Bert M. Coursey[1], Philip J. Mattson[2], Naouma Kourti[3], Erik Puskar[1], William Billotte[4], Jennifer Marshall[1] and Lisa R. Karam[5] on the current status of performance standards for CBRNE detection

Standard practice

Introduction

The terrorist attacks in the United States in 2001 and the increasing number of attacks around the world today have provided emergency responders with greater awareness of their needs for technologies and standards to detect, prevent, respond to and remediate the effects of chemical, biological, radiological/nuclear and explosives (CBRNE) agents. Prior to this century, detection technologies were mainly in the hands of specially-trained response teams set up by federal agencies in the US and European Union member states to address weapons of mass destruction (WMD) or CBRNE acts. There were no standards of performance for the hand-held or mobile detectors that those teams took to the field; often their main tasks were to take samples to be sent to reach-back facilities for sometimes lengthy analyses by laboratory personnel using sophisticated methods and instrumentation.

After the attacks of September 11, 2001, markets for CBRNE equipment for responders developed quickly in both the US and EU and continue to expand today. These new markets differ significantly from the old ones in the US, which had consisted primarily of one major buyer, the Department of Defense (DOD). The current CBRNE market includes federal, state and local responders acquiring equipment useful in their specific jurisdictions. These responder organizations use varying procurement strategies and may or may not coordinate requirements with other jurisdictions. This broad "responder" community includes hazardous-material (HAZMAT) response personnel, as well as emergency medical service (EMS) personnel, fire fighters, law enforcement and explosive ordnance disposal (EOD) technicians. The equipment needed in these disciplines had been developed in parallel for military applications. Military personnel, however, use such technologies under a specified concept of operations that includes extensive training on the use of the equipment and the interpretation of results, for example, false negative and false positives, that arise from the use of a CBRNE detector.

These differences led to the development of the US National Strategy for CBRNE Standards [1]. This strategy relies on the idea of the development and implementation of national consensus standards to provide a foundation for reliable performance, quality and interoperability across all users and all markets (military, public health, public safety and law enforcement). In addition, the consensus standards encouraged by this National strategy provide opportunities for innovative detection technologies to be introduced into the markets and evaluated for potential advantages.

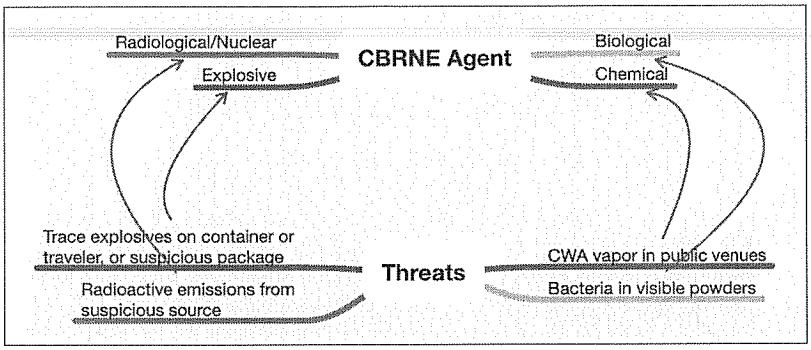


Figure 1. Categories of CBRNE agents

The EU has had challenges similar to those in the US regarding CBRNE threats and expanding markets of commercial instruments. They have been pursuing a Research, Development, Test & Evaluation (RDT&E) strategy along the same lines as the US. In 2008 and 2009, the EU established their Action Plan on Enhancing the Security of Explosives [2] and a CBRN Action Plan [3], respectively. The EU Explosives Action Plan called for the Member States, together with the European Commission, to: a) establish supply chain assurance (i.e., storage, transport and traceability) for the chemicals that could be used to make an explosive, b) develop minimum detection standards, and c) create a network to exchange information and best practices. The EU CBRN Action Plan called for the Member States and the Commission to: a) document requirements for sampling and detection of CBRN materials, b) exchange best practices, operating procedures and methodologies for quality assurance, c) establish an EU validation and certification scheme, d) establish EU testing methodologies for performance and quality of existing capabilities, and e) establish a EU demonstration capability for tools and systems in the field environment. Both action plans promote the utilization of EU-wide Common Workshop Agreements and Standards as mechanisms to achieve goals.

In a sense, this global effort to develop standards is a part of the *commoditization of CBRNE technology*. That is, these tools are no longer intended solely for federal/military experts but are rapidly becoming commercial off-the-shelf (COTS) technologies that must meet standards, testing and conformity assessment requirements set by the global market place to assure confidence for the user community. Additionally, the fact that a limited number of manufacturers are selling the same technologies around the world argues for harmonization of standards of performance to enable interoperability and facilitate commerce.

The CBRNE Threat

The "CBRNE threat" is in fact four distinct threats that comprise more than a thousand different dangerous agents. It is convenient to think of each of these threats grouped into categories as shown in Figure 1.

To bound the problem somewhat, the focus can be on the most common uses of CBRNE detection equipment used by responders called to investigate suspicious materials. Examples are shown in Table 1.

Various tools are available to responders for use in field measurements. Chemicals and trace explosives can be detected by ion mobility spectrometry (IMS), and closed packages of possible explosives can be evaluated by portable x-ray systems. Biologically-derived remnants, such as bacteria and viruses, can be detected by polymerase chain reaction (PCR) assays, while radionuclides are often detected by gamma-ray spectrometry. Since September 2001, there has been a rapid expansion in the types and numbers of commercial hand-held detectors that address needs in threat agent detection.

