

Standards for Biothreat Detection

Standards Development in Response to Terrorism Threats

ANSI Homeland Security Standards Panel

Tenth Annual Plenary Meeting: Achievements from the Past Decade and Charting the Path Forward

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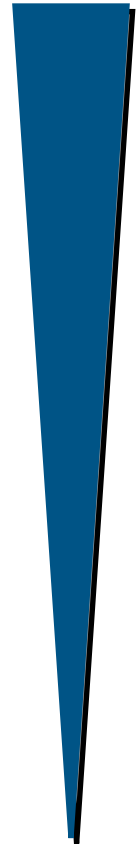
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Agenda

- A National Strategy for CBRNE Standards
- Framework for a Biothreat Field Response Mission Capability
- ASTM E2770-10 Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent
- ASTM E2458-10 Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces
- Standard Method Performance Requirements

*Requirements &
Coordination*



Implementation



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A National Strategy for CBRNE Standards

Strategy scope for CBRNE standards

- Specifies high-level goals
- Identifies lead activities
- Provides a foundation to bridge current gaps

*Facilitate U.S. Government
Wide Coordination on
Investments in Standards*

Federal, State, Local and Tribal Applicability

- Equipment used by responders for CBRNE detection, protection and decontamination
- Does not cover medical monitoring or diagnostic equipment in the health and safety arena

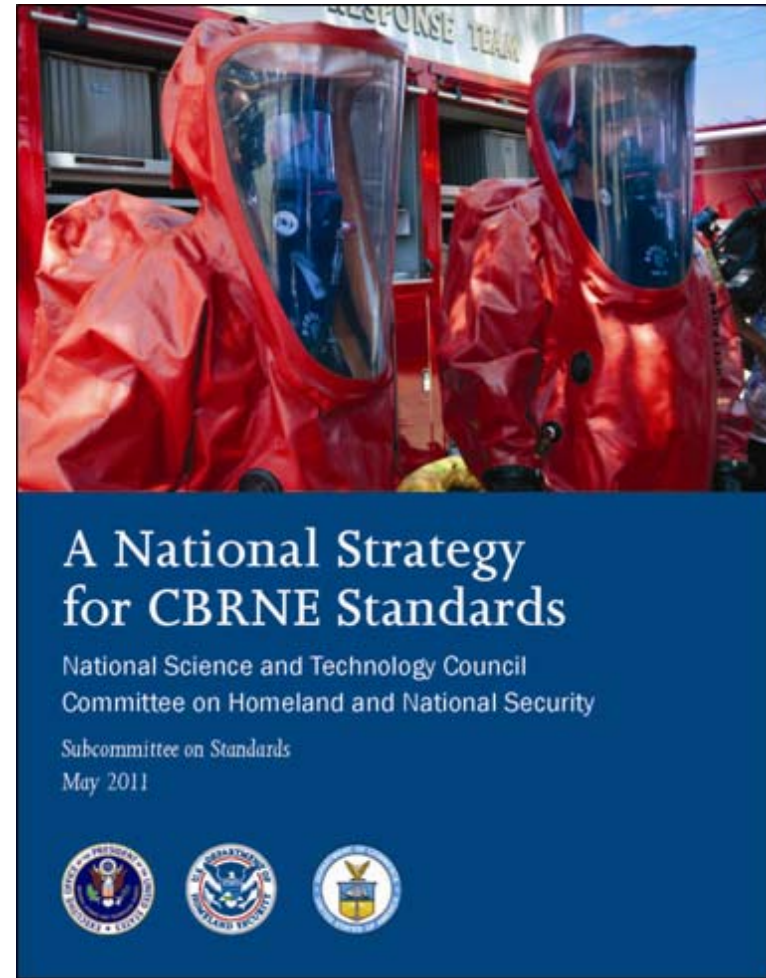


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Goals of the National Strategy

