Framework for a Biothreat Field Response Mission Capability

April 5, 2011

Homeland Security

Science and Technology

Framework for a Biothreat Field Response Mission Capability

April 5, 2011

Developed by an Interagency Working Group (IAWG) convened to develop guidance to First Responders for the Biological Assessment of Suspicious Powders

Co-Chairs

Bert Coursey
Director
Office of Standards
Test, Evaluation & Standards Division
Science & Technology
Department of Homeland Security

Richard B. Kellogg
Coordinator
Laboratory Response Network
Division of Preparedness and Emerging Infections
Centers for Disease Control and Prevention
Department of Health and Human Services

Agency Principal Representatives

Douglas L. Anders
Hazardous Materials Science Response Unit, Laboratory Division,
Federal Bureau of Investigation, Department of Justice

William So
Biological Countermeasures Unit, Weapons of Mass Destruction Directorate,
Federal Bureau of Investigation, Department of Justice

Jayne B. Morrow
National Institute of Standards and Technology, Department of Commerce

Marissa Mullins
Homeland Security Laboratory Response Center, Office of Emergency Management,
Environmental Protection Agency

Additional Agency Representatives

Matthew Arduino, Department of Health and Human Services, Centers for Disease Control and Prevention
Kristine Beardsley, Department of Justice, Federal Bureau of Investigation
Lance Brooks, Department of Homeland Security
Michele Burgess, Environmental Protection Agency
Matthew Davenport, Department of Homeland Security
Lisa Delaney, Department of Health and Human Services, Centers for Disease Control and Prevention
Doug Drabkowski, Department of Homeland Security
Pete Estacio, Lawrence Livermore National Laboratory
Schatzi Fitz-James, Environmental Protection Agency
Laura Jevitt, Department of Health and Human Services, Centers for Disease Control and Prevention
Malcolm Johns, Department of Homeland Security
Robert Kobelski, Department of Health and Human Services, Centers for Disease Control and Prevention
Kenneth Martinez, Department of Health and Human Services, Centers for Disease Control and Prevention
Deborah McKean, Environmental Protection Agency
Stephen Morse, Department of Health and Human Services, Centers for Disease Control and Prevention
Segaran Pillai, Department of Homeland Security
Robert Scripp, Department of Justice, Federal Bureau of Investigation
Angela Weber, Department of Health and Human Services, Centers for Disease Control and Prevention

Acknowledgments

The working group co-chairs would like to acknowledge the contributions of the following subject matter experts for the development of this document.

Dr. Christina Egan, Wadsworth Center, New York State Department of Health Laboratories
Dr. Cheryl Gauthier, Massachusetts Department of Public Health
Kathryn M. Hansen, California Department of Public Health
David M. Ladd, Massachusetts Department of Fire Services
CPT Bryon Marsh, 4th Civil Support Team, Weapons of Mass Destruction Unit
Dr. Jim Pearson, Virginia Division of Consolidated Laboratory Services

Photo Credits: CPT Bryon Marsh

Executive Summary

Responders are called to address suspicious packages with an associated powder material on a daily basis throughout the United States of America and at U.S. Embassies around the world. In the United States, law enforcement entities have responded to over 30,000 incidents involving suspicious powders, liquids and chemicals since 2001[1]. Nationwide, jurisdictions still report continual responses to suspicious packages or powders with local FBI Weapons of Mass Destruction (WMD) Coordinators responding on site to an average of six scenes per week and responding additionally to an average of five phone calls per week. Currently, there are numerous technologies on the market claiming the ability to rapidly evaluate suspicious materials for potential biothreats[2] (www.rkb.us reported 89 "biological detectors" 3/1/2011). It should be noted that in the context of this Framework document the term "assay" is used to describe any test, method, detector, tool, or technology used in the field or laboratory to assess a suspicious sample for the presence of a biothreat.

In contrast to the number of biothreat assays for use in the field by first responders, there is a paucity of national performance standards and third-party testing to demonstrate that assay works reliably in the hands of users. In addition, there is a paucity of other critical elements required to integrate the use of the assays into a mission capability that will allow responders to take appropriate public safety action.