CBRNE Agent	Threat
Chemical	CWA vapor in public venues
Biological	Bacteria in visible powders
Radiological/Nuclear	Radioactive emissions from suspicious source
Explosive	Trace explosives on container or traveler, or suspicious package

Table 1. Example list of CBRNE agents and typical threats

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Metrics, Attributes, Requirements, Specifications

The first and, perhaps, most difficult step in establishing performance standards is achieving consensus among stakeholders on what the detector will be used for and what limitations are imposed for practical applications. In the 2010 document, *Chemical and Biological Sensor Standards Study II*, the DOD's Defense Advanced Research Projects Agency (DARPA) identified four key metrics and seven other attributes for CB sensors [4].

Key Metrics:
Sensitivity, Probability of Detection, False Positive Rate and Response Time
Other Attributes:
Unit Cost, Operation Cost, Maintenance (mean time before maintenance), Reliability (mean time before failure), Size, Weight and Power Consumption.

The DOD favors the use of "Spider Charts" such as the one shown in Figure 2 to permit a visual representation of numerical measures of these attributes. This approach has advantages for quickly comparing sensors (or detectors) from different manufacturers or different designs. They can be useful in establishing baselines for specifications for the key attributes that may then make their way into a performance standard.

In this depiction, the key metrics are essentially "false negatives," "false positives" and "response time" against the design threat. False negatives are critical because failure to detect a real threat can have disastrous consequences, while false positives are important because frequent alarms - whether due to background or nuisance materials - are costly and tend to lead users to discount any signals from the detector (or turn it off completely). Finally, speed of detector response is critical to allow the users to take immediate action to protect themselves and the public.

Threat	Chemical	Biological	Radiological/Nuclear	Explosive (trace)	Explosive (bulk)	All Hazards
Standards	ASTM E 2885-13	AOAC SMPR 2011	IEEE ANSI N42 N42.34 (2006) N42.48 (2008)	ASTM E 2520-15	IEEE ANSI N42.55 (2013)	ASTM E 2852-13
Key Metrics	Sensitivity Response time Probability of Detection False alarms	Probability of Detection (POD) at Acceptable Minimum Detection Level (AMDL) Inclusivity Exclusivity	Radionuclide identification False identification Response time	Limit of Detection for alarm, mass of analyte LOD90A Clear down time	Image quality Depth of penetration Spatial resolution	None - References to standards for specific threat agents
Environmental	Yes	None	Yes	No	Yes	Yes
Electromagnetic	Yes	None	Yes	No	Yes	Yes
Mechanical	Yes	None	Yes	No	Yes	Yes
Annexes	Listing of agents of interest	None	Human factors considerations	Technical issues Data sheets Web-based tool to calculate LOD90A	Statistical methods	Suggested selection criteria

Table 2. Performance standards for hand-held CBRNE detectors developed by Standards Developing Organizations since 2003. Access to current versions of the ASTM International *, AOAC International and IEEE ANSI N42 standards is provided on the web sites for the three SDOs [5-7]. Some references are provided here to other specific standards.
*Certain commercial products are identified in this paper to foster understanding. Such identification does not imply recommendation or endorsement by National Institute of Standards and Technology or the Joint Research Centres of the European Union, nor does it imply that the materials or equipment are necessarily the best available for the purpose.

Once sensors are considered outside the DOD structure, a variety of other interests (including concerns of civilian users and manufacturers) become more relevant. Standards for CBRNE detectors that have been developed in open consensus processes by Standards Developing Organizations (SDOs) have some differences from the DOD requirements. Table 2 lists how these requirements are gathered in standards by ASTM International, AOAC International, and the Institute of Electrical and Electronics Engineers (IEEE) American National Standards Institute (ANSI) IEEE ANSI N42 for field use detectors for chemical, microbiological and radiological/nuclear and explosives agents. The consensus standards developed in the SDO process do not generally address costs directly, but depend upon the buyer to determine if the product is cost-effective for their purposes. The standards address specific requirements for safety as well as environmental, electromagnetic compatibility and mechanical performance.

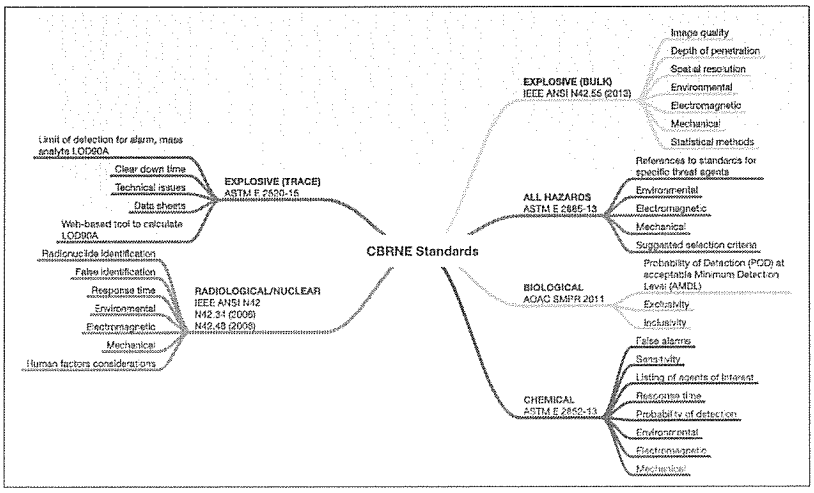


Figure 2. Spider chart model for evaluating chemical and biological sensor requirements – after a DARPA 2010 study on standards for chemical and biological agent sensor standards [4].