- Establish an **interagency group for CBRNE standards** to promote the coordination of such standards among Federal, state, local, and tribal communities
- Coordinate and facilitate the development and adoption of CBRNE **equipment performance standards**
- Coordinate and facilitate the development and adoption of CBRNE equipment **interoperability standards**
- Promote enduring CBRNE **standard operating procedures**
- Establish voluntary CBRNE **training and certification standards** and promote policies that foster their adoption
- Establish a comprehensive CBRNE **equipment testing and evaluation (T&E) infrastructure** and capability to support conformity assessment standards



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<http://www.whitehouse.gov/blog/2011/08/30/path-emergency-reponse-standards>

Framework for a Biothreat Field Response Mission Capability

Develop guidance to first responders for the biological assessment of suspicious powders

- Interagency effort involving DHS, CDC, FBI, and EPA
- Defines a Mission Capability (a.k.a., an Actionable Assay – the Onion)
- Outlines the accomplishments and remaining gaps
 - First Responder Operational Guidelines (i.e., ConOps)
 - First Responder Training
 - First Responder Proficiency Testing
 - First Responder Sample Collection Standards
 - The Assay
 - Performance Specification Standards
 - Testing and Certification of Assays

https://www.rkb.us/contentdetail.cfm?content_id=270212&query=270212&overridesubtype=950



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Framework for a Biothreat Field Response
Mission Capability

April 5, 2011

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ASTM E2770-10



Designation: E2770 – 10

Standard Guide for
Operational Guidelines for Initial Response to a Suspected
Biothreat Agent¹

Provide a guidance document for the responders to follow in response to a suspected biological threat

- Fundamentals needed for development of a bio-terrorism response, sampling, screening and field-testing program within a jurisdiction or practice area to assure proper involvement, communication and coordination
- Minimum training and PPE requirements for persons conducting field sampling, screening and presumptive testing
- Risk assessment that is conducted to determine if a visible powder is deemed a credible biological threat.
- Threat assessment should be integrated with law enforcement and FBI for determination of credible biological threat



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Contact Dr. Jayne Morrow (NIST; jmorrow@nist.gov) for more information on ASTM E2270-10 and ASTM E2458-10



Designation: E2458 – 10

ASTM E2458-10

Standard Practices for
Bulk Sample Collection and Swab Sample Collection of
Visible Powders Suspected of Being Biothreat Agents from
Nonporous Surfaces¹

E2458 is a sample collection procedure for:

- Visible powders
- Biological threat for all biothreat agents (*not* limited to anthrax)
- Solid, nonporous surfaces such as sealed concrete, plastic and polished wood surfaces including desktops, and tile
- Dispersed in a limited area
- Method A: Bulk Powder and Primary Item Collection
- Method B: Residual Powder Sample Collection
- Sample from Method B can be used in on-site biological assessment

Limited scope with an overall goal to develop a suite of validated consensus standards and to develop partnerships to facilitate the development of future standards



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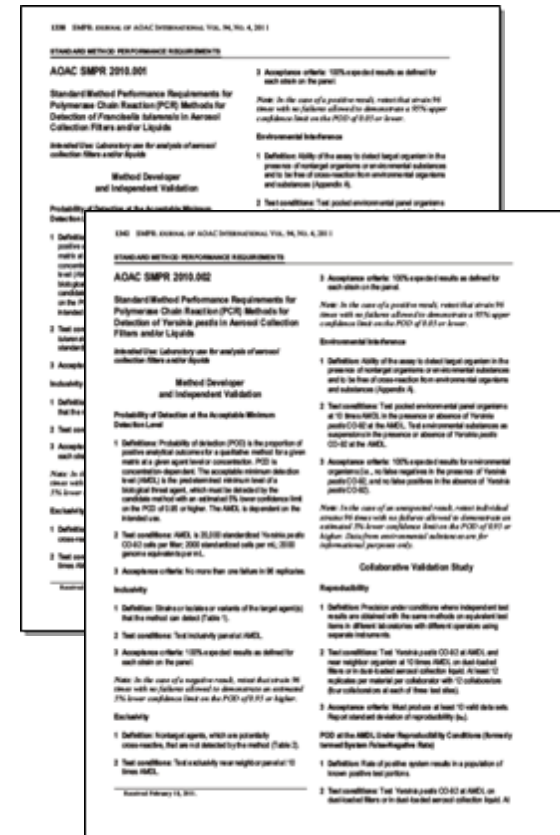
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Standard Method Performance Requirements

