protect the public and to characterize and control an overt, threatened, or potential biological agent release. This model only addresses the activities that will occur during the initial phases of incident characterization and response. Some agencies and elements participating in the initial public safety response will also participate in or contribute to surge capacity, outpatient treatment or rehabilitation, forensics, source eradication, remediation, or economic recovery, but these activities are beyond the scope of this model.

Sample collection will be performed as part of the initial response and will entail field screening to support short-term tactical decision making on actions such as evacuating or imposing access/re-occupancy restrictions and managing potentially exposed individuals (e.g., temporary quarantine/segregation, decontamination, and transport to the hospital).¹³ Other actions may include:

- Limiting public exposure/spread of contamination
- Defining the extent of contamination
- Protecting critical infrastructure (including economic impacts to commerce)
- Enabling the pursuit of criminal investigations
- Protecting the health of first responders and the nation

This model assumes that public safety emergency response organizations may include career-full-time, call-volunteer, or mixed public-private entities. These organizations may be operated and funded by local, county, state, or tribal governments that possess the legal authority and responsibility to deploy and execute duties and capabilities that prevent, limit, or mitigate threats to the public. Traditionally, such organizations include law enforcement, fire/rescue, and emergency medical services.

With their specialized response capabilities, HMRTs are a natural fit for validated biothreat response teams. However, while they are designed to respond to industrial and transportation chemical accidents and are subject to federal regulation under SARA, Title I, team composition and training requirements vary widely across the country, and even within jurisdictions. Federal regulations (e.g., Occupational Safety and Health Administration, Environmental Protection Agency) and state regulations place responsibility on the employer for determining training requirements, equipment, and capabilities. Consequently, there is very little consistency across HMRTs in compliance with requirements and standards. This variability in training, equipment,

¹³ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

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and capabilities of HMRTs means they cannot serve as a baseline for a validated bioterrorism response team.

5. KEY ELEMENTS OF THE MODEL

This model is constructed to meet the needs of the first responder. Laboratory and public health response is well documented and refined. However, the baseline for the first response capability is not as well defined or promulgated.

This model comprises objectives for each of the five critical elements of the biothreat response mission capability described in the SPADA Onion and DHS Framework. The model proposes a strategy that lays the groundwork for an implementation plan; this document outlines what needs to happen, but not necessarily how to get there.

Goal of the Bioterrorism Response Model

To create and sustain Validated Bioterrorism Response Teams that are

- Locally owned and operated
- Trained to a high level of competency
- Equipped with validated field equipment
- Operating under accepted methods and procedures
- Working collaboratively with LRNs and the FBI

5.1 Objective 1: Establish Standards for Field Biodetection Devices and Assays

This objective assumes that quick-test biodetection devices and assays (i.e., field kits) will be used to support decision making on initial response activities, beginning with low-regret actions (e.g., cordoning off the immediate area or notifying other agencies). A minimum performance standard for the field kit must be established; reliance solely on manufacturers' claims is not sufficient. There is a wealth of information, though little consensus, regarding the minimum necessary requirements for validating available equipment/assay systems. An effective standard requires that stakeholders agree on a required level of system performance that is also not prohibitively expensive. Ideally, an independent party would perform the testing and involve state and local public health LRN member laboratories as appropriate.¹⁴ Testing results also provide useful information about a system's use and end-user limitations. This objective is further addressed in Section 7.5: Equipment & Certification for Use.

¹⁴ The Need for a Quality Assurance Program for Kits and Devices Used in the Field to Screen for Hazardous Biological and Chemical Warfare Agents, APHL Position Paper, Association of Public Health Laboratories, January 2013.

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5.2 Objective 2: Mandate Standard Procedures for Sampling and Sample Handling

Every bioterrorism response team will be required to follow published standard procedures for collecting and handling samples.¹⁵ Using the proper sample collection method is critical to proper assay performance and to maintaining chain of custody.

5.3 Objective 3: Establish a Proficiency Testing Program

For a biothreat detection test to be of value, it must be easy to use and have proven performance. So too must users be able to confirm—on a regular basis and under realistic conditions—their ability to analyze a sample and interpret the results.