The Chemical Threat

Threats from chemical agents persist. Sarin gas was used in the lethal terrorist attack in a Tokyo subway in 1995 that killed 16 people and injured thousands. In 2013, the Syrian government used sarin, killing over 1400 and leading to a deal brokered by the international community for destruction of the Syrian stockpiles of these weapons [8]. The US government subsequently destroyed tons of sarin precursors and sulfur mustard blistering agents.

In the US and EU, emergency response to suspected chemical incidents is facilitated by teams trained to handle hazardous materials; these responders deal with chemical spills on a daily basis and are well-equipped to identify limited toxic industrial chemicals (TICs) and toxic industrial materials (TIMs) with the many chemical vapor detectors on the market today. Unfortunately, none of their detectors have been demonstrated to meet stringent performance standards for chemical warfare agents (CWAs) and multiple TICs. To address this gap, a diverse collection of stakeholders from industry and government laboratories participated in consensus development of the hand-held chemical point vapor detector standard, ASTM E 2885-13. Although the standard is technology agnostic, most of the detectors marketed in this sector are ion mobility spectrometers (IMS), and this is reflected in the standard.

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The ASTM subcommittee had agreed that it would be appropriate for sensors to detect multiple agents. The document includes which types of chemicals to cover and the level of performance to include and exclude from the performance standard. Although a list of 20 CWAs and TICs to be considered is given in a table in ASTM E 2885-13, it is not a requirement that a detector be able to detect all of these chemicals. In addition, the standard has a list of possible interferents, including gas and diesel fumes, which often lead to false alarms. The sheer number of possible agents, their different chemical properties, and the false positives from background chemicals increase the challenges for manufacturers.

The ASTM standard E 2885-13 identifies performance requirements for detectors capable of detecting and alarming when exposed to chemical vapors that pose a risk as defined by the Environmental Protection Agency (EPA) Acute Exposure Guideline Levels (AEGL) for selected airborne chemicals [9]. The standard calls for the detector to alarm in less than 2 minutes to the AEGL-2 concentration of sarin – that is, 8.5 parts per billion (ppb). If the general population were exposed to that level for 30 minutes, they would suffer serious adverse health effects. This same ASTM committee also produced a standard for stationary point chemical vapor detectors, ASTM E 2933-13. This standard applies to cabinet-type stationary detectors which can contain more than one type of chemical sensor linked to a common data display. A remote command center can monitor and control these devices. The performance requirements are similar to those in the ASTM standard for the hand-held detector, but longer acquisition times can be used because the detector is remote from the operator and can be continuously operated.

Table 3 shows the EPA guideline levels for airborne concentrations of CWAs.

CHEMICAL	AEGL-3 (30 min)	AEGL-2 (30 min)	AEGL-1 (30 min)
	parts-per-million (ppm)		
Tabun (GA)	0.057	0.0075	0.0006
Soman (GD)	0.025	0.0033	0.00026
Sarin (GB)	0.032	0.0085	0.00068
Cyclosarin (GF)	0.027	0.0035	0.00028
VX	0.0014	0.00038	0.00003
Mustard (HD)	0.41	0.030	0.020
Lewisite (L)	0.17	0.027	NR

Table 3. Selected List of EPA Acute Exposure Guideline Levels (AEGLs) for Chemical Warfare Agents [9]

The chief difficulty in a full implementation of this standard continues to be the lack of test facilities in the US to verify that a detector meets the requirements in the standard. In the US, CWAs are classified as select agents, and only three or four test facilities are authorized to retain such agents and conduct live testing. The TICs are also hazardous agents, and their test and evaluation requires special purified reagents and certified test chambers for instrument testing. For these reasons, state-of-the-art detectors on the market may have been tested for only a few TICs and CWAs; these tests were mainly financed by federal agencies for specific government purchases.

While US standards have been focused directly on detectors for agents in vapor form in the environment, the more expansive 2009 EU CBRN Action Plan calls for a) plans to ensure security of high-risk chemical facilities; b) supply chain controls on high-risk chemicals and equipment by the chemical industry; and c) licensing schemes for high-risk chemicals including CWA precursors, drug precursors and chemical weapons as described by the Chemical Weapons Convention. Recent activities include the examination of threats to water supplies. The EU Joint Research Centre (JRC), in Ispra, Italy has organized an activity under the European Reference Network for Critical Infrastructure Protection (ERNCIP) [10], which has a Thematic Group with participation from across the EU with a focus on chemical and biological risks in the water sector. This group has recommended the use of the ISO 15839 Water Quality – On-Line Sensors/Analysing Systems for Water – Specifications and Performance Tests (2003) [11], which describes the performance testing of on-line sensors/analyzing equipment for water. While this standard applies to most detection and measurement equipment, it also recognizes that not all such equipment can be subjected to performance tests. The international standard itself specifically:

- defines an on-line sensor/analyzing equipment for water quality measurements.
- defines terminology describing the performance characteristics of on-line sensors/analyzing equipment.
- specifies the test procedures (for laboratory and field) to be used to evaluate the performance characteristics of on-line sensors/analyzing equipment.

In the US, standard methods for analysis of contaminants in water supplies are promulgated by the EPA. The EPA's Homeland Security Research Center in Cincinnati, Ohio has led the efforts to identify methods for selected CWAs in matrices such as wipes, soil and water [12]. Most of the methods listed in that study rely on an extraction of the analyte from the matrix followed by gas chromatography/mass spectrometry (GC/MS) analysis.

The Biological Threat

The US learned first-hand of the challenges in responding to biological threats during the anthrax attacks in 2001. Letters mailed from Trenton, New Jersey to prominent news correspondents and political figures in the US led to the deaths of several people. Several billions of US dollars were required to clean up contaminated facilities. This event led to an accelerated program to develop biological-agent detection capabilities for response, biosurveillance, decontamination monitoring and attribution forensics.

