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Standard Guide for Operational Guidelines for Initial Response to Suspected Biological Agents and Toxins¹

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INTRODUCTION

A threat with a biological agent or toxin is a serious matter that affects public health, public safety, the economy and the general confidence of the people. The National Strategy for Homeland Security and its National Response Framework focuses homeland security efforts on preventing and disrupting terrorist attacks, protecting the American people, our critical infrastructure and key resources, and responding to and recovering from incidents that do occur while continuing to strengthen the foundation of our nation. As laid out by the National Response Framework, a coordinated and synchronous response to suspected acts of bio-terrorism requires advance planning, including the equipping and training of emergency responders prior to an incident. The goal of this standard guide is to support national standards for responding to and collecting suspected biological agents and toxins with guidance centered on coordination among representatives of emergency response teams, including hazardous materials response teams, law enforcement, public health, including the Centers for Disease Control and Prevention (CDC) national Laboratory Response Network (LRN), and the Federal Bureau of Investigation (FBI). This standard guide provides uniform guidance that covers all of the following components: response planning, responder training, competency evaluation, proficiency testing, concept of operations, hazard assessment, threat evaluation, sample collection, field screening, risk communication and documentation for responding to an incident suspected of a biological agent or toxin, or both.

1. Scope

1.1 This guide provides considerations for decision-makers when responding to incidents that may involve biological agents and toxins. This guide provides information and guidance for inclusion in response planning, on activities to conduct during an initial response to an incident involving suspected biological agents or toxins, or both.

1.2 This guide delineates fundamental requirements for developing a sampling and screening capability for biological agents or toxins, or both, within a jurisdiction, practice, or operational area to assure proper involvement, communication, and coordination of all relevant agencies.

1.3 This guide applies to emergency response agencies that have a role in the initial response to unknown threats that are suspected biological agents and toxins. This guide is designed

for but not limited to emergency response services such as law enforcement, fire departments, hazardous materials, public health, and emergency management.

1.4 This guide assumes implementation begins well before the recognition of an event with a suspected biological agent or toxin, or both, and ends when emergency response actions cease or the response is assumed by federal response teams.

1.5 This guide utilizes risk-based response architecture and the guidance as described in the National Response Framework and is intended to be coupled with the authority having jurisdiction's (AHJs) understanding of local vulnerabilities and capabilities when developing its plans and guidance documents on response to incidents involving a suspected biological agent or toxin, or both.

1.6 This guide is compliant with the National Incident Management System (NIMS) and uses Incident Command System (ICS) common terminology. Full compliance with NIMS is recognized as an essential part of emergency response planning. In developing this standard, every effort was made to ensure that all communications between organizational elements during an incident are presented in plain language

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according to NIMS 2008. In keeping with this NIMS requirement, key definitions and terms, using plain English, are incorporated.

1.7 *This guide 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 and health practices and determine the applicability of regulatory limitations prior to use.*

1.8 *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

E2458 Practices for Bulk Sample Collection and Swab Sample Collection of Visible Powders Suspected of Being Biothreat Agents from Nonporous Surfaces
E2601 Practice for Radiological Emergency Response
F2412 Test Methods for Foot Protection
F2413 Specification for Performance Requirements for Protective (Safety) Toe Cap Footwear

2.2 Federal Government Regulations:³

18 USC 178 Definitions
18 USC 1038 False Information and Hoaxes
DOT - 49 CFR, Parts 171-180 Hazardous Materials Regulations
DOT - 49 CFR 172, Subpart H Transportation Training
DOT - 49 CFR 173 General Requirements for Shipments and Packaging
DOT - 49 CFR 178 Specifications for Packaging
EPA - 40 CFR 300 National Oil and Hazardous Substances Pollution Contingency Plan (NCP)
EPA - 40 CFR 311 Worker Protection
NRC - 10 CFR 20 Standards for Protection against Radiation
NIOSH - 42 CFR 84 Respiratory Protective Devices
OSHA - 29 CFR 1910 Subpart Z and 29 CFR 1926 Subpart Z Toxic and Hazardous Substances
OSHA - 29 CFR 1910.1096 and 29 CFR 1926.53 Ionizing Radiation
OSHA - 29 CFR 1910.120 Hazardous Waste Operations and Emergency Response (HAZWOPER) standard
OSHA - 29 CFR 1910 Subpart I (Sections 132 to 139) Personal Protective Equipment
OSHA - 29 CFR 1910.1200 Hazard Communication

2.3 Federal Guidance:

FBI-DHS-HHS/CDC Coordinated Document, Guidance on Initial Response to a Suspicious Letter/Container with a Potential Biological threat, November 2, 2004.