5.4 Objective 4: Establish Training Standards

Operators screening for suspected agents with field biothreat detection devices must be properly trained to produce reliable results. Many references for this exist, but supervision is needed to ensure that minimum training standards are met. Any biothreat mission specific training should meet the guidance provided in NFPA 472, Annex B at a minimum.¹⁶

5.5 Objective 5: Mandate Concept of Operations Competency

Every operator must be well-versed in the concept of operations for the field-based mission capability. Document ASTM E2770-10¹⁷ supplies the standard guidance. This information should be common knowledge to anyone working a biothreat incident in the field.

6. PROPOSED APPROACH

6.1 Develop Requirements and Standards for Validated Biothreat Response Teams

The institution of validated biothreat response teams will require consensus-developed requirements and standards. These standards will be based on measures for responder training and testing; validated technologies for screening and field testing; consistent procedures for sampling, packaging, and transporting samples; and risk communication. As with the Subcommittee on Chemical, Biological, Radiological, Nuclear, and Explosives (CBRNE) Standards, the primary function of the committee that develops the validated biothreat response team

¹⁵ Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces, E2458-10, ASTM International, November 2010; Emergency Response Resources: Surface sampling procedures for Bacillus anthracis spores from smooth, non-porous surfaces, CDC, April 2012.

¹⁶ Standard for Competence of Responders to Hazardous Materials/Weapons of Mass Destruction Incidents, NFPA 472, National Fire Protection Association, 2013.

¹⁷ Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent, E2770-10, ASTM International, October 2010.

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standards would be to facilitate cooperation in developing and using consensus test methods and standards among the agencies involved in bioterror response.¹⁸ This concept is based on cooperation and collaboration is similar to the current LRN program, in which state and national laboratory partners agreed to use the same protocols, instruments, and reagents when testing for bioterrorism agents. It allows a common foundation of training and skills, yet remains flexible enough to meet the individual needs and requirements of the state public health laboratories.

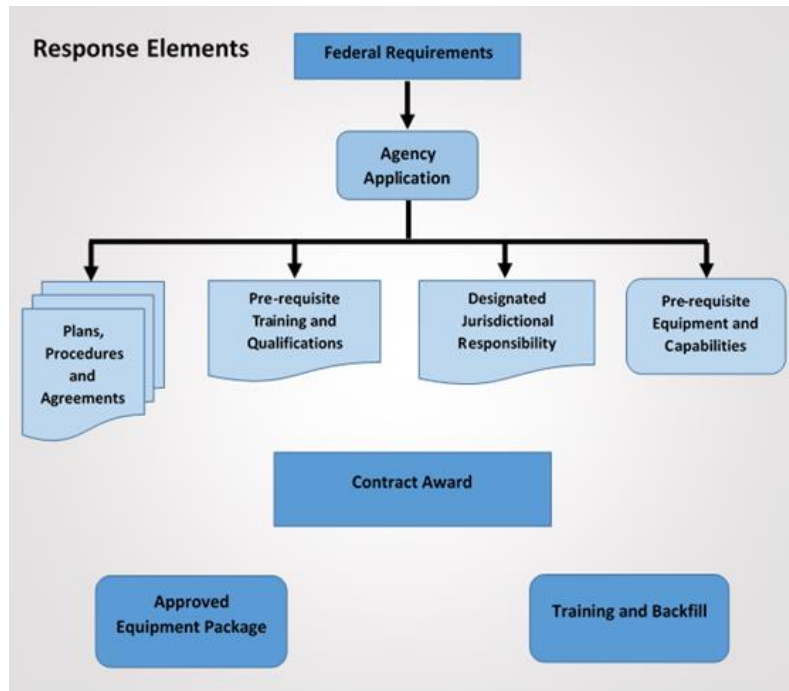


Figure 2. The model’s recommended Response Elements

6.2 Federally Funded Biothreat Response Capability

Once developed and published, the validated biothreat response team standards will define the services at the local, county, state, and tribal level that responder organizations must be able to provide to be eligible for a federal contract as a validated biothreat response team. This contract will be similar to the LRN contracts whereby agencies that meet federal or national requirements provide services within their jurisdictions.¹⁹ The following federally funded capabilities are needed for an effective biothreat response system.

Training

Under contract, participating public safety responder organizations send designated first responders (i.e.,

Benefits of Standardized Response Teams

- Certification to a known capability
- Assurance of standards compliance
 - CONOPS
 - Training
 - Equipment
 - Relationships
 - Risk communication

¹⁸ Charter of the Subcommittee on CBRNE Standards Committee on Homeland and National Security, National Science and Technology Council, April 2011.