US federal agencies moved to establish performance standards for several biothreat agents, which led to formation of the AOAC International Stakeholder Panel on Agent Detection Assays (SPADA) and its supporting working groups. The AOAC was the ideal SDO to develop such standards due to their expert stakeholders from US industry and federal agencies, including the Food & Drug Administration (FDA), US Department of Agriculture (USDA), the National Institute of Standards and Technology (NIST) and EPA. The SPADA team included additional federal agencies, including the DOD and the Department of Homeland Security (DHS). Teams of experts from the AOAC had already established a system, which included a standards setting process to capture and document the analytical requirements of the testing community to evaluate methodologies for microbiological assays for foods, drugs and agricultural products. These analytical requirements are codified into the AOAC Standard Method Performance Requirements (SMPRs) that define and specify the key metrics for a given analytical method or assay. For the types of assays being used to detect anthrax spores, known colloquially as 'hand-held' assays, the relevant SMPR specifies performance parameters such as Probability of Detection at the Acceptable Minimum Detection Level (POD at AMDL). The anthrax spore SMPR also specifies the acceptance criteria and the strains and species that should be evaluated as part of the Inclusivity panel (target agents) and the Exclusivity panel (for non-target agents that are potentially cross reactive). As the time to alarm will be dictated by several other factors that are not addressed in the SMPR, the speed of detection is not specified in the standard. In addition, the ruggedness requirements, such as those identified for chemical and radiological/nuclear detectors, are not specified for the biological threat agent detectors. The extensive and elaborate measurements required to validate the probability of detection under a multitude of different temperature and relative humidity regimes would make testing cost prohibitive.

A critical requirement of the AOAC SMPRs is that they require a collaborative validation study wherein "precision under conditions where independent test results are obtained with the same methods on equivalent test items in different laboratories with different operators using separate instruments." Accordingly, multiple identical samples of the threat agent must be distributed to 12 or more collaborators. It is not a problem to identify 12 laboratories to test a method for species of Listeria in milk, but logistical problems are much different for live specimens of anthrax (Bacillus anthracis) or smallpox (Variola major). As with chemical agents, there are limited locations that can test these materials. To respond to this difficulty, the AOAC included a provision to allow for four collaborators at each of three test sites so as to provide 12 data sets. These sites are usually federal contract laboratories that have access to

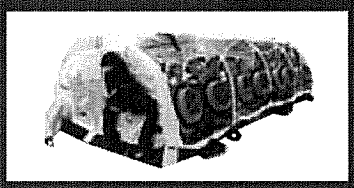
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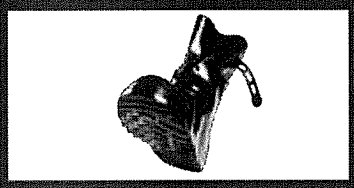




ISO-POD

Individual Patient Isolation System

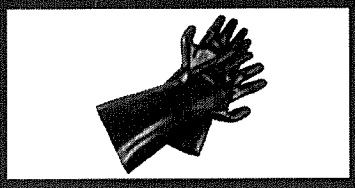
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Standard Practice

BioSafety Level 3 (BSL 3) facilities to handle the necessary test materials.

The standards initially developed in this open collaboration were directed at 1) visible white powders suspected of being biological agents, and 2) aerosol collection filters deployed to monitor potential airborne releases of biological agents. For both white powders and filter samples, the "detector" is a microbiological assay based on biomolecular reactions. These assays are critically dependent on the preparation of the sample and delivery to the device, as well as the purity of the reagents and the environmental conditions of the reaction. The first AOAC SPADA standards were developed for lateral flow immunoassays for Bacillus anthracis spores. In the simple lateral flow immunoassays, like the home pregnancy test kit, the target analyte is introduced in solution form to a test strip. Capillary action moves the solution on a paper strip until the target, if present, is bound to a site containing an antibody that is specific to the target analyte. A detectable label that attaches to the analyte-antibody complex is then added. The detectable label may be a fluorescent chemical compound that can be measured by a fluorometer or a chromophore that can be seen visually or measured with a colorimeter. These biomolecular reactions are relatively fast (a few minutes) and the results can be either a simple visual indication or a readout from a colorimetric/fluorometric reader. However, an immunoassay is not very sensitive to low levels of bacteria. The AOAC SMPR 2010.004 specifies an Acceptable Minimum Detection Level (AMDL) of 107 Colony Forming Units (CFU)/mL, essentially 10 million Bacillus anthracis spores. This amount is consistent with the ASTM standard for sampling suspicious powders (ASTM E 2458-2010) which assumes 107 spores in the form of a visible powder the size of a pea. If that amount of spores were taken up in 1 mL of buffer solution, and 100 µL of that solution were placed on the strip, this would correspond to an effective AMDL of one million spores.

The AOAC standard requires that an immunoassay be capable of detecting 15 different strains of Bacillus anthracis from all over the world as shown in Table 4. These strains comprise the Inclusivity Panel. At the same time, the assay must not give a positive result for 36 strains of nearest-neighbor bacteria (the Exclusivity Panel). Additionally, the assay must not test positive for 18 common interfering powders and chemicals (Environmental Factors Panel), including powdered coffee creamer, dry wall dust and powdered sugar.