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 Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.

NIMS 2008 National Incident Management System⁴
Planning Guidance for Recovery Following Biological Incidents, Biological Decontamination Standards Working Group, Subcommittee on Decontamination Standards and Technology Committee on Homeland and National Security, National Science and Technology Council, May 2009⁴

NRF 2008 National Response Framework⁴

OSHA - CPL 02-02-073 Inspection Procedures for 29 CFR 1910.120 and 1926.65, Paragraph (q): Emergency Response to Hazardous Substance Releases

EPA - Safety, Health, and Environmental Management (SHEM) Guide No. 44 Personal Protective Equipment, October 2004

EPA - Safety, Health, and Environmental Management (SHEM) Guideline No. 46 Respiratory Protection, dated October 2004

EPA - Order 1460.1 Occupational Medical Surveillance Program, June 18, 1996

EPA All Hazards Receipt Facility Screening Protocol (EPA/600/R-08/105) September 2008⁵

NIOSH Publication No. 2009-132 Recommendations for the Selection and Use of Respirators and Protective Clothing for Protection Against Biological Agents

FBI Laboratory Publication: Handbook of Forensic Services 2013

DOT, current version, Emergency Response Guidebook (ERG)⁶

CDC/NIOSH Surface Sampling Procedures for *Bacillus anthracis* Spores from Smooth, Non-porous Surfaces, April 26, 2012⁷

DHS - Framework for a Biothreat Field Response Mission Capability, April 2011⁸

2.4 NFPA Standards:⁹

NFPA 472 Standard for Competence of Responders to Hazardous Materials/Weapons of Mass Destruction Incidents, 2008 Edition

NFPA 1994 Standard on Protective Ensembles for Chemical/Biological Terrorism Incidents

NFPA 1600 Standard on Disaster/Emergency Management and Business Continuity/Continuity of Operations Programs, 2016 Edition

2.5 IATA Standards:¹⁰

IATA PI 602 Infectious Diseases (Infectious Substances)

IATA PI 650 Shipping of Diagnostic Samples

IATA DGR 46th Edition 2005

IATA DGR Addendum I January 2005

⁴ Available from Federal Emergency Management Agency (FEMA), 500 C St., SW, Washington, DC 20472, <http://www.fema.gov>.

⁵ Available from Environmental Protection Agency (EPA), 1200 Pennsylvania Ave, NW, Washington, DC 20460, <http://nepis.epa.gov>.

⁶ Available from <http://HAZMAT.dot.gov/pubs/erg/gydebook.htm>.

⁷ Available from <http://www.cdc.gov/niosh/topics/emres/surface-sampling-bacillus-anthraxis.html>.

⁸ Available from <http://www.hsdl.org/?view&did=767721>.

⁹ Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, <http://www.nfpa.org>.

¹⁰ Available from the International Air Transport Association, 800 Place Victoria, PO Box 113, Montreal-H4Z 1M1, Quebec, Canada.

IATA DGR Addendum II March 2005

IATA DGR Addendum III July 2005

2.6 *ANSI Standards:*

ANSI Z87.1-2003 American National Standard for Occupational and Educational Personal Eye and Face Protection Devices

ANSI Z88.2-1992 American National Standard Practices for Respiratory Protection

ANSI Z88.10-2001 American National Standard for Personal Protection - Respirator Fit Testing Methods

ANSI/ISEA Z89.1-2003 American National Standard for Personal Protection - Protective Headwear for Industrial Workers Requirements

ANSI/Compressed Gas Association, CGA G-7.1-1997 Commodity Specification for Air

2.7 *International Standards and Guidance:*

IAFC International Association of Fire Chiefs (IAFC) Guidance, Model Procedures for Responding to a Package with Suspicion of a Biological Threat, October 2008

ISO/IEC Standard 17043 Conformity assessment—General requirements for proficiency testing

3. Terminology

3.1 *Definitions:*

3.1.1 *aseptic technique, n*—operation or performance of a procedure or method under carefully controlled conditions to reduce the risk of exposure and prevent the introduction of unwanted material/matter (contamination) into a sample.

3.1.2 *authority having jurisdiction (AHJ), n*—the organization, office, or individual responsible for enforcing the requirements of a code or standard, or approving equipment, materials, an installation, or a procedure. **NFPA**

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 another living organism; (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 *bulk powder, n*—a visible powder, at least approximately 1 tsp or 5 mL in volume amassed or dispersed over a limited area (optimally, area should be less than 20 by 20 cm (approximately 8 by 8 in.)).

3.1.5 *chain of custody, n*—set of procedures and documents to account for the integrity of a sample by tracking its handling and storage from point of sample collection to final disposition of the sample.

