



## Methods

### Standards activities to support a biothreat mission capability in the United States

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Since the letters laced with *Bacillus anthracis* spores were mailed in 2001, U.S. law enforcement entities have responded to over 30,000 incidents involving suspicious samples [1]. Emergency responders still receive calls on a daily basis throughout the U.S. involving suspicious powder materials. In many instances, responders perform field assessment of these samples. Stakeholders from across the U.S. recognize that to support responders in their mission to collect and assess suspicious materials and take appropriate public safety actions based on the result requires voluntary consensus standards for (1) a concept of operations; (2) training and certification of the responder; (3) proficiency testing of the responder; (4) sample collection; and (5) a certified detection technology [2]. The purpose of this article is to summarize the standards developed to date that support three of these critical areas in response to a suspicious powder or package: a concept of operations, sample collection, and the certified detection technology.

#### Development of Voluntary Consensus Standards

In the U.S., Federal agency participation in the development of voluntary consensus standards is facilitated by the National Technology Transfer and Advancement Act of 1995 [3] and Office of Management and Budget Circular A-119 [4]. The intent of the law is at least two-fold: (1) to ensure that standards are developed to meet the needs of all relevant stakeholders; and (2) to guide the Federal government to preferentially develop standards using a voluntary consensus standards body (VCSB). Standards development by a VCSB follows an open, documented, consensus-based process allowing full participation by all stakeholders impacted by the standard. For biothreat response and the standards described in this document, the stakeholders include representatives from Federal, state, and local governments, the first response and public health communities, academia, and industry. Including these stakeholders and following the due process of the VCSB yields standards that provide economic and security benefit to the many rather than the few. In addition, the VCSB ensures longevity to the standards by continually reviewing and renewing the documents it develops and publishes.

#### Concept of Operations (ConOps) Standard

A coordinated and synchronous response to a suspected act of bio-terrorism requires advanced planning and preparation prior to the incident. The coordination and communication necessary at all levels of government in the US is laid out in the National Response Framework and further defined in the National Incident Management System (NIMS). In order to support a coordinated field response to suspicious samples, the stakeholder community developed ASTM E2770-10 *Operational Guidelines for Initial Response to a Suspected Biothreat Agent* [5]. Development was led by the *National Institute of Standards and Technology* (NIST) with extensive

involvement of first responders and public health communities from across the U.S., as well as state and Federal agencies. ASTM E2770-10 focuses on coordinating the initial response to suspected biothreats with the first responders, receiving public health laboratories, and law enforcement. The ConOps recommended by these stakeholders covers: (1) response planning, training, and protocol development; (2) coordinating the approach and deciding when to collect a sample; (3) sample collection method and packaging; and (4) transporting, and submission of a sample to a reference laboratory in the CDC Laboratory Response Network (LRN)<sup>(1)</sup> for confirmatory testing.

#### Sample Collection Standards

ASTM E2458-10 *Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Samples* [6] outlines best practices for emergency responders for the collection and transport of suspicious powders to the CDC Laboratory Response Network for confirmatory and forensic evaluation led by the FBI (Method A). The standard provides guidance for sample conservation during field screening for explosive, radiological, and acute chemical hazards. ASTM E2458-10 ensures preservation of the integrity of the material in the event that it becomes evidence, while recognizing that the main focus of the standard is on public safety response. ASTM E2458-10 should be used in conjunction with ASTM E2770-10 which provides guidance on determining when to collect a sample and how to coordinate with FBI and CDC. ASTM E2458-10 also provides guidance on sampling of residual powder (Method B) for first responders to utilize in any on-site biological assessment capabilities they have on hand. Use of the sample collection standard along with the guide ensures reduced exposure risk, minimizes on-site sample consumption for preservation of public health samples and forensic samples, and reduces variability associated with sample handling and

(1) The CDC Laboratory Response Network is the public health laboratory network responsible for handling clinical specimens and environmental samples containing suspected biothreat agents.



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analysis, and increases the reliability of the sampling procedure when collecting a sample of suspect bioterror materials. Additional efforts in the US government are working toward validation data for recovery efficiency of bioterror samples from carpets and porous surfaces.

### Performance Standards for Detection Technologies

Once the sample is collected following ASTM E2458-10, an emergency responder may perform on-site assessment of the residual sample. Numerous commercially available technologies claim the ability to evaluate suspicious materials for potential bioterror threats [7]. However, only one immuno-based Handheld Assay (HHA) has been tested and certified by a third-party [8, 9]. The Department of Homeland Security Science & Technology Directorate (DHS S&T) has funded AOAC INTERNATIONAL to establish the Stakeholder Panel on Agent Detection Assays (SPADA). SPADA, a VCSB with over 100 stakeholders from the communities described above [10], has established eight Standard Method Performance Requirements (SMPRs). The SMPRs define consensus detection performance standards the tools should meet or exceed in third-party testing, as well as required reference material panels. SMPRs include detection performance requirements for polymerase chain reaction (PCR)-based technologies that detect aerosolized *Francisella tularensis* [11], *Yersinia pestis* [12], *Bacillus anthracis* [13], *Burkholderia pseudomallei* [14], and *Burkholderia mallei* [15]. In addition, there are three SMPRs for tools that assess a suspicious powder sample for the presence of a bioterror. Two define requirements for tools that screen for for *Bacillus anthracis* spores using an immuno-based HHA or a PCR-based portable tool ([16] and [17], respectively). The third SMPR defines performance criteria for immuno-based HHAs that screen for ricin [18]. It should be noted that all eight SMPRs define requirements for testing performed in a laboratory setting. Testing in the hands of end-users is critical and remains an unmet need.

### Conclusion

Response to suspicious packages and materials is an on-going mission for emergency responders in the U.S.A. and around the world. In order to perform that mission, responders need voluntary consensus standards that support their public safety response mission. Standard procedures for the collection and assessment of suspicious powders are critical in preserving the material for public health confirmatory analysis and forensics assessment and building confidence in results for field detection technologies. Standards assist in determining a course of action for initial response for jurisdictions of all sizes and response capabilities through coordination with their public health laboratory, law enforcement, and supporting Federal agencies.

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