One drawback to the immunoassays for Bacillus anthracis spores is the possibility of false negatives due to the limit of detection of about a million spores. The AOAC SPADA team recognized these limitations and developed, in parallel, SMPR 2010.003 for PCR detection of Bacillus anthracis spores in aerosol collection filters and/or liquids. These assays are based on amplification or replication of small amounts of DNA material and are being rapidly developed for medical diagnostics and forensics; some of the PCR assay kits are marketed for field use for biothreat agents. The AMDL is 20,000 standardized Bacillus anthracis Ames strain spores per filter, 2000 standardized spores per mL, or 2000 genome equivalents per mL. For these PCR assays, the Inclusivity Panel is the same as that in Table 4 but the Exclusivity Panel is smaller (20 near-neighbor bacteria). However, the Environmental Factors Panel is greatly expanded for PCR assays due to concerns about potential cross-reactivity to DNA and DNA fragments that naturally occur in the environment. While the limits of detection with PCR assays are several orders of magnitude lower than that of the immunological assays, the complete assay of a suspicious material may take up to one hour.

Immunoassays do provide a robust method for the determination of ricin, a highly toxic substance extracted from castor beans, for a properly prepared sample. Due to its ready availability, ricin incidents occur on a regular basis. The lethal dose (LD50) of ricin is 5 µg/kg -15 µg/kg if the exposure is from injection or inhalation (about 1 mg -2 mg for an average adult) [14]. The AOAC standard for ricin detection assays intended for field use by responders to suspicious powders, SMPR 2010.005, defines an AMDL of 25 ng/mL Ricinus communis Agglutinin II (RCA 60) in candidate method sample collection buffer solution. Thus, the minimum detectable amount for ricin is orders of magnitude below the lethal amount, and the immunoassays are often used to confirm its presence when responders have reason to suspect its presence.

Both immunoassay and PCR assay kits for field use have capabilities for assays of up to 16 targets such as Bacillus anthracis, Francisella tularensis, Ricinus communis, Salmonella species, Variola major, and Yersina pestis. There are AOAC SMPRs for many of these analytes, and a summary table is given on the AOAC web site [6].

No.	Strain	Origin
BA1	Canadian bison	Wood bison (Canada)
BA2	V770-NP-1R	Vaccine (USA)
BA3	PAK-1	Sheep (Pakistan)
BA4	BA1015	Bovine (Maryland, USA)
BA5	Ames	Bovine (Texas, USA)
BA6	K3	South Africa
BA7	Ohio ACB	Pig (Ohio, USA)
BA8	SK-102 (Pakistan)	Imported wool (Pakistan)
BA9	Vollum 1B	USAMRIID* (USA)
BA10	BA1035	Human (South Africa)
BA11	RA3	Bovine (France)
BA12	2002013094 (240)	Louisiana (USA)
BA13	Pasteur	USAMRIID (USA)
BA14	Sterne	USAMRIID (USA)
BA15	Turkey No. 32	Human (Turkey)

Table 4. Bacillus anthracis Inclusivity Panel, modified from Table 1 in AOAC SMPR 2010.004 Journal of AOAC International, Vol. 94, No.4, p 1352, 2011 [13]. * USAMRIID is the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, Maryland.

The Radiological/Nuclear Threat

Prior to September 11, 2001 detectors for radiological/nuclear agents were used extensively in the commercial nuclear power industry and research laboratories for worker protection. The military also has a tradition of using general purpose, portable detectors for field measurements. As with most sectors, heightened interests in security following September 11, 2001 led to markets for several classes of radiological/nuclear detectors for a wider community.

Detectors are available for alpha- and beta-particles, but they are chiefly used for monitoring surface contamination. Standards for performance of those detectors have been developed by the health physics community [15]. The main detectors in use for the radiological/nuclear threat, however, are for more penetrating radiations (e.g., gamma rays and neutrons). To address the need for standards of performance for these types of systems, the IEEE US National Committee on Radiation Instrumentation American National Standards Institute (ANSI) N42, an expert working committee with decades of expertise in the field, initiated work in radiological/nuclear detector standards for homeland security applications.

With support from NIST and several federal agencies such as the Department of Energy (DOE), DOD, and DHS, the ANSI N42 committee was able to quickly establish working groups in 2002 and developed four consensus standards for these types of instruments within about one year. These standards were directed at four types of detectors: radiation pagers for use by emergency responders; radiation survey meters for establishing the nature of the radiation and control zones; radionuclide identifiers to identify specific threats; and radiation portal monitors for use in scanning personnel and cargo passing through checkpoints. These standards, first published by IEEE in 2003 and

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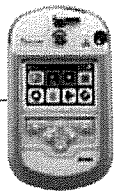
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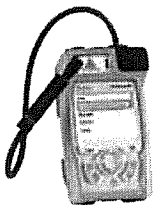
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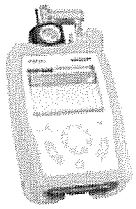