¹⁹ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

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hazardous materials (HAZMAT) technicians) to attend the national training program described in Section 6.4. The supervising federal entity will provide the national training program to the organization without charge. Additionally, personnel costs incurred by organizations for overtime backfill members meeting in national training will be reimbursed.²⁰

Validated equipment for biothreat screening

The national bioterrorism response system will further provide validated instrumentation for biological threat screening and field testing. This equipment will remain the property of the supervising federal agency and will be maintained under the direction and financial responsibility of that agency. This direct control by the supervising federal entity will assure exclusive use of validated equipment, a program for equipment upgrade, and maintenance of equipment to ensure that standards and inspections are upheld.

Sampling supplies

Sampling supplies, exclusive of personal protective equipment, will also be provided by the supervising federal entity and will be controlled at the national level. These controls, similar to those for screening and testing equipment, will assure that all validated biothreat response teams are using currently accepted materials for biothreat sample collection and packaging. Both the equipment and sampling supply programs can reduce costs through high volume purchases and federal contracting provisions.

6.3 Participating Responder Organizations

In this model, participating responder organizations will be public safety emergency response organizations. Those organizations under contract with the lead U.S. agency will agree to comply with national standards for training, demonstrated competency, operating procedures, and equipment use for response to suspected bioterrorism incidents. Participating responder organizations will receive direct federal funding for training and equipment and, where applicable, be issued equipment and support.

These services will be delivered under the terms of the contract for that organization's normal and customary jurisdiction. This includes other jurisdictions that the organization may normally assist under local mutual aid contracts, covenants, or through Emergency Management Assistance Compacts or International Emergency Management Assistance Compacts. Should the

²⁰ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

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parties agree, each may negotiate a separate federal agreement to expand their response area based upon a request from the authority having jurisdiction.²¹

6.4 Training and Proficiency Testing²²

Though responders are as critical to bioterrorism response as detection technologies, virtually no national investment has been made to develop an effective national bioterrorism response training system. Effective training teaches first responders to understand bioterrorism threats; to effectively characterize agents; to efficiently collect samples, to effectively use threat identification technologies, and to properly communicate risks. The credibility of first responders, which begins with training and competency validation, is essential to assuring response partners (e.g., LRN, law enforcement, public health, and public policymakers) that samples have been competently collected, screened, and tested in the field.

Benefits of Standardized Training

- Demonstrates individual competency
- Demonstrates organizational consistency
- Attests to compliance with standards through national certification
- Provides confidence in applied methods for partners
- Provides national reference for risk communication

As part of this model, the InterAgency Board (IAB) recommends that a national program of bioterrorism response education be developed through a consensus process involving the full range of biothreat response stakeholders. The training program also should include a system of testing to demonstrate competency of both individuals and response teams. This testing should meet the standards for knowledge and capability established through the stakeholder consensus deliberation.

Any such training program must be delivered locally or at least regionally within each state and territory. The Federal Emergency Management Agency (FEMA) and DHS model of national training and education offered through regional centers of excellence has proven to

Proposed training model

- National training program administered by (?)
- Delivered in each state by a training team of LRN and CST with local support
- Demonstrated competency testing administered by the training team
- Agency and individual certifications issued by (?) annual online didactic testing and demonstrated competency of selected skills

²¹ A National Strategy for CBRNE Standards, Subcommittee on Standards, National Science and Technology Council Committee on Homeland and National Security, May 2011.

²² Framework for a Biothreat Field Response Mission Capability, DHS, April 2011.

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be valuable for select individuals from many jurisdictions. However, for the purposes of this model, a national center of excellence model could not accommodate the number of individuals who would require training, meet the required rate of completion, nor withstand the inevitable attrition associated with the public safety sector that would otherwise compromise this national capability. Accordingly, this bioterrorism response model proposes developing a national program that can be delivered by designated training teams within each state and possibly at each team location.

