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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.