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

Overview of Problem

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

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

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

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

Consequences

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

Need

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

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

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

Start of a Program Meeting the Need

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

systems. DHS S&T contracted AOAC INTERNATIONAL, an independent, third-party scientific organization, and the Midwest Research Institute (MRI) to establish and make publicly available a scientifically based set of standards and processes for the independent evaluation and validation of threat agent detector systems including PCR-based methods and hand-held assays. The intent of DHS is that this program will become a national enduring capability administered by a third party and funded by those who wish to have their technologies independently validated.

An essential activity in the development of the standards, processes, and ultimate enduring capability is the formation of a Stakeholders Panel on Agent Detection Assays (SPADA) where key stakeholders from government (CDC, DOD, FBI, DHS, USPS, EPA, FDA), public health, first responders, and industry are brought together to reach consensus on the performance requirements for PCR-based methods for *Bacillus anthracis, Yersinia pestis,* and *Francisella tularensis.* In addition, another aspect of the contract is to execute a pilot project in which a selected method that detects *B. anthracis* will be evaluated using the standards and process established by SPADA. The process involves subjecting the pilot method to the most rigorous independent evaluation and validation schemes available—AOAC INTERNATIONAL's time-tested and internationally recognized *Performance Tested*[SM] and *Official Methods*[SM] programs.

Once the pilot is completed, DHS, the emergency preparedness and public health communities, as well as private sector stakeholders, need this program to continue to establish performance criteria for other technologies, for many other agents, and for many kinds of end users and applications. Any future program needs to be sustainable to evaluate and validate all the necessary threat agent detection tools needed by the public and private sectors. But to be sustainable, the system must also make economic sense to the assay developers in order for them to use it.

Future Direction of a Program to Meet the Needs of Emergency Responders

A Town Hall meeting, sponsored by DHS S&T, was held on September 12, 2008 in Rockville, MD to provide a forum to and discuss the needs of the threat agent detection community, and to offer guidance on future DHS programs that would best benefit DHS clients and the safety and welfare of the American public.

Almost 150 Town Hall meeting attendees included:

- U.S. government stakeholders (representatives from CDC, OSTP, The White House, Senate, DOD, FBI, DHS, EPA, IAB and others);
- Government and private sector threat agent detection system developers;
- The public health community;
- The assay end-users community (emergency responders and building, facility, and infrastructure protection representatives).

In the spirit of a true Town Hall meeting, attendees discussed, amended, and voted on Articles that were drafted by a Town Hall Meeting Steering Group and distributed to meeting invitees prior to the meeting.

The resulting Articles and results of vote serve as a position document and provide strategic recommendations on the development of standards for Chemical, Biological, Radiological, Nuclear, and Explosive (CBRNE) detector technologies and their use.

Articles Adopted by the Town Hall Meeting Assembly:

1. DHS should expand its effort to coordinate the development of CBRNE detection technologies and devices.

2.a. DHS should develop, in collaboration with other agencies, standardization organizations and industry, a program to qualify detection technologies and devices by an independent third party and make this program available to the private sector as a best practice

2.b. Once the program is available, detection technologies and devices must be qualified prior to their purchase by grantees and federally regulated venues.

3. In cooperation with other agencies, DHS should lead the development of guidelines and standards that lead to the implementation of training, proficiency testing and certification of the operator in the use of qualified detection technologies.

4. In cooperation with other agencies, DHS should lead the development of guidelines for SOPs which shall include the appropriate use and operation of qualified detection technologies, as well as interpretation and response by the end user.

5. DHS, in cooperation with other agencies, should develop strategic guidance on standards for CBRNE detector technologies for use by relevant critical infrastructure sectors, key resources and others.

The Town Hall Meeting Minutes that include a list of close to150 meeting attendees and all Appendices are under attachment.

Recommendation for Next Steps:

To meet the needs of emergency responders, public and private facilities' protection community, the public health community, government representatives, and the private sector technology providers as expressed in the Articles, the following next steps are recommended:

- After discussion with the Office of Science Technology & Policy (OSTP), Executive Office of the President, deliver results of Town Hall meeting in a format that meets the needs and goals of the OSTP and the Subcommittee on Standards (SoS);

- Under the umbrella of SoS, leverage existing organizations and groups (IAB, PCIS, SPADA) by using them as observers and commentators to help inform the decisions and meet the goals of the SoS;

- Devise a Plan to best implement the Articles to meet needs of customers and communities represented at the Town Hall Meeting;

- Identify specific challenges and mitigate problems in implementing the Articles to meet customer needs;

- Determine costs for the implementation of the Plan and present to appropriate legislative bodies;

- Engage independent third party organizations (AOAC, ASTM, IEEE, ANSI) to develop stakeholder consensus based standard performance criteria for priority area detection technologies and devices;

- Work from the bottom up by focusing first on priority end-users and applications, and then on technologies and threat agents;

- The overwhelming need of Town Hall meeting attendees centered on a national program to qualify threat agent detection technologies and have national guidelines for SOPs in the use, operation, interpretation, and response by end users of those technologies.

  AOAC recommends that DHS hold another broad based Town Hall meeting in 2009 to address details regarding progress on implementation of the Articles and to listen to their customers to ensure DHS is on the right track to meet their needs as expressed in the Articles.

About AOAC INTERNATIONAL

AOAC INTERNATIONAL is a globally recognized, 501(c)3, independent, not-for-profit association founded in 1884 to facilitate the resolution of trade disputes, by bringing together government and industry stakeholders to reach consensus on method performance requirements and then to ensure that the methods are fit-for-purpose. AOAC provides a science-based solution and its *Official Methods of Analysis* give defensibility, credibility, and confidence in decision-making. In addition, AOAC provides other quality measurement tools including proficiency testing and training.