Stakeholders from Federal, state, and local governments, public health, first responders, and industry have recognized a need to develop a mission capability for responding to suspicious powders and packages. This document resulted from work by an interagency working group as part of their response to an original request, by Senator Joseph Lieberman's Congressional Committee, for updated guidance on handheld assays suitable for use in field assessment of suspicious powders for *Bacillus anthracis* (Ba, the causative agent of anthrax). The mission capability defined herein mirrors that which has been firmly established and is rigorously practiced in fixed laboratory settings, such as public health laboratories. A mission capability, whether field-based or laboratory-based, requires development of five critical mission elements that enable coordination and communication at all levels of response and enables users to have confidence in the results obtained. The critical elements of a mission capability for biothreat response include:

1. A concept of operations (ConOps) to support use of fielded assays and coordination of response among the key stakeholders in the jurisdiction;
2. Training and certification of end-users;
3. Proficiency testing in the hands of the end-user in the field;
4. Sample collection and handling standards; and

[1]Personal communication, Federal Bureau of Investigation, Weapons of Mass Destruction Directorate

[2] Responder Knowledge Base; www.rkb.us; 89 biological detection technologies listed as of March 1, 2011

5. Assays that have been properly tested by a qualified third party and certified to meet or exceed appropriately recognized national voluntary consensus standards for performance.

This document describes significant progress toward development of the first, fourth, and fifth critical elements listed above and that are needed to support a field-based mission capability. The first critical element listed was accomplished through recent publication of ASTM E2770-10 consensus operational guidelines (i.e., ConOps) to enhance communication and coordination among the response community for initial response to suspected biothreats[3]. The fourth critical element listed has been achieved through publication of ASTM E2458-10 consensus sample collection and handling standard for use by first responders to collect and send the majority of a suspected biothreat sample to a member of the Centers for Disease Control and Prevention's Laboratory Response Network (LRN) for rapid presumptive and confirmatory testing[4]. Lastly, progress has been made on the fifth critical element listed through development of national consensus performance standards that define the minimum performance requirements for assays that evaluate suspicious powders for *Ba*[5] and ricin toxin[6] in the field.

In addition to describing the progress that has been made, this document describes which elements require remaining work to develop a field-based mission capability, as well as a framework for how these elements should be integrated to build a mission capability for biothreat detection in the field. The field-based mission capability will enhance communication and coordination for initial response to suspected biothreats among members of the response community, including: local HAZMAT and law enforcement, emergency response officials, EPA's On-Scene Coordinators and Environmental Response Team, FBI Hazardous Materials Response Teams, FBI WMD Coordinators, public health officials and reference laboratories that participate in the CDC Laboratory LRN. These key stakeholders at the Federal, state and local levels have worked to develop several of the critical elements. Additionally, the laboratory-based mission capability is described in this document and is the essential confirmatory follow-on activity to any field testing for biothreat agents.

Elements of a Field-Based Biothreat Detection Mission Capability

Building a mission capability requires the integration of five essential elements to allow appropriate public safety action to be taken in response to suspected biothreats (Figure 1). The consensus opinion of local, state and Federal response communities is that the five key interdependent elements must be developed and supported at all levels of the response to ensure that assays (any test, method, detector, tool, or technology used to assess a suspicious sample for the presence of a biothreat) are fit for their intended use and purpose of application. First, the use of the assay must be incorporated into a ConOps

[3] ASTM E2770-10 Operational Guidelines for Initial Response to a Suspected Biothreat Agent.

[4] ASTM E2458-10 Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Non Porous Surfaces.

[5] Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of *Bacillus anthracis* Spores in Visible Powders. SMPR 20010.004 (2011) *J. AOAC Int.* 94:4. Pg. 1352-1355.

[6] Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of Ricin in Visible Powders. SMPR 2010.005 (2011) *J. AOAC Int.* 94:4. Pg. 1356-1358.

that integrates the capabilities and responsibilities of other Federal, state, and local stakeholders in alignment with their jurisdictional authorities for decision making. Second, end-users should be trained and certified in the proper use and application of the assay as well as interpretation and integration of the assay result. Optimally, proper training would include an assessment of user competency and be integrated into a public health supported proficiency testing program. The next element is sampling and handling procedures that ensure that the bulk of the sample is collected and sent to an LRN reference laboratory for testing and that the sample is properly packaged and transported safely. The last of these elements is an assay, for use with residual powder, which has been tested and certified to meet or exceed nationally recognized voluntary consensus performance standards developed by the stakeholder community (e.g., the Stakeholders Panel on Agent Detection Assays (SPADA) performance specifications). In essence, an actionable assay is part of a mission capability agreed upon, and employed in cooperation by, state and local first responder and public health communities, with support of appropriate Federal agencies. Components of an assay include, but may not be limited to: sample preparation and extraction, reagents, platform, and algorithm. Field- and laboratory-based biothreat material assays can be divided into three groups based on level of performance, integration and evaluation.