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IEEE Standard	Use	Associated IEC Standard
ANSI N42.32 - 2006	Performance Criteria for Alarming Personal Radiation Detectors for Homeland Security	IEC 62401 - 2007
ANSI N42.33 - 2006	Portable Radiation Detection Instrumentation for Homeland Security	IEC 62533 - 2010
ANSI N42.34 - 2006	Performance Criteria for Hand-Held Instruments for the Detection and Identification for Radionuclides	IEC 62327 - 2006
ANSI N42.35 - 2006	Evaluation and Performance of Radiation Detection Portal Monitors	IEC 62244 - 2006
ANSI N42.37 - 2006	Training Requirements for Homeland Security Purposes Using Radiation Detection Instrumentation for Interdiction and Prevention	
ANSI N42.38 - 2006	Performance Criteria for Spectroscopy-Based Portal Monitors Used for Homeland Security	IEC 62484 - 2010
	Highly sensitive hand-held instruments for neutron detection of radioactive material	IEC 62534 - 2010
ANSI N42.41 - 2007	Performance Criteria for Active Interrogation Systems Used for Homeland Security	
ANSI N42.42 - 2012	Data Format Standard for Radiation Detectors Used for Homeland Security	IEC 62755 - 2012
ANSI N42.43 - 2006	Performance Criteria for Mobile and Transportable Radiation Monitors Used for Homeland Security	
ANSI N42.48 - 2008	Performance Requirements for Spectroscopic Personal Radiation Detectors (SPRDs) for Homeland Security	IEC 62618 - 2013
ANSI N42.49 A - 2011	Performance Criteria for Personal Emergency Radiation Detectors (PERDs) for Exposure Control	
ANSI N42.53 - 2013	Performance Criteria for Backpack-Based Radiation-Detection Systems Used for Homeland Security	IEC 62694 - 2014

Table 5. US Standards and corresponding international (IEC) standards for radiological/nuclear detectors. NIST has listed protocols for test and evaluation against many of these standards as well as data sheets on their web site [16].

2004, are shown as the first four standards in Table 5. The ANSI N42 committee continues with active standards development today, with broad participation by industry and continued federal support from US agencies. This has led to the additional 13 standards listed in Table 5. The leadership of this committee is also active in the International Electrotechnical Commission (IEC) Subcommittee SC 45B, and many of the IEEE ANSI N42 standards have a counterpart in the IEC as shown in the last column of Table 5. The dates listed with the standards show the most recent published version of the standard, but many of these are under review and revision at any given time.

A number of the important detector standards have not been revised since 2006, as the requirements have stayed the same and attention has turned to testing protocols. Further discussion in this review will focus on the standards for hand-held gamma-ray spectrometers (ANSI N42.34 and N42.48).

A typical use-case for a hand-held radionuclide identifier is a scenario in which an inspector approaches a cargo container at a border crossing or weigh station to detect and identify radioactive materials. There are frequent detector alarms with such inspections because the gamma-ray detectors are sensitive to naturally occurring radioactive materials (NORM); radionuclides of uranium, thorium and potassium are present at relatively high levels in agricultural products and industrial materials containing rocks, sand, ceramics, road salt and kitty litter. The radionuclides often encountered - and listed in the N42.48 standard - are given in Table 6.

Key metrics for these detectors – false negatives, false positives and speed – are addressed in considerable detail. The section devoted to radiological tests includes:

- General test information
- Rate of false alarms
- Time to alarm; photons (x rays and gamma rays)
- Time to alarm; neutrons (if detector is designed to detect neutrons)
- Detection of gradually increasing radiation levels
- Accuracy
- Personal radiation alarm
- Over-range response
- Interfering ionizing radiation
- Radionuclide identification.

The radionuclides listed in Table 6 are considered of particular interest for spectroscopic radiation detectors (SPRDs). Manufacturers of these detectors include a built-in library of gamma-ray spectra for many of these radionuclides. Of considerable interest to responders are detectors that can distinguish a weak signal from a threat radionuclide in the presence of the cluttered gamma-ray response to natural background radiation. Details are given in the standards on how to measure the background radiation, which standard radioactive sources to use to measure detector response and how to carry out the measurements to establish quantitative agreement with target levels of the key metrics. These hand-held instruments are required to give a rapid response to a threat level of a gamma-ray emitting radionuclide. For example, the radiation alarm "shall be activated within 2 seconds when the detector is exposed to a 137Cs source producing a radiation field of 100 microgray per hour" (IEEE ANSI N42.48).

In a collaboration in 2010, the EU JRC invited participation from the US DHS's Domestic Nuclear Detection Office (DNDO) along with NIST and the International Atomic Energy Agency (IAEA) in a test and evaluation program for radiation detectors called ITRAP+10 (Illicit Trafficking Radiation Assessment Program+ 10) [17].

"Collectively, the U.S. and its European partners will have access to nearly 100 devices across nine different categories of detection equipment. To date, devices have been proposed for testing by 27 vendors from 11 different countries.

ITRAP+10 will provide the opportunity to ensure that standards for radiological and nuclear detection devices are clearly defined, comprehensive and realistic. This program's internationally collaborative features may also help achieve greater homogeneity in U.S. and international detection standards. In addition, ITRAP+10 will allow the U.S. and European partners to better understand how commercially available detection equipment performs and drive industry to technological advances, ultimately ensuring nuclear security success." [17]

Under this program, technical staff from a JRC facility in Ispra, Italy conducted tests of commercial radiation detectors in eight of the nine of the categories listed in Table 5 [18]. The general requirements (i.e., the key metrics) for the detectors mirror those in the IEC and ANSI N42 standards listed in Table 6. For example, the spectrometric personal radiation detectors needed to meet requirements given in the IEC 62618-2013 and ANSI N42.34-2006. The

Special Nuclear Materials	Uranium (used to indicate ^{233}U, ^{235}U, ^{238}U), ^{237}Np, ^{239}Pu
Medical Radionuclides	^{18}F, ^{67}Ga, ^{51}Cr, ^{75}Se, ^{85}Sr, ^{90}Mo, ^{99m}Tc, ^{103}Pd, ^{111}In, Iodine (^{123}I, ^{125}I, ^{131}I), ^{153}Sm, ^{201}Tl, ^{133}Xe
Naturally Occurring Radioactive Materials	^{40}K, ^{138}La, ^{232}Th and daughters, ^{238}U and daughters
Industrial Radionuclides	^{57}Co, ^{60}Co, ^{133}Ba, ^{137}Cs, ^{192}Ir, ^{204}Tl, ^{226}Ra, ^{152}Eu, ^{22}Na, ^{241}Am

Table 6. Radionuclides of greatest interest in four categories (IEEE ANSI N42.48 – 2008). List should not be considered all-inclusive.