The following training program is proposed:

- Train public health laboratory staff on the LRN method of executing the national bioterrorism response and demonstrated competency program and engage them through a continuing contract to train designated first responders within the state or jurisdiction they serve.
- Provide training for elements or positions within the National Guard WMD-CSTs during delivery of the national bioterrorism response and demonstrated competency program. Engage these through a continuing contract to train designated first responders within the states or jurisdictions that they serve.
- Designate a lead federal agency, such as the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). That agency will manage the curriculum and be the certifying institution for programs and first responders. The lead agency will be responsible for training the trainers, executing the necessary contract vehicles to enable training in each state, and providing ongoing funds to sustain the program.
- Provide funds to ASPR through an annual appropriation in the HHS budget and thereby to the LRN program. These funds will be used to provide trainers from each LRN laboratory to support delivery of the national bioterrorism response training and competency testing.
- Provide funds to the National Guard Bureau through an annual

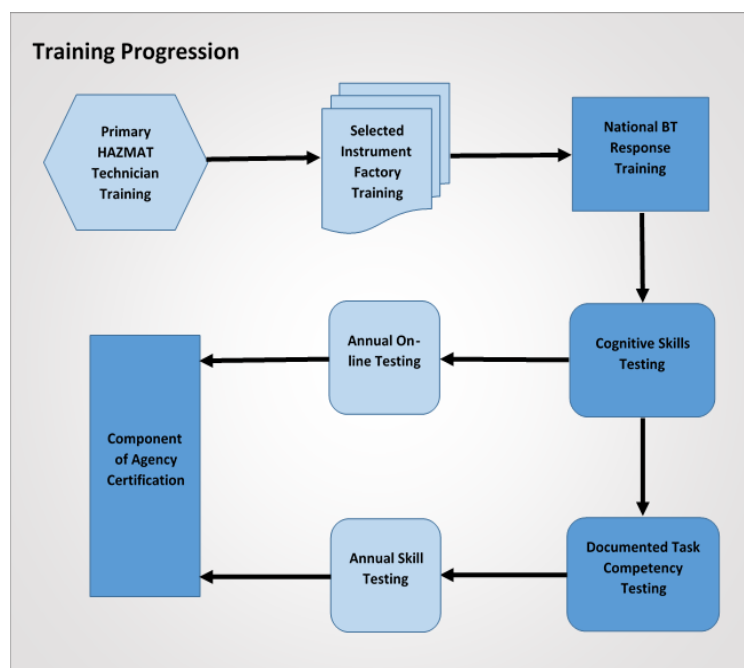


Figure 3. The model’s recommended training progression

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appropriation in the DOD budget and thereby to the WMD-CST program. These funds will be used to provide trainers from each CST to deliver the national bioterrorism response training and competency testing.

- Provide DHS Grant funds through FEMA to public responder organizations that meet established requirements and enter into agreement to train designated first responders of sufficient quantity to establish a bioterrorism response capability under the program(s) as recommended in this bioterrorism response model.
- The national bioterrorism response training curriculum will, at a minimum, provide comprehensive education in relevant topic areas, sufficient that first responders are, upon completion, competent to carry out the tasks and make decisions detailed further in this section. Topics will include, but not be limited to:²³
 - Understanding biological agents
 - Defining the biothreat emergency response team
 - Coordinating with biothreat emergency response team members
 - Understanding the purpose, operation, and limitations of screening technologies
 - Understanding threat evaluation procedures
 - Understanding the purpose and operation of screening technology
 - Developing risk communication
 - Identifying methods for isolation and containment
 - Following personal protection equipment recommendations
 - Executing aseptic technique
 - Executing proper sample collection methods
 - Following sample packaging and transportation procedures
 - Following documentation policies
 - Executing incident termination procedures
- A competency assessment will be conducted to assess proficiency of first response personnel across the range of knowledge, skills, and abilities identified in the training program as related to performing duties associated with biothreat response. Successful completion of a training program demonstrates responders' ability to:²⁴
 - Protect the LRN reference laboratory from unknowingly receiving hazardous samples which could injure laboratory personnel or cause damage to the facility.

²³ Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent, E2770-10, ASTM International, October 2010, Section 7, Training.

²⁴ Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent, E2770-10, ASTM International, October 2010, Section 8, Responder Competency Assessment.