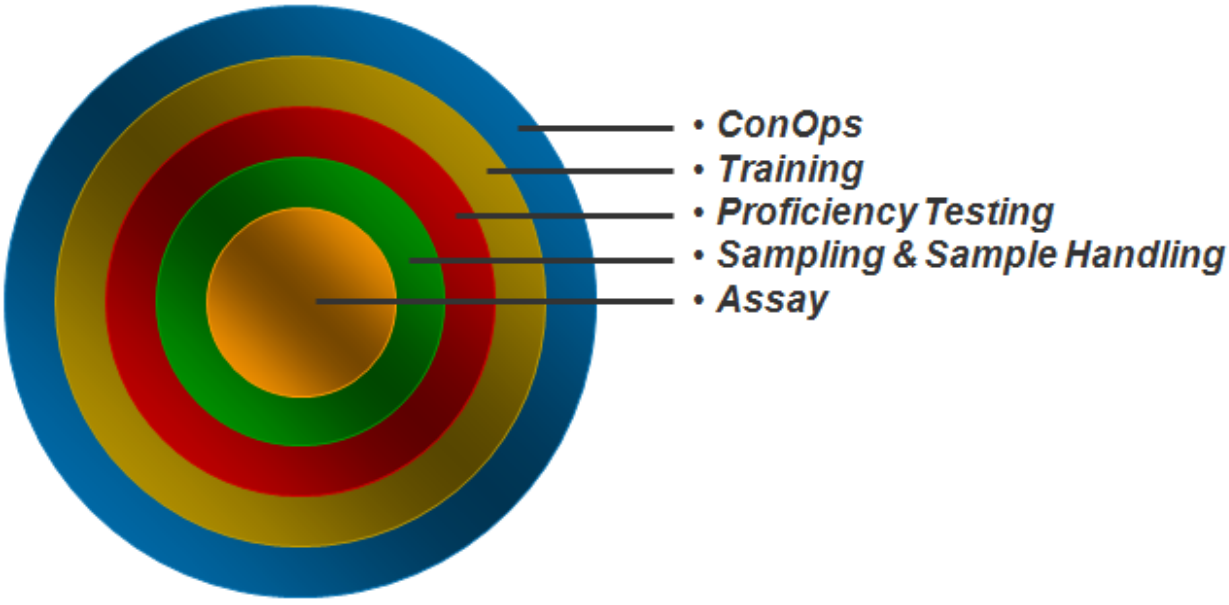

Figure 1. Components of a Mission Capability.

On-Site Biological Assessment is a field-based assessment that includes measurements of properties inherent to biological materials performed using rapid, field-based procedures and assays.

On-site biological assessment is used for initial sample evaluations of suspicious substances that are either general in nature (e.g. protein test) or have not been tested and/or certified as meeting nationally recognized consensus standards (e.g. SPADA performance specifications). On-site biological assessment and traditional field screening for explosive hazards, radiological hazards, and acute chemical hazards utilized early in the site assessment process to define and delineate the potential risks present, may support tactical decision making and address localized operational safety measures.

Public Safety Actionable Assays (PSAAs) are field-based assays that have been third-party tested and certified to meet or exceed nationally recognized consensus performance standards[7]. PSAAs provide sufficient sensitivity and specificity to support public safety actions including expedient transport and delivery of sample to an LRN reference laboratory for rapid presumptive and confirmatory testing, closing facilities or portions of facilities, and shutting down ventilation systems. Negative PSAA testing results cannot rule out the presence of all potential threat agents or biological agents. Therefore, jurisdictions choosing to integrate the use of a PSAA into response procedures should do so in accordance with ASTM E2458-10 and ASTM E2770-10, which provides a method for use of the residual powder when the primary source and bulk powder sample have first been collected and packaged for transport to the LRN reference laboratory.