ITRAP+10 testing combined the requirements of both the ANSI and IEC standards. The JRC and US staff engaged in these tests are also active in the IEC SC45 Working Group B15 to develop and refine these standards. In the US, additional test and evaluation procedures for these detectors are being developed by the DOD T&E Executive's, Capabilities and Methodologies Integrated Process Team (CAPAT), in collaboration with NIST [19].

The Explosive Threat

The explosive threat continues to be a global problem, with many examples of person-borne improvised explosive devices (PBIED) such as the "underwear bomber" in December 2009 and the 2016 attacks in Paris and Brussels. Explosive threat materials and concealed explosives are detected by a variety of means, chief of which are canines, trace explosives detectors for chemical agents [called explosive trace detectors (ETDs)], and x-ray scanning systems. Standards and training regimes for explosive-sniffing dogs are beyond the scope of this article. Performance standards for the other two classes of explosive detectors are developed by two different communities. Chemical experts develop standards for ETDs under the auspices of ASTM International Committee E 54, while physicists develop standards for radiation-based scanners under the auspices of IEEE ANSI N42.

Explosive Trace Detectors (ETDs)

ASTM E 2520-15 describes a standard practice that "may be used for measuring, scoring, and improving the overall performance of detectors that alarm on traces of explosives on swabs." Although this standard is directed towards ion mobility spectrometry (IMS) and mass spectrometry (MS), the general provisions may be suitable for other types of trace chemical detectors. The intended users of the standard are not first responders, but manufacturers of trace detectors, testing laboratories and agencies responsible for enabling effective deterrents to terrorism.

This standard differs markedly from ASTM E2885-13, the performance standard for IMS used for chemical agent detection mentioned previously. The trace explosive standard relies heavily on procedures for preparing swabs to be used for measurement of the limits of detection (LOD) for the detector under test. The standard is applicable for detectors directed towards compounds of eight known types of explosives shown in Table 7, along with 16 chemical compounds that are associated with these types.

Similar to ASTM E 2885, this standard considers common interferents by providing procedures for preparing Background Challenge Materials (BCM) that could be picked up in the swab sampling process: agricultural soil, domestic dust, and particulates that may contain nitrates from combustion processes. Nitrates are a particular problem for ETDs given that many of the target explosives contain nitrogen compounds. The standard also lists NIST Standard Reference Materials (SRMs) that can prove useful in preparing the BCMs.

The key metric in ASTM E2520-15 is the "LOD90A," which is the limit of detection (LOD) for alarm (the mass of a particular analyte that elicits a detection alarm 90 % of the time (90 % confidence level) in a particular ETD while process blanks elicit alarms less than 10 % of the time). This is a convenient tool for combining the false negatives and false positives in a single metric. The statistical basis for the LOD90A is taken from ASTM E2677-14. The calculations involved for determining an LOD are performed using a web-based tool, which imparts consistency in data reduction and allows the desired risk tolerance and uncertainty characteristics of the LOD to conform to detection concepts established by the international Joint Committee for Guides in Metrology (JCGM).

The time to alarm is not as critical for this class of detectors as the clear down time to allow the instrument to return to a baseline setting after responding to a target agent. The clear down time is a determinant of the operational throughput for detectors that are often intended for continuous use at a checkpoint (as a benchmark, the IMS detection time for explosives is quite fast, on the order of 8 seconds.) The ASTM standard includes data sheets for recording BCM alarm responses and alarm response thresholds for different challenge masses of the target compounds, as well as the LOD90A values for each.

The sampling of the potential threat is equally important to the efficacy and speed of the detector. The key to detection is getting the particles of explosive trace material, which may have low vapor pressure, into the IMS via the swab sample. For example, the active ingredient of the common explosive C-4 is RDX. Bomb making results in trace residues on surfaces containing large numbers of RDX particles less than 100 ng in mass; an IMS can rapidly detect 3 ng or less [20]. The challenge is that swab sampling methods must collect a few particles from these essentially invisible residues and then successfully introduce them to the detector. Subsequently, the detector must successfully identify the chemical signature of the RDX from the background interferences imparted by the sampling process. This measurement process can go awry unless each step is carefully controlled [21].

X-ray Scanners for Bulk Explosive Detection

Prior to September 11, 2001, there were already a few standards for x-ray scanners used for bulk explosives detection from ASTM and the Department of Justice's (DOJ's) National Institute of Justice (NIJ). These standards were geared mostly toward metal detection (weapons) for secure entry points (e.g., prisons, schools, courtrooms). In the past decade, there has been an impressive body of work on technical performance standards and radiation safety standards for x-ray (and gamma-ray) scanners developed by IEEE ANSI N42 specifically for security applications. This effort, under the leadership of the US National Committee on Radiation Instrumentation, is closely allied with the standards developed for radiological/nuclear detectors referenced above. Experts from DHS and NIST work with industry leaders and experts from other federal laboratories to develop the US standards and coordinate their incorporation into IEC standards on the international level. The secretariat for radiation safety standards (ANSI N43) is held by the Health Physics Society (HPS), and some safety standards are also given in the US Code of Federal Regulations (CFRs). As mentioned previously for the radiation