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- Support decision making for short-term tactical decisions as necessary to manage the emergency response and protect the public from further risk within the levels of technical capability available.
- Competencies evaluated will include:
 - Risk assessment coordination/performance
 - Proper sample collection including proper use of standard methods and selection of collection materials
 - Proper field screening based on threat evaluation/sample quantity
 - Field safety screening capabilities for:
 - Explosives
 - Flammables
 - Radiation sources
 - Corrosives
 - Additional volatile chemicals as warranted
 - Sample documentation evaluated will include:
 - Field screening report
 - Sample submission form
 - Chain of custody form
 - A total competency assessment program should include:
 - Hands-on competency assessment (proficiency panels), designed in coordination with the receiving LRN reference laboratory. The International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17043:2010 (Conformity assessment – General requirements for proficiency testing) standard can serve as a guide for developing proficiency testing programs for field response.²⁵
 - Field exercises or drills that conform to the Homeland Security Exercise and Evaluation Program where appropriate.
 - Competency evaluations, performed at least annually, in coordination with the receiving LRN reference laboratory and the FBI.

²⁵ Conformity assessment – General requirements for proficiency testing, ISO/IEC 17043, International Organization for Standardization, February 2010.

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6.5 Equipment and Certification for Use²⁶

While numerous commercial biodetection products are available for field sample screening, most have not undergone suitable testing to determine their performance. First responder and HMRT procurements of these products are often based on colleague recommendations or vendor claims. Performance testing of field instruments and assays is necessary to ensure that instruments meet the needs of end users for the desired application. Independent third-party testing improves the first responders' and other involved response agencies' confidence in testing results. While funding for this testing likely would have to come from federal (or state/local) resources, this investment is cost effective (because funding will not be wasted on equipment that does not meet standards) and operationally effective (because equipment with higher rates of false positives or negatives will not be selected for use).

Standardized testing methods vetted by the bioresponse community, end users, stakeholders, and manufacturers will be required to support valid comparisons. Standards-based testing should generate results that define the probability of detecting a biothreat agent at a given confidence level, which will provide responders with a quantifiable level of confidence in the field screening results. Performance-based testing also results in valuable product use and limitation information for end users (e.g., problematic matrices, tips and tricks for conducting measurements/interpreting data, and "dos and don'ts").

Performance standards do not currently exist for PCR instruments used for field screening suspicious visible powders for biothreat agents. In addition, previously developed AOAC SMPRs have not been adapted for this purpose to date due to the high cost of testing, the relatively small size of the civilian market, and the fact that there is no requirement for the detection equipment to meet any standard (e.g., no FEMA-imposed grant funding restrictions).

Standards must balance the need for a product that has established performance criteria with testing requirements that are not cost- or time-prohibitive. This is particularly true for biodetection products because of the rapid development pace of new technology and frequent emergence of new instruments and assays. Additionally, while field testing is required to ensure products perform under real-world conditions, laboratory testing is also required to evaluate products under controlled conditions (i.e., trained operators, controlled environmental factors) to identify deficiencies prior to more expensive and challenging field testing.

Agency-imposed requirements (e.g., FEMA grant requirement that an instrument meet a certain performance standard) would help ensure first responders procure and use only those products

²⁶ Framework for a Biothreat Field Response Mission Capability, Department of Homeland Security, April 2011.

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that have known performance metrics and facilitate the overall acceptance by other agencies involved in a biothreat response. Also, products tested to a certain performance level may induce other products to be tested with voluntary procurements, driving sales of tested products above other competing products (e.g., given the choice of a tested and proven product vs. an untested one, most organizations would be compelled to purchase the prior). In either case, equipment/assay testing standards are an absolute necessity.

7. FUNDING

7.1 Scope of Participation as an Impact on Cost

Implementing and sustaining the bioterrorism response model involves three types of expenses: annual national program costs for WMD-CST and LRN participation of \$22,237,824; participating response organizations start-up costs (per team) of \$353,660—developed using a notional community;²⁷ and annual participating response organizations costs of \$66,332. This model does not address costs for validating field detection equipment performance, which could be significant. It is unknown whether equipment manufacturers would be willing to bear the expense of testing, whether stakeholders would require independent third-party testing, or which federal or state organization would fund testing efforts. Furthermore, without suitable testing standards, the cost of testing cannot accurately be projected. They could run as high as several million dollars per instrument and would require samples for testing. Performance testing of field detection equipment is a critical required component to realizing an effective response capability and must be considered in any budgeting considerations.