Public Health Actionable Assays (PHAAs) are laboratory-based assays that are used to support public health decisions and which have been qualified according to consensus performance standards developed by a recognized and representative body from the stakeholder community[8]. PHAAs are developed and utilized to support public health actions involving the potential exposure of an individual or, more commonly, groups of individuals to biothreat materials such as *Ba* spores. PHAAs have high specificity, high sensitivity, and are highly robust to provide critical information on agent-specific confirmation and further characterization to support public health decisions such as initiating a national or local health alert warning, initiating a public health investigation, conducting risk assessments to support post exposure prophylaxis distribution and initiating public health risk communications. These assays are intended to be employed in well-established controlled laboratory environments, such as an LRN reference laboratory, using an established ConOps and where professional training and user proficiency certification are established.

---

[7] Coates, S.G., Brunelle, S.L., Davenport, M.G. (2011) Development of Standard Method Performance Requirements for Biological Threat Agent Detection Methods. *J. AOAC Int.* 94:4. Pg. 1328-1337.

[8] Interagency project between Department of Homeland Security Science & Technology Directorate and Centers for Disease Control and Prevention LRN Program Office

Accomplishments & Recognized Gaps toward an Established Field-Based Mission Capability

Note: The laboratory-based mission capability for biothreat agents is robust and has existed in LRN reference laboratories for a number of years. Thus this section will focus on accomplishments and existing gaps for the field-based mission capability.

Development of a field-based mission capability is needed to reliably support initial on-scene public safety decisions, and ensure assays are systematically supported for efficacy in the hands of the user. Progress toward development and support of the five essential elements and remaining gaps include:

First Responder Operational Guides:

In the area of ConOps, Department of Homeland Security (DHS) Science and Technology Directorate (S&T) sponsored the recently published operational guidance entitled, "Operational Guidelines for Initial Response to a Suspected Biothreat Agent" (ASTM E2770-10). The operational guidance was developed by the National Institute of Standards and Technology (NIST) and two focus groups of first responders and public health officials from across the nation. Additional feedback from Federal stakeholders, the Interagency Board for Equipment Standardization and Interoperability, the International Association of Fire Chiefs, and the Association of Public Health Laboratories was integrated. The operational guidance calls for coordination among representatives of emergency response teams, local, state, and Federal law enforcement and public health. The guidance provides recommendations on: planning, training, competency evaluation, proficiency testing, ConOps, hazard assessment, threat evaluation, sample collection, field screening, communication and documentation. In addition, the guidance recommends that the jurisdiction assuming responsibility involve all stakeholders in the response planning to determine requirements for training and sample collection as described in ASTM E 2458-10 (see Sample Collection Standards section).

Response guidance is focused on facilitating initial public safety decisions by first responders while preserving evidence and assuring the bulk of a sample is transported to the LRN reference laboratory. Laboratory evaluation includes rapid presumptive and confirmatory testing (i.e., PHAA) allowing timely public health decisions when a biological agent is suspected.

Recommendation: This framework recommends that ASTM E2770-10 become a core training course within the proposed national training curriculum (see First Responder Training section).

First Responder Training:

Training is essential to ensure accurate and coordinated sample collection, equipment use, and communication with other stakeholders for appropriate public safety decision making during a suspected biothreat incident. Current training for on-site biological assessment is spread over several Federal agencies and too often focuses on mission specific capabilities for law enforcement, hazmat and Federal responders. Unfortunately, this distributed approach to training does not support the coherent and cooperative response needed on the part of multiple stakeholders to the incident. Although training on the use of a field-based assay is often supported by the manufacturer, the training on assay

integration with response activities (using accepted sampling and handling standards as well as a coordinated ConOps) is not covered and is left to the local jurisdiction. Coordinated training programs at local, state, and Federal levels are needed that engage the first responder community and communicate the needs of public health, law enforcement, and Federal responders. Training standards are needed to support these programs to ensure that assay use is tightly coupled to standards for operational performance of the assay, technical knowledge of the user, and the response capabilities of the jurisdiction. Additional standards are needed to establish methods to assess capabilities of users, instructors, training centers, and agencies. Any training standards and programs developed must be done in coordination with first responders, public health, law enforcement, and Federal stakeholders. Since its creation in 2003, DHS has assumed an increasing role in the training of civilian first responders in the response to events potentially involving biothreat agents, including the appropriate use of field-based assays. Although DHS provides first responders with training in addition to funds for training and equipment, a national training curriculum needs to be established to specifically address assessment of potential biothreat agents and that incorporates the other four critical elements in order to support a full and reliable mission capability.

