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Standard Guide for Surrogate Materials for Field Evaluation of Nucleic Acid-Based On-Site Biological Assessment Technologies[1]

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INTRODUCTION

Emerging infectious disease and deliberate biological threats are ever-present concerns that can affect the health and safety of the public. Constant vigilance and cooperation among law enforcement, public health, and public safety communities across the globe are required to respond to and minimize the impact of these threats. Significant investments in technology innovation and development have led to the availability of a large number of on-site biological assessment technologies to support the missions of emergency response personnel. On-site biological assessment involves field-based measurements of properties inherent to biological materials for presumptive analysis of suspected biological agents; confirmatory analysis is performed by public health laboratories. Previously published ASTM standards, including Guide E2770 and Practices E2458 as well as the DHS *Framework for a Biothreat Field Response Mission Capability*, articulate the need for routine evaluation of on-site biological assessment technologies to support the use of validated fielded assays. However, there are limited mechanisms to reliably and routinely assess technology performance in the hands of users due to the ever-changing threat of emerging disease and the challenges of working in the field with biological agents that can be used as threat materials. In these instances, surrogate materials, that is, non-threat biological materials, can be utilized to provide a safer alternative to biological agents for evaluating operational performance of a technology. These materials may go through the entire workflow process, thereby allowing for assessment of and providing confidence in routine operation of an on-site biological assessment technology, where the operational performance encompasses the workflow, the technology, operator capabilities, proper controls, and integration of results into a concept of operations such as described in Guide E2770. This guide describes important factors to consider when developing, selecting, and using a surrogate material for a qualitative confidence check or quantitative process assessment to evaluate on-site biological assessment technologies. A process assessment requires additional quantification of the surrogate material as compared to a confidence check. Surrogate materials are not meant to be used for proficiency testing or validation of biological agent assays.

1. Scope

1.1 This guide describes factors to consider when developing, selecting, and using a surrogate material for evaluating the operational performance of nucleic acid-based on-site biological assessment technologies. Operational performance includes the workflow, technology, operator, controls, and result reporting.

1.2 Users of this guide include developers and manufacturers of on-site biological assessment technologies or surrogate materials, as well as the initial responder community and other operators of the technologies.

1.3 This guide recommends the use of surrogate materials to support training; improve the knowledge, skills, and confidence of operators; and enable confidence check and process assessment demonstrations in support of jurisdictional biothreat mission capabilities as recommended in Guide E2770, Section 8.

1.4 This guide recommends the use of surrogate materials in combination with a training program as articulated in Guide E2770 and coordinated among the initial responder organization, hazardous materials response unit, Urban Search and Rescue (US&R) team, National Guard Civil Support Team (CST), Laboratory Response Network (LRN) reference

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laboratory, local law enforcement, the Federal Bureau of Investigation (FBI), and other agencies as defined by jurisdictional protocols.

1.5 This guide recommends the selection of a surrogate material that challenges the workflow in a way similar to the challenge imposed by suspected biological agents encountered in real-world emergency response scenarios while posing minimal health and safety risks.

1.6 This guide describes considerations when using a surrogate material for a confidence check of nucleic acid-based on-site biological assessment technologies.

1.7 This guide describes factors involved in the use of a surrogate material to perform a process assessment when the operator has access to well-characterized nucleic acid-based assays specific to the surrogate material that enable the operator to target the analytical process applied to on-site biological assessment.

1.8 This guide does not replace third-party validation of on-site biological assessment technologies to assess the ability of the technologies to correctly detect and identify a biological agent. This guide recommends that all on-site biological assessment technologies be demonstrated to perform according to internationally recognized consensus standards (for example, AOAC Standard Method Performance Requirements) as consistent with Guide E2770 and Practices E2458.

1.9 For the purposes of this guide, sample collection should be performed according to Practices E2458.

1.10 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.11 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E1301 Guide for Proficiency Testing by Interlaboratory Comparisons (Withdrawn 2012)[3]

E2458 Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biological Agents and Toxins from Nonporous Surfaces

E2770 Guide for Operational Guidelines for Initial Response to Suspected Biological Agents and Toxins

2.2 *International Standards and Guidance:*[4]

ISO/IEC 17043:2010 Conformity Assessment – General Requirements for Proficiency Testing Eurachem Guide: The Fitness of Purpose of Analytical Methods: A Laboratory Guide to Method Validation and Related Topics: Second edition (2014)

Standard Method Performance Requirements (SMPRs) from the Stakeholder Panel for Agent Detection Assays (SPADA), AOAC International[5]

2.3 *Clinical and Laboratory Standards Institute (CLSI) Guidelines:*[6]

EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition (2012)

2.4 *NIST Technical Notes:*[7]

1776 (2012) Best Practices for Sample Collection and Transport During an Initial Response to Potential Biothreat Materials

2.5 *DHS Documents:*[8]

Framework for a Biothreat Field Response Mission Capability (2012)

2.6 *U.S. Government Standards:*[9]

18 USC 178 Definitions

3. Terminology

3.1 *Definitions:*

3.1.1 *accuracy, n*—the closeness of agreement between a test result and the accepted reference value. **E1301**

3.1.2 *assay, n*—collection of one or more reagents and materials that are used in a prescribed fashion to quantitatively or qualitatively characterize a biological material.

3.1.3 *biological agent, n*—any microorganism (including but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: (*1*) death, disease, or other biological malfunction in a human, an animal, a plant, or other living organisms; (*2*) deterioration of food, water, equipment, supplies, or material of any kind; or, (*3*) deleterious alteration of the environment. **(18 USC 178)**

3.1.4 *competency assessment, n*—evaluation of proficiency of emergency response personnel across the range of

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] For referenced International Standards and Guidance standards, visit ISO, Eurachem, and JCGM websites, www.iso.org, www.bipm.org, www.eurachem.org, or contact ISO Customer Service at customerservice@iso.org, Eurachem Customer Service on the website, or JCGM Customer Service at webmaster@bipm.org.