The largest cost variable is the number of participating response organizations. Currently, it is not possible to forecast the scope of participation (i.e., the number and size of teams). Ideally, every HMRT would participate. However, without a uniform definition of HMRTs, and with the lack of a current national inventory of such teams, that number cannot be identified. In addition, some HMRTs, and the jurisdictions that manage them, may opt not to implement the bioterrorism response model.

HMRTs serving major jurisdictions in cities, counties, states, and tribal nations that reasonably perceive risk are likely to implement the bioterrorism response model. A focused effort may be warranted in advance of legislation to define, identify, and quantify potential participation such that sufficient and reasonable appropriations may accompany the enabling legislation.

²⁷ See Section 8.

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Program costs as outlined below, illustrate expenses by representative jurisdictions and, for state and local supports, are based upon the numbers of entities (LRN and other laboratories, and National Guard WMD-CSTs) known to exist. Certain assumptions, such as the cost of backfilling roles needed to conduct training and the costs and longevity of equipment, are estimated based on the shared experience of the developers of this bioterrorism response model.

7.2 National Baseline Expenses

National and state baseline expenses exist in LRN laboratories and in WMD-CSTs for providing personnel to coordinate and conduct response team training. The roles of positions in these organizations place them as critical elements of training, and as described in this bioterrorism response model, serve to strengthen interagency confidence and cooperation.

LRN laboratories are responsible for testing suspected biological threats per validated CDC methods and protocols. These protocols include materials and procedures for collecting biological samples for laboratory testing. Knowledge of pathogens and LRN methods is a critical resource for response teams. Each laboratory will require 1.0 full-time equivalent trainer at an estimated cost of \$120,000 (\$100,000 with 20% benefits). With 140 LRN laboratories currently in the U.S., an annual budget increase of \$16,800,000 would be necessary.

National Guard WMD-CSTs will provide critical core competency skills training to participating response teams. Two additional non-commissioned officers (NCOs) for each of 57 WMD-CSTs are recommended to cover the additional workload. Table 1 depicts costs for 57 CSTs with an annual projected operating cost of \$15,168,394 and projected costs for the additional NCOs.²⁸

Table 1. Projected costs for additional officers to CSTs*

Annual Expenses	E6	E7	Notes
Base Pay	\$40,872	\$49,672	E6: averaged pay for 6–14 years of service/ E7: averaged pay for 10–18 years of service
Basic Allowance for Housing	\$40,860	\$41,508	Assumed married with children
1 st Year Temporary Duty (TDY) Training Costs	\$22,200	\$22,200	1 st year training TDY ballpark estimate (assumes 4 months TDY and includes lodging and per diem rates (CSSC is 2 months)) (Airline, rental car, and other expenses not captured)
TDY to Conduct Mission	\$22,200	\$22,200	TDY expenses for an additional 4 months to conduct training of first responders (Airline, rental car, and other

²⁸ Note: Line #3 of the table identifies “1st Year TDY training costs” and a start-up expense only. The authors of the strategy believe that it is reasonable to include this as an annual expense to provide for training updates and assignment change through attrition or matriculation. Additionally, the CSTs referred to in this document operate within the continental U.S. and its territories.

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Annual Expenses	E6	E7	Notes
			expenses not captured)
Tricare Medical Costs			Unknown
Hazardous Duty Pay	\$1,800	\$1,800	
Clothing Allowance	\$400	\$400	Averaged Air Force and Army costs
Total:	\$128,332	\$137,780	
Total per CST:	\$266,112		
Total for 57 CSTs:	\$15,168,384		

* Per diem rates use metropolitan Boston as an example.

Table 1 presents two alternative models for the use of these two additional officers (shown as E6 and E7). The first assumes that both positions are dedicated training staff. The second absorbs the two additional personnel into the overall staffing and operation of the WMD-CST. The developers of this model favor the second alternative above the first, as it tends to increase the collaboration, familiarity, and communication between the WMD-CST members and the response teams. However, the authors recognize that this decision should be made by the National Guard Bureau, state Adjutant Generals, or by individual WMD-CST commanders.

7.3 Per Response Organization: Startup Costs

As previously noted, without in-depth data, local startup costs for implementing this bioterrorism response model cannot be definitively determined. Accordingly, representative costs for notional jurisdictions (i.e., local, county, and state) have been generated with data from jurisdictions represented by the IAB. The notional jurisdictions were derived randomly from communities across the country and are presumed to be fair representations.