Recommendation: This framework recommends that DHS develop, in coordination with other Federal stakeholders, a national training certification program with a focus on developing standards for curriculum design to provide metrics for assurance in the field to support establishment of a reliable mission capability.

First Responder Proficiency Testing Program Development:

Proficiency testing (PT) and competency assessment are necessary to establish and maintain confidence in application of an assay when coupled with first responder training to a national standardized curriculum and integration of uniform operational guidance for initial response. Regular PT evaluation is limited or not available to first responders due to the lack of testing programs and the inability of first responders to work with biothreat materials in the field. The development of a sustained PT program, including testing protocols and reference materials, is required. To address these gaps, new reference materials for regular evaluation of assay performance in the hands of the user are being developed as are consensus documentary standards that support both the receiving laboratories and the assay users' ability to integrate PT into planning and training efforts. Sustainability of such a PT program is best achieved by having local training and certification integrated into state-wide and Federal first responder training and certification requirements. Several states such as Massachusetts and New York have taken steps toward establishing statewide competency assessment and are moving toward PT requirements for first responders involved in bioterrorism response events. However, no locally focused sustainable first responder PT program based on a uniform national training curriculum exists.

Recommendation: The framework recommends that DHS develop a coordinated PT program that can be used by the jurisdictions to provide confidence in assay performance, proper application of assays in response ConOps and communication of results between the lab and the field. A PT program includes an initial competency assessment for application of the assay by the user in combination with a third party administration of regular PT challenge samples to ensure the ability of the user to apply an assay

in the field. DHS is funding work to identify and develop generic surrogate reference materials and standards needed to establish regular PT programs; however support is needed to build and manage PT programs to generate a national response capability. Such a program would include administering the PT, providing reference materials, data collection forms, data analysis of results, and remediation for users that do not pass PT.

First Responder Sample Collection Standards:

An initial standard for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat agents from Nonporous Surfaces, ASTM E2458, was published in 2006 and revised in 2010 to provide a method to collect the bulk of the material and transport to an appropriate laboratory (i.e., LRN reference laboratory) for rapid presumptive and confirmatory analysis. In September 2010 CDC National Institute for Occupational Safety and Health (NIOSH) published a complementary document, "Surface sampling procedures for *Bacillus anthracis* spores from smooth, non-porous surfaces". Current interagency efforts between NIST and CDC NIOSH are focused on providing guidance for collection from porous and carpeted surfaces and the ASTM E2770 Operational Guidelines encourage the jurisdiction assuming responsibility to determine methods and procedures for sample collection for surface types and environments not addressed in E2458 in accordance with all the necessary participants in response planning (public health, environmental health, LRN reference laboratory, local law enforcement and FBI). ASTM standards available have undergone extensive review by stakeholders in the Federal, state, local and scientific communities.

ASTM E 2458 is considered a best practice method for collecting bulk powders from nonporous surfaces with the primary purpose of transporting the bulk of the powder to an LRN reference laboratory for rapid presumptive and confirmatory testing. This step was recognized by all stakeholders as essential regardless of how well field screening is performed.

Recommendation: The framework recommends that DHS coordinate and fund the development of additional standard sampling methods for porous and carpeted surfaces. Additional guidance for sample collection strategies should follow the framework for interagency collaboration and coordination established in ASTM E2770 and methods should be consistent with method A of ASTM E2458 for bulk sample collection and submission.

Assay

This critical element is a combination of two sub-elements that are necessary to achieve this element. The two sub-elements are: performance specification standards; and testing and certification.

Performance Specification Standards:

To achieve the first sub-element, the DHS S&T has sponsored the development of voluntary consensus performance standards for assays used by first responders and the private-sector (i.e., Public Safety

Actionable Assays) consistent with Office of Management and Budget (OMB) policy[9]. These standards have been developed by a voluntary consensus standards body, SPADA, which consists of over 100 representatives from Federal, state, and local governments, public health, first responders, and industry. SPADA has developed voluntary consensus performance standards required for testing of assays that evaluate suspicious powders for *Ba* and ricin toxin. These include standards for lateral-flow antigen-detection Hand Held Assays (HHAs) that detect *Ba* and ricin toxin. SPADA has also developed performance standards for field deployable nucleic acid based detection assays, as well as standards for automated assays that detect aerosolized biothreat agents.