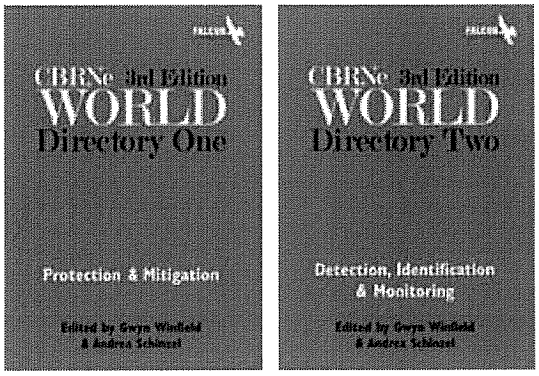
Chemical Class or Explosive Type	Target Compounds*
Nitramines	RDX, HMX
Nitro-esters	PETN, ETN
Nitro-aromatics	TNT, Tetryl
Nitrosamines	R-salt
Peroxides	HMTD, TATP
Inorganic nitrates	AN, CAN, KNO_3
(Per)chlorates	$NaClO_3$, $KClO_4$
Smokeless powders	NG, EtC

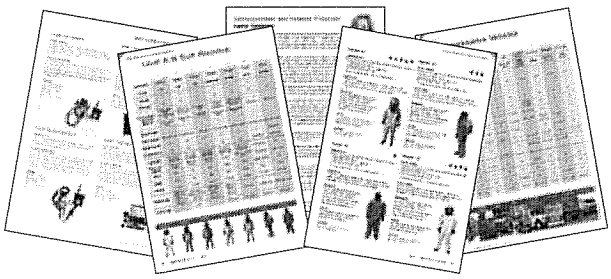
Table 7. Explosives types and associated chemical compounds. From Table 1 in ASTM E2520-15. *See ASTM E2520-15 for definitions of abbreviations of target compounds.

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Venue	Technical Performance (US)	Technical Performance (International)	Radiation Safety (US)	Radiation Safety (International)
Checkpoint (cabinet x-ray systems)	ANSI N42.44 ASTM F792	IEC 62963	ASTM F1039* 21 CFR 1020.40	
Computed Tomography (CT) (checked luggage)	ANSI N42.45	IEC 62945 IEC 62963	ASTM F1039*	
Cargo/Vehicle (radiographic imaging and active interrogation systems)	ANSI N42.46 ANSI N42.41	IEC 62523	ANSI N43.16 ANSI N43.14 10 CFR 20 29 CFR 1910.1096	IEC 62523
Whole Body Imaging	ANSI N42.47	IEC 62709	ANSI/HPS N 43.17	IEC 62463
Bomb Squad (portable x-ray sources)	ANSI N42.55 NIJ 0603.01		29 CFR 1910.1096	ANSI/HPS N43.3 ANSI/ANS 6.1.1

Table 8. US and International standards for x-ray inspection systems.
* ASTM F1039 is a test method for radiation to a product (content) of luggage passing through a CT scanner. It was withdrawn in 2002 and is under revision.

detection standards, many of these are under revision and efforts are being made to harmonize the US and IEC standards to the greatest extent possible.

The technical performance standards and radiation safety standards for five different classes of bulk detection systems are given in Table 8.

ANSI 42.55-2013 is the American National Standard for the performance of portable transmission x-ray systems for use in IED and hazardous device disarming and render-safe operations. The portable system includes an x-ray generator and image capture and display components. This system is quite different from the other CBRNE hand-held detectors in that it produces a two-dimensional transmission x-ray image (still or video) of the object under investigation, and the quality of the image is of key importance. Metrics for measuring image quality are provided in the standard, which also references a series of test objects, step wedges and foils of different materials, and describes the test methods for their use. As these systems are designed for field use, there are mechanical, environmental and electromagnetic compatibility (EMC) requirements that mirror those of the other standards developed under the IEEE ANSI N42 umbrella.

This suite of standards in Table 8 is particularly important because of the large and expanding global market for x-ray scanners; manufacturers of these systems in the US, EU and Asia Pacific Economic Cooperation (APEC) install these systems around the world. Harmonized standards for technical performance and radiation safety are necessary to meet customer needs and regulatory requirements in different markets.

Conclusions

The tables presented in this review are indicative of the substantial progress that has been made on all fronts in developing new standards for detectors of CBRNE threat agents since 2002; approximately 40 standards are referenced. These standards have been and continue to be key enablers in the rapid growth of the manufacture and deployment of CBRNE sensors and detection systems as they enable users to specify minimum performance requirements and manufacturers to have clear target design-goals for new products. The concerted effort on the part of the R&D community investing in levels of anticipatory standards has resulted in a great deal of synergy in development of detectors for different threats – often CBRNE detectors are different product lines in the same company. This benefits customers who can achieve a plug and play capability with enhanced interoperability. From an economic benefit, more robust competition has both lowered costs and increased capabilities for manufacturers and end users. There has been slow but steady progress towards common global standards that are needed for the global marketplace. The IEC is leading the way with suites of standards for radiological/nuclear and bulk explosives detection standards. However, standards for trace explosives and those for chemical and biological sensors are still not widely used outside the US.

Key impediments to the widespread use of CBRNE standards are the lack of accessible T&E facilities which allow manufacturers to demonstrate that a product meets the standards. Most of the T&E facilities equipped to perform these tests are US government-operated and have special requirements on accepting systems for testing. This is a choke point in the system that limits the number of validated detectors on the market.

Still, the future looks positive for continued development of CBRNE detector standards. Well-established standards working groups under traditional SDOs show promise for continued revisions of existing standards and development of new standards as both threats and the technologies to counter them continue to evolve.

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