3.1.6 *cold zone, n*—the uncontaminated area where workers are unlikely to be exposed to hazardous substances or dangerous conditions; also known as Clean Zone or Support Zone. **CPL 02-02-071 Directive**

3.1.7 *confirmatory analysis, n*—a test or a series of assays that definitively identifies the presence of a suspected substance or agent.

3.1.7.1 *Discussion*—Confirmatory analysis of a biological

agent for public health action can only be performed by a LRN national or reference laboratory.

3.1.8 *decontamination, n*—the physical or chemical process, or both, of reducing and preventing the spread of contaminants from people, animals, the environment, or equipment involved at hazardous materials/weapons of mass destruction (WMD) incidents. **NFPA**

3.1.9 *emergency operations center (EOC), n*—the physical location at which the coordination of information and resources to support domestic incident management activities normally takes place. An EOC may be a temporary facility or may be located in a more central or permanently established facility, perhaps at a higher level of organization within a jurisdiction. EOCs may be organized by major functional disciplines (for example, fire, law enforcement, and medical services), by jurisdiction (for example, Federal, State, regional, county, city, tribal), or some combination thereof. **NIMS**

3.1.10 *emergency responder, n*—includes state, local, and tribal emergency public safety, law enforcement, emergency response, emergency medical (including hospital emergency facilities), and related personnel, agencies, and authorities. See Section 2 (6), Homeland Security Act of 2002, Pub. L. 107-296, 116 Stat. 2135 (2002). Also known as Emergency Response Provider. **NIMS**

3.1.11 *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.

3.1.12 *evacuation, n*—organized, phased, and supervised withdrawal, dispersal, or removal of civilians from dangerous or potentially dangerous areas, and their reception and care in safe areas. **NIMS**

3.1.13 *field screening, n*—field measurements utilized early in the response to define and characterize the potential hazards present, including corrosive, flammable, volatile, radioactive, or oxidizer hazards, and to support tactical decision making to address operational safety measures.

3.1.13.1 *Discussion*—Field screening does not include measurements of biological properties, which is termed on-site biological assessments (see 3.1.20).

3.1.14 *hazard, n*—something that is potentially dangerous or harmful, often the root cause of an unwanted outcome; a danger or peril. **NIMS**

3.1.15 *HAZMAT responder, n*—a trained and certified individual who is a member of a hazardous material response team or qualified to respond to incidents involving toxic industrial chemicals, chemical warfare agents and other weapons of mass destruction, or both. A HAZMAT response specialist will have additional training that may include response to specific weapons of mass destruction.

3.1.16 *hot zone, n*—the area, located on the site where contamination is either known or expected and where potential for greatest exposure exists; also known as Exclusion Zone or ExZ. **CPL 02-02-071 Directive**

3.1.17 *incident commander (IC)*, *n*—the individual responsible for all incident activities, including the development of strategies and tactics and the ordering and release of resources. The IC has overall authority and responsibility for conducting incident operations and is responsible for the management of all incident operations at the incident site. **NIMS**

3.1.18 *jurisdiction*, *n*—a range or sphere of authority. Public agencies have jurisdiction at an incident within their area of responsibility. Jurisdictional authority at an incident can be political, geographic (for example, city, county, tribal, State, or Federal boundary lines) or functional (for example, law enforcement, public health). **NIMS**

3.1.19 *multiagency coordination system (MACS)*, *n*—a system that provides the architecture to support coordination for incident prioritization, critical resource allocation, communications systems integration, and information coordination. MACS assist agencies and organizations responding to an incident. The elements of a MACS include facilities, equipment, personnel, procedures, and communications. Two of the most commonly used elements are Emergency Operations Centers and MAC Groups. **NIMS**

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

3.1.21 *personal protective equipment (PPE)*, *n*—the equipment provided to shield or isolate a person from the chemical, biological, physical, and thermal hazards that can be encountered at hazardous materials/weapons of mass destruction (WMD) incidents. **NFPA**

3.1.22 *presumptive test*, *n*—non-definitive test used to evaluate a material for the presence of a substance or agent, or the presence of signatures of a substance or agent.

3.1.23 *risk*, *n*—the probability of suffering a loss or harm or injury; peril.

3.1.24 *secondary threats*, *n*—any object designed, or person(s) with an intent, to cause harm to persons responding to an incident (emergency responders) or to increase the number of civilian casualties. Secondary threats are normally devised to cause harm after persons have responded to an incident scene.

3.1.25 *termination*, *n*—termination of the incident in the context of this standard is the end of life safety operations, investigative work, and assurance of protective measure implementation. This will include documentation of hazards present and conditions found.