Although standards have been developed for the abovementioned biothreat detection assays, the development of additional standards is required for: (1) assays that detect other high-priority biothreat agents; and (2) assays that use other detection methodologies and/or innovative technologies. Consensus performance standards for additional biothreat agents and technologies need to be promulgated in keeping with identified national priorities.

Recommendation: This framework recommends that DHS continue using the established SPADA process to develop consensus performance standards for additional biothreat agents and detection assays that are commercially available and under development. These activities should continue to be supported by DHS with participation of other Federal agencies.

Testing and Certification of Assays:

First responders currently rely on manufacturer's claims rather than independent third-party testing when making procurement decisions on the purchase of field-based biothreat assays. In addition, laboratory bench performance and evaluation of these assays must be followed by actual field use performance evaluations conducted in the hands of the end user community. Since the ConOps, sampling and handling procedures, and testing and certification standards for PSAAs are newly developed, no PSAAs currently exist; however evaluation of two potential PSAAs is underway. At this time, an HHA to detect ricin toxin is currently going through third-party testing against the SPADA detection standards in the laboratory environment and additional field evaluation is required. No HHAs for evaluation of suspicious substances for *Ba* have been submitted for testing. Once performance specification standards are in place, additional testing is needed for other available field-based assays, including those based on different technologies and for additional priority biothreat agents. Further testing and evaluation for ruggedness in the field environment is needed to determine if assays that have been evaluated in the laboratory environment can be used in the field environment, operating under various environmental conditions, sustaining rugged transport and deployment, and meeting suitability and operational needs of the responder. Priority on what assays to test will be aligned with the development of the consensus standards.

[9] OMB Circular A-119

Testing relies on manufacturers paying qualified third-party laboratories to test and certify that their assays meet the performance requirements outlined in the consensus standards. The incentive for industry to use this "pay-to-play" model is that certification provides a market advantage over competitors that are not certified. It is clear that the first responder biothreat detection market is not large enough for industry to obtain a return on investment for any sufficiently robust testing and certification process. Therefore, the Federal Government may need to intercede through a cost sharing process with industry for additional rounds of testing to ensure first responders have qualified assays for procurement and integration into a field-based biothreat mission capability.

Recommendation: The framework recommends additional testing of assays that are commercially available and being procured by first responders. In addition, the framework recommends that DHS determine the feasibility of a cost-sharing mechanism with industry for third-party testing to ensure qualified assays are available for procurement by first responders. Lastly, the working group recommends that third-party laboratories used for testing have ISO 17025 certification for their quality management system at a minimum.

Conclusion:

Our local first responders are critical to an effective response during a suspected biological attack. They are often called upon to respond to suspicious materials and render tactical decisions, taking public safety actions within minutes to hours upon arriving on scene. This framework, prepared with extensive contributions from state and local public health and emergency response subject matter experts, represents a great stride toward developing a national capability for field response to suspected biothreats. The national capability envisioned here includes five major elements; ConOps, training and certification of end-users, proficiency testing, sample collection and handling standards and assays properly tested and certified against national voluntary consensus standards for performance. Further, the agency representatives that developed this document acknowledge that there is a role for Federal agencies in developing standards and guidance to support the five critical elements in order to provide best practices for jurisdictions to adopt or adapt. Development and fulfillment of all five critical elements described in this document is required to successfully enable a mission capability with an integrated initial response to suspect biothreats. Of the five critical elements identified, significant progress has been achieved through the provision of an Operational Guidance document (ASTM E2770-10), sampling and sample handling guidance for collection of bulk samples from non-porous surfaces (ASTM E2458-10), and performance specification standards developed for assays to detect *Ba* and ricin toxin. The three critical elements described above had to be accomplished before training and proficiency efforts could be initiated. Significant effort and resources will be required to support the needed training and proficiency testing program development defined here. DHS S&T developments in this area along with the concomitant national infrastructure to evaluate assay performance, provide first responder training, assess first responder performance and provide for first responder capability

certifications will require additional investments of time and resources at the local, state and Federal levels.