In addition, because consensus training standards do not yet exist, the baseline training requirement is assumed to be 40 hours. This figure is derived from a combination of existing training programs and typical manufacturers’ training requirements for new equipment to meet warranty obligations. Similarly, since no specific equipment has yet been formally accepted for use, the cost of each item of field analytical technology to be provided under contract to participating response teams in this model is estimated at \$50,000–\$60,000. This figure is representative of several of the equipment types likely to be recommended based on 2016 pricing.

Estimated local response team costs are derived from the community data shown in Table 2.²⁹

²⁹ This information was gathered via survey of IAB members in March 2016.

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Table 2. Local response team costs

Number of Persons/Unit	Number of Units/Teams in Jurisdiction	Average Overtime Rate per Hour	Population	Jurisdiction Area (sq mi)	Population density (Pop/sq mi)
80	1	\$45.00	389,262	129	3,018
60	1	\$40.00	19,385	6.4	3,043
10	1	\$45.00	811,943	217.2	3,739
12	1	\$65.00	298,165	80	3,749
32	2	\$35.00	188,040	44.6	4,216
52	1	\$60.00	662,400	83	7,981
2	4	\$82.00	3,957,022	469	8,437
45	1	\$50.00	220,173	26	8,478
153	4	\$65.00	663,736	61.1	10,872
125	5	\$66.00	617,594	48.3	12,792
36	1		8,550,405	468.9	18,235
55	2	\$55.30	1,488,920	190	7,687

Using averages of the data collected, the authors created the notional local jurisdiction with a population of 1,488,920. The notional community operates an HMRT with 55 persons and 2 response vehicles. The description of costs that follows will forecast training and equipment costs to enable this community to have the capability for effective bioterrorism response.

The training requirements described in Section 6.4 of this bioterrorism response model require 40 hours of training for each member. In accordance with staffing needs and collective bargaining, assuming training must be conducted when not assigned to apparatus and, therefore, on overtime or premium time pay, the following equation gives the backfill or overtime costs for the training of team members:

Number of members:	55
Average overtime rate:	× \$55.30
Number of hours:	× 40
Training costs	\$121,660

7.4 Per Response Organization: Equipment Costs

At startup, equipment costs assume that the response team does not possess the technologies prescribed through the consensus process. This bioterrorism response model limits provided equipment to non-disposable detection and analytical instruments. Personal protective

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equipment, communications equipment, and supplies will remain the responsibility of the jurisdiction, but will be excluded from other grant programs.

The following equipment type and cost is recommended for each team:

- Radiological survey instrument: \$7,000 per unit
- Fourier Transform Infrared Spectroscopy: \$60,000 per unit
- Raman Spectroscopy: \$60,000 per unit
- Mass Spectroscopy: \$55,000 per unit
- PCR Thermocycler: \$50,000 per unit

Equipment cost total for one response vehicle unit: **\$232,000**

The notional community used for expressing costs in this strategy operates two response vehicles; thus the equipment list must be sufficient for two units (two of each item). The cost for this community is, therefore, \$464,000.

As part of the national investment, a back-up equipment ratio of 1:10 should be maintained by the federal agency managing this system. This inventory will provide for replacement of equipment during periods of service or repair and can serve as surge capacity for National Security Special Events in participating jurisdictions.

7.5 Per Response Organization: Estimated Sustainment Costs

Sustainability is a critical element of this capability. Elements of the bioterrorism response model must include long-term sustainability and a pathway for continued improvement. Components of sustainability include:

- Recurrent primary training sufficient to address attrition rates
- Annual continuing education and periodic demonstration of competency
- Equipment maintenance and warranty costs
- Cost of equipment depreciation

Such costs are illustrated for this model as follows:

Recurrent Primary Training. Attrition occurs for a variety of reasons, including promotion, injury, retirement, or reassignment. The model assumes a 10% attrition per year.

To maintain capability, a minimum of 30% of team members must be certified, thus necessitating repeating primary training every three years to maintain proficient team strength. To meet this need,

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the annual budget should include approximately **\$12,000** per team per year to support recurrent primary training to meet the needs of attrition.