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

3.1.27 *toxin*, *n*—the toxic material or product of plants, animals, microorganisms (including but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes: (1) any poisonous substance or biological product that may be engineered as a result of biotechnology produced by a living organism; or (2) any poisonous isomer or biological product, homolog, or derivative of such a substance. **18 USC 178**

3.1.28 *warm zone*, *n*—the transition area between the Exclusion Zone (ExZ or hot zone) and the Support Zone (SZ or cold zone) used to reduce and limit the amount of contamination on people and equipment, and in the air, water, and soil that may be transferred into nonhazardous areas; the CRZ contains decontamination facilities, and functions as a buffer zone surrounding the ExZ; also known as the contamination reduction zone or CRZ. **CPL 02-02-071 Directive**

3.1.29 *weapon of mass destruction (WMD)*, *n*—any weapon or device that is intended, or has the capability, to cause death or serious bodily injury to a significant number of people through the release, dissemination, or impact of (1) toxic or poisonous chemicals or their precursors; (2) a disease organism; or (3) radiation or radioactivity. **U.S. Code Title 50, Ch. 40, Sect. 2302 War and National Defense Definitions**

3.2 Acronyms:

- 3.2.1 *AHJ*—Authority Having Jurisdiction
- 3.2.2 *ANSI*—American National Standards Institute
- 3.2.3 *ASTM*—American Society for Testing and Materials
- 3.2.4 *CDC*—Centers for Disease Control and Prevention
- 3.2.5 *CFR*—Code of Federal Regulations
- 3.2.6 *CRZ*—Contamination Reduction Zone
- 3.2.7 *CST*—Civil Support Team
- 3.2.8 *DHS*—Department of Homeland Security
- 3.2.9 *DOT*—Department of Transportation
- 3.2.10 *EOC*—Emergency Operations Center
- 3.2.11 *EPA*—Environmental Protection Agency
- 3.2.12 *ExZ*—Exclusion Zone
- 3.2.13 *FBI*—Federal Bureau of Investigation
- 3.2.14 *FEMA*—Federal Emergency Management Agency
- 3.2.15 *HAZMAT*—Hazardous Materials
- 3.2.16 *HHS*—Health and Human Services
- 3.2.17 *HSEEP*—Homeland Security Exercise and Evaluation Program
- 3.2.18 *IAFC*—International Association of Fire Chiefs
- 3.2.19 *IATA*—International Air Transport Association
- 3.2.20 *IC*—Incident Commander
- 3.2.21 *ICS*—Incident Command System
- 3.2.22 *IEC*—International Electrotechnical Commission
- 3.2.23 *ISEA*—International Safety Equipment Association
- 3.2.24 *ISO*—International Organization for Standardization
- 3.2.25 *LRN*—Laboratory Response Network
- 3.2.26 *MACS*—Multiagency Coordination System
- 3.2.27 *NFPA*—National Fire Protection Association
- 3.2.28 *NIMS*—National Incident Management System
- 3.2.29 *NIOSH*—National Institute for Occupational Safety and Health
- 3.2.30 *NRC*—Nuclear Regulatory Commission
- 3.2.31 *OSHA*—Occupational Safety and Health Administration

- 3.2.32 *PPE*—Personal Protective Equipment
- 3.2.33 *SZ*—Support Zone
- 3.2.34 *UC*—Unified Command
- 3.2.35 *US&R*—Urban Search and Rescue Teams
- 3.2.36 *WMD*—Weapons of Mass Destruction

4. Summary of Guide

4.1 This guide provides the critical elements essential for emergency response agency personnel to plan, develop, coordinate, implement and train on standardized guidelines that encompass policy, strategy, operations, and tactical decisions prior to responding to a threat event with a biological agent or toxin, or both.

4.2 This document provides guidance for the responders to an incident involving a potential biological threat. Emergency responders (for example, HAZMAT response teams) work with local and federal law enforcement and public health officials to determine if there exists a credible threat incident involving a biological agent or toxin, or both. The determination of a credible biological threat is made through consultation with the FBI. Responders should involve, inform, consult, and defer to the FBI in all cases where a credible biological threat is encountered.

4.3 This guide provides recommendations for effective response planning and program development.

4.4 This guide addresses collecting samples for public safety purposes.

4.5 This guide addresses the fundamentals needed to support sampling and screening capability development by emergency responders within a jurisdiction or practice area to assure proper involvement and communication among responding organizations.