Detection performance requirements established by the Stakeholder Panel on Agent Detection Assays and published in the *Journal of AOAC INTERNATIONAL*

Five SMPRs and two additional publications are published:

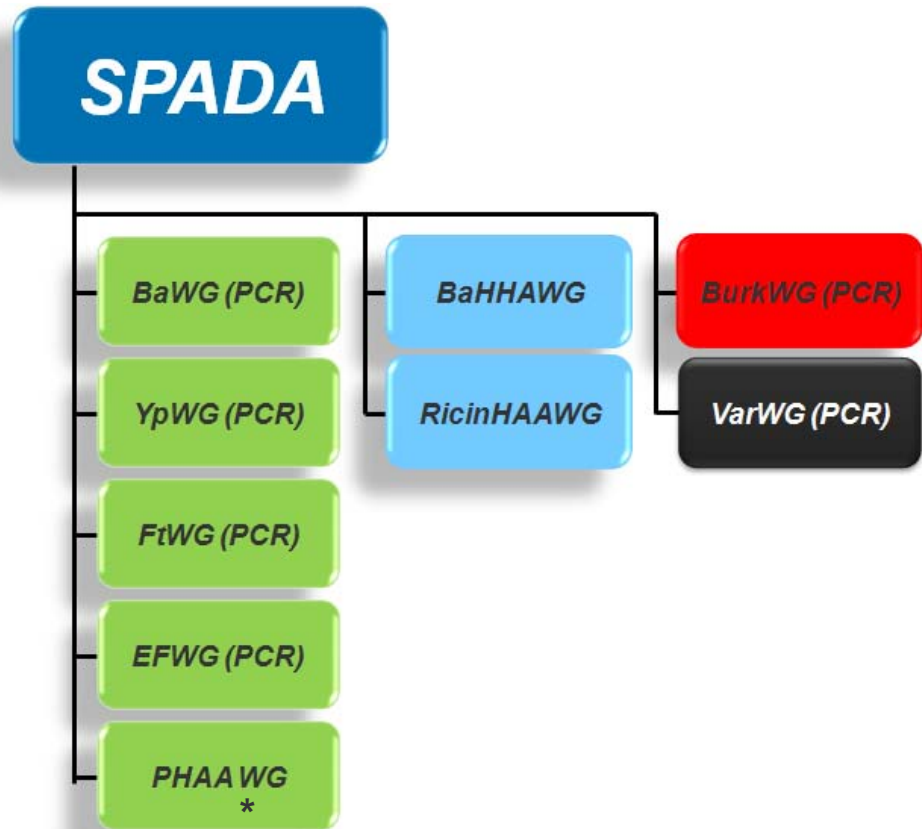
- Development of Standard Method Performance Requirements for Biological Threat Agent Detection Methods (SMPR-SPADA Overview)
- AOAC Biological Threat Agent Method Validation Guideline (BTAM Guideline)
- AOAC SMPR 2010.001** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Francisella tularensis* in Aerosol Collection Filters and/or Liquids
- AOAC SMPR 2010.002** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Yersinia pestis* in Aerosol Collection Filters and/or Liquids
- AOAC SMPR 2010.003** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Bacillus anthracis* in Aerosol Collection Filters and/or Liquids
- AOAC SMPR 2010.004** Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of *Bacillus anthracis* Spores in Visible Powders*
- AOAC SMPR 2010.005** Standard Method Performance Requirements for Immunological-Based Handheld Assays (HHAs) for Detection of Ricin in Visible Powders*



SPADA Sets the Standards

The Stakeholders Panel on Agent Detection Assays (SPADA)