[5] For referenced AOAC International SPADA standards, visit the AOAC website, www.aoac.org, and follow to the SPADA SMPRs link, or contact AOAC Customer Service at AOAC@aoac.org.

[6] For referenced CLSI standards, visit the CLSI website, www.clsi.org, or contact CLSI Customer Service at customerservice@clsi.org.

[7] For referenced NIST Technical Note, visit the NIST Publication portal website, http://www.nist.gov/customcf/get_phd.cfm?pub_id=909556.

[8] For referenced DHS documents, visit the AOAC website, www.aoac.org, and follow to the SPADA resources link, or contact AOAC Customer Service at AOAC@aoac.org.

[9] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

knowledge, skills, and abilities identified in the training program as related to performing duties associated with biothreat response; includes hands on assessment of proficiency panels, field exercises, or drills performed in coordination with the receiving laboratory, and performed annually. **E2770**

3.1.5 *confidence check, n*—the use of a surrogate material for qualitative evaluation of operational performance of on-site biological assessment technologies, ranging in applicability from developing performance characteristics of a technology to checking operator capabilities.

3.1.5.1 *Discussion*—For confidence checks, a surrogate material does not need to be thoroughly characterized for quantity.

3.1.6 *emergency response, n*—the performance of actions to mitigate the consequences of an emergency for human health and safety, quality of life, the environment, and property. It may also provide a basis for the resumption of normal social and economic activity. **E2770**

3.1.7 *limit of detection (LOD), n*—the lowest amount of analyte in a sample that can be detected with (stated) probability. **CLSI EP17-A2**

3.1.8 *on-site biological assessment, n*—measurements of properties inherent to biological materials performed in the field using rapid, field based procedures and assays. **E2770**

3.1.9 *on-site biological assessment technology, n*—a rapid, field based procedure or assay used to make measurements of properties inherent to biological materials.

3.1.10 *operator, n*—a person operating an on-site biological assessment technology.

3.1.11 *process assessment, n*—the use of a surrogate material to quantitatively evaluate performance characteristics of on-site biological assessment using technologies that provide quantitative results.

3.1.11.1 *Discussion*—For process assessments, a surrogate material should be well characterized in terms of quantity.

3.1.12 *provider, n*—a person or manufacturer who produces a surrogate material suitable for use in a confidence check or process assessment.

3.1.13 *specificity/selectivity, n*—the ability of a measurement procedure to determine accurately and specifically the analyte of interest in the presence of other components in the sample matrix under the stated conditions of the test. **Eurachem Guide**

3.1.14 *surrogate material, n*—a non-threat organism, particle, or substance detectable by a biological assessment technology in a laboratory or field environment and capable of challenging the technology performance in place of a biological agent.

3.1.14.1 *Discussion*—In this guide, the focus is on nucleic acid-based assessment technologies and surrogate materials that can be detected using these technologies.

3.1.14.2 *Discussion*—Substances that interfere with assessment of a biological agent are not considered surrogate materials.

3.1.15 *target, n*—a nucleic acid sequence in a material that is used to demonstrate the presence of the material in a nucleic acid-based assay.

3.1.16 *threat, n*—an indication of possible violence, harm, or danger and may include an indication of intent and capability. **E2770**

3.1.17 *workflow, n*—the process of assessing the presence of a given target, including steps such as sample collection, processing, and analysis.

4. Significance and Use

4.1 This guide provides guidance on how a surrogate material can be selected and inserted into a field workflow for confidence checks and process assessments of on-site biological assessment technologies to demonstrate that the technology is working in the field environment in the hands of operators.

4.2 Use of a surrogate material instead of an inactivated or attenuated biological agent (or its components) is beneficial due to (*1*) ease of production and handling, (*2*) ease of acquisition and transportation, (*3*) the ability to use the material with minimal equipment and facility constraints, for example, biosafety containment, and (*4*) minimized risk of contamination of personnel, equipment and the environment with a potential biological agent.

4.3 This guide covers the basic design of confidence checks and process assessments that may be used to target (*1*) the workflow in the field, (*2*) the performance of the on-site biological assessment technology, and (*3*) the operator's ability to process a material in the field workflow, in order to increase confidence in each component. These demonstrations provide emergency responders with insight into routine operation of a nucleic acid-based biological assessment technology and the opportunity to assess and demonstrate their capabilities according to a defined training program in their jurisdiction.

4.4 This guide may be used to aid operators in the routine use of any nucleic acid-based on-site biological assessment technology. Using a surrogate material, operators are able to gain confidence in their ability to perform operations in the workflow and gather routine information (for example, operator performance, assessment results over time) in the field.

4.5 This guide should be used in accordance with Practices E2458 and Guide E2770.

4.6 This guide should be used according to the appropriate risk reduction measures (including personal protective equipment) that are needed for the biosafety level of the surrogate material (preferably Biosafety Level 1; the level should be verified with the provider of the surrogate material).

4.7 This guide is not meant to provide performance characterization of biological agent assays used with on-site biological assessment technologies.

5. Suitable of a Surrogate Material

5.1 A surrogate material should be readily available to the responder community through a provider, such as the technology manufacturer, the assay developer, a reference material provider, or other entity.

5.2 A surrogate material should have minimal health and safety risks and should be appropriate for Biosafety Level 1 facilities, when possible, in order to facilitate procurement and