Annual Continuing Education. An eight-hour annual review session and demonstrated competency is the minimum annual education for this program and should be administered by the training team. Accordingly, 20% of the baseline training salary costs should be expected to be expended each year for this purpose. Using the notional community, the annual cost per team is calculated to be \$24,332.

Total annual training costs to participating teams are calculated to be **\$36,332**. This amount is expected to cover training maintenance and demonstrated competency.

Equipment Maintenance and Warranty Costs. Some of the technologies specifically needed for this strategy and appropriately provided and supported as part of the system require annual warranty, cost of ownership, or maintenance contracts. Current costs of these classes of instruments, at a rate of one per team, amounts to approximately \$18,000. Using the notional community, operating two response units doubles these costs, so budgets should allow for **\$36,000** per year for equipment maintenance contracts.

Equipment Depreciation. While the provided equipment may still be functional after ten years' use, experience shows these technologies should be upgraded at least every ten years. To provide for equipment depreciation, 10% of the purchase price of equipment, per unit—not per team—should be budgeted into the program in capital appropriations to allow for replacement. A yearly appropriation or capital appropriation calculated for annualization should allow **\$46,400** per team, per year.

7.6 Summary of Funding Considerations

In summary, three categories of costs are described in this model: 1) annual, national program costs for WMD-CST and LRN participation totaling \$22,237,824; 2) per team start-up costs, developed using a national community, of \$353,660 per participating response organization; and 3) annual participating organization costs of \$66,332. The largest variable in the cost of the model is the number of participating response organizations; therefore, a complete cost estimate cannot yet be calculated.

Please contact the InterAgency Board at info@interagencyboard.us with any comments, feedback, and questions. Additional information on the InterAgency Board is available at www.interagencyboard.org.

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APPENDIX A. SPADA SUMMARY REPORT AND ARTICLES ADOPTED BY THE TOWN HALL MEETING ASSEMBLY

The full report can be found at: <http://www.interagencyboard.org/system/files/resources/SPADA%20Town%20Hall%20Meeting%20Summary%20Report.pdf>

National Standard Program For the Development and Use of Qualified Threat Agent Detection Technologies A Summary Report Submitted by AOAC INTERNATIONAL to DHS, S&T Directorate

Overview of Problem

There is a lack of a comprehensive, standard program for the development, evaluation, and validation of threat agent detectors, triggers, and sensors. Performance claims are currently assessed using variable standards and in-house data. In the absence of an independent third-party evaluation and validation of the technologies based on standard performance criteria, purchasers and users of the technologies must rely on the performance claims of the manufacturers. This applies to technologies that are on the Standard Equipment List, Authorized Equipment List, or are Safety Act Certified.

As a result, decisions by federal, state and local government municipalities and private facilities protection entities on what threat agent detection technologies to buy take much time and many resources, and may take weeks and even months to research.

Furthermore, a system for sharing this information does not exist, resulting in many agencies duplicating efforts at considerable cost to the U.S. taxpayers.

Finally, end users of these technologies, both public and private, have different response plans and often lack guidelines in the use, operation, and interpretation of results of tests.

Consequences

User confidence in the results of tests suffers. Not knowing the level of confidence in technologies being used, and the lack of Standard Operating Procedures (SOPs) in the appropriate use, operation, and interpretation of results of tests can cost public municipalities and private organizations millions of dollars and cause dangers to the public. This has happened in at least two well publicized incidents, one at the Skyline office complex in Falls Church, VA in March 2005, and the other at the headquarters of Lehman Brothers when a false positive from a sensor shut down the facilities, costing millions of dollars.

Need

Commercial industry, emergency responders, public health, and the government must have reliable and validated threat agent detection technologies with known rates of false positives and false negatives to make critical decisions and take appropriate action. Therefore, performance standards must be developed by independent third party organizations to enable industry to make available threat agent detection technologies that meet the needs of the emergency responder communities.

National guidelines and standards need to be developed that lead to implementation of training, proficiency testing, and certification of the analyst in the use of qualified threat agent detection technologies.

National guidelines are needed for SOPs in the use, operation, interpretation, and response by end users of those technologies.

Start of a Program Meeting the Need

The Department of Homeland Security, Science and Technology Directorate (DHS S&T) recognizes the need to provide a national system to identify reliable threat agent detector