- A voluntary consensus standards body established via a DHS S&T contract with AOAC INTERNATIONAL
- Includes representation from DHS, CDC, DoD, DoJ, FDA, EPA, USPS, NIST, State & Local Public Health, First Responders, Industry, and Academia
- Establishes method performance requirements and panels of reference materials (and validation protocols)



Upcoming SPADA Standards

Three more SMPRs to be published:

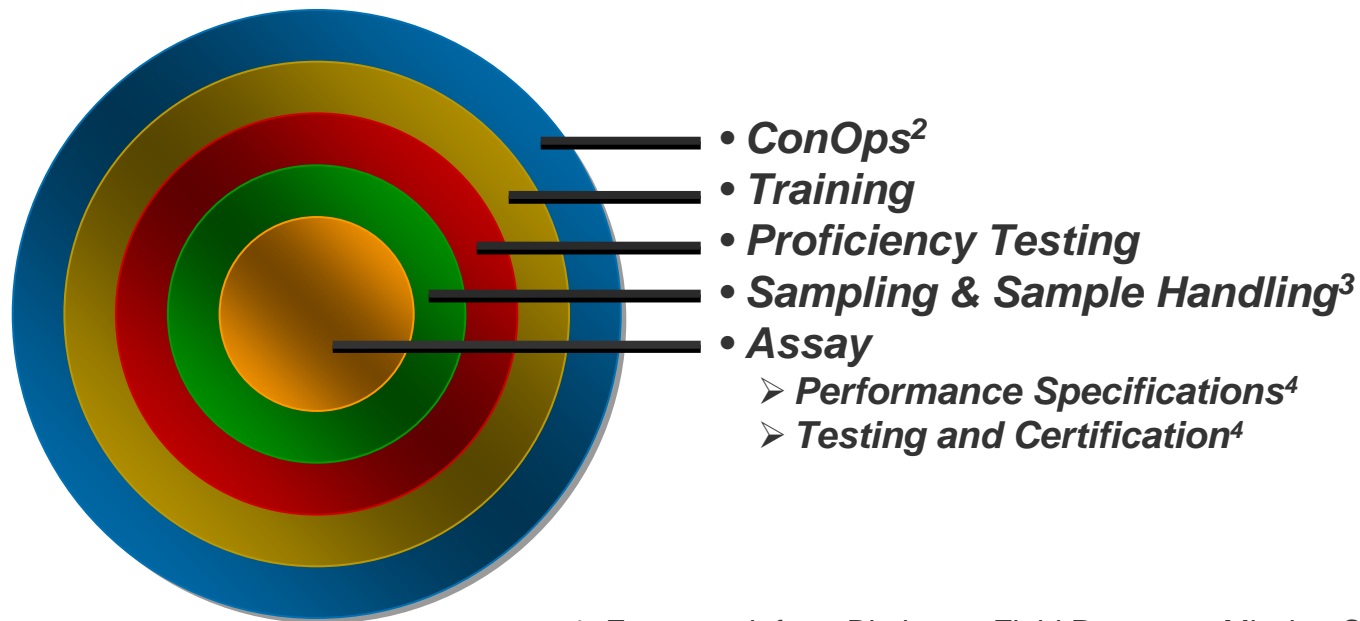
- **AOAC SMPR 2011.XXX** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Burkholderia psuedomallei* in Aerosol Collection Filters and/or Liquids
- **AOAC SMPR 2011.XXX** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Burkholderia mallei* in Aerosol Collection Filters and/or Liquids
- **AOAC SMPR 2011.XXX** Standard Method Performance Requirements for Polymerase Chain Reaction (PCR) Methods for Detection of *Bacillus anthracis* Spores in Visible Powders*

Variola standards are in development

Assay Controls Working Group established

Mission Capability

A Mission Capability for responders requires a series of competencies in addition to the assay¹



1. Framework for a Biothreat Field Response Mission Capability
2. ASTM E2270-10 Standard Guide for Operational Guidelines for Initial Response to a Suspected Biothreat Agent
3. ASTM E2458-10 Standard Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces
4. SPADA Standard Method Performance Requirements (DHS Public Safety Actionable Assay Project)



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