4.6 This guidance includes minimum training requirements, including requirements for individuals trained to work with hazardous materials in the hot zone (Ref: NFPA 472 or OSHA - 29 CFR 1910.120), requirements for training to perform initial explosive substance, chemical and radiological screening and for persons conducting the field screening and sample collection in response to potential threats with biological agents or toxins, or both.

4.7 This guide provides references for determining the appropriate level of personal protective equipment (PPE) to mitigate hazards during sample collection and screening in an incident with a potential biological agent or toxin, or both.

5. Significance and Use

5.1 Community knowledge and experience related to emergency response to threats with a biological agent or toxin at the Federal, State, tribal, and local levels has been translated into a standard guide to assist responder agencies' progress toward the goal of building operational guidelines for the sample collection and response to a potential biological agent or toxin. The guide is intended to enhance the ability, knowledge, and communication between emergency response team representatives, including fire department, HAZMAT, local law

enforcement, Federal Bureau of Investigation, and public health personnel as well as other responders that are responsible for responding to a threat incident involving a biological agent or toxin, or both.

5.2 This guide supports, and should be utilized as an accompaniment to standard sample collection methods (for example, Practices E2458). Standard guidance insures reduced exposure risk, minimizes on-site sample consumption for preservation of public health samples and forensic samples, reduces variability associated with sample handling, and analysis, and increases the reliability of the sampling procedure when collecting a sample of suspect biological agents and toxins.

5.3 Development of this standard was at the request and with considerable contributions from the public health and first responder communities in the United States to facilitate collection and evaluation of potential biological agents and toxins in the field.

5.4 This guide should be incorporated as a reference in Emergency Operation Centers (EOCs), emergency operations plans (EOPs) and Multiagency Coordination Systems (MACS) to assist in policy formation and development of strategic objectives consistent with the needs of the Incident Commander (IC).

5.5 Documents developed from this standard guide should be referenced and revised as necessary and reviewed on a two-year cycle (at a minimum). The review shall consider new and updated requirements and guidance, technologies, and other information or equipment that might have a significant impact on the management and outcome of biological incidents.

6. Planning for Response to Incidents Involving Biological Agents and Toxins

6.1 Participants in the planning process should include, for each jurisdiction assuming responsibility:

6.1.1 Reference laboratory(s) within the LRN.

6.1.2 Public health, including:

6.1.2.1 Public health officers and their designated Bioterrorism Coordinators, if applicable.

6.1.2.2 Environmental health.

6.1.2.3 Occupational safety and health.

6.1.2.4 Epidemiology.

6.1.2.5 Communicable disease.

6.1.2.6 Applicable members of the National Association of County and City Health Officials (NACCHO).

6.1.3 Executive policy makers for the jurisdiction.

6.1.4 Law enforcement.

6.1.4.1 Local.

6.1.4.2 County.

6.1.4.3 State.

6.1.4.4 Tribal.

6.1.4.5 Federal.

(1) Federal Bureau of Investigation.

(2) U.S. Postal Inspection Services.

6.1.5 Fire departments.

6.1.6 Special resources, including:

6.1.6.1 Hazardous materials (HAZMAT) response teams.

6.1.6.2 Bomb squads.

6.1.6.3 National Guard Weapons of Mass Destruction (WMD) Civil Support Teams (CSTs).

6.1.6.4 Urban Search and Rescue Teams (US&R).

6.1.7 Special target/high risk facilities or institutions.

6.1.8 Federal Emergency Management Agency (FEMA).

6.1.9 State, County, and Local Emergency Agencies.

6.2 Planning participants should meet to develop agreements consistent with jurisdictional policies pertaining to all aspects of the response; specifically for this guide, planning shall focus on coordination for initial response including but not limited to:

6.2.1 Roles and responsibilities.

6.2.2 PPE and appropriate protective measures.

6.2.3 Notification and communications including risk communication.

6.2.4 Decision making process for sample collection, submission to and acceptance by the receiving LRN reference laboratory.

6.2.4.1 For resource management purposes and to avoid the unnecessary testing of samples that potentially pose no public health threat, the LRN reference laboratory, in coordination with the jurisdiction and the FBI, should develop a list of acceptance criteria for sample submission which can be modified as needed.

6.2.4.2 The jurisdiction may choose to prioritize (for example, FBI-led threat credibility evaluation is required) or classify an incident to determine if a sample is collected. A jurisdiction or the receiving LRN reference laboratory may require a sample to be prioritized to accept the sample. The receiving LRN reference laboratory may also choose to prioritize samples in order to effectively execute sample analysis for specific samples in the case that several samples are submitted at the same time.

6.2.4.3 The jurisdiction may develop guidance including a flow chart that specifies procedures for both threat and hazard assessment of an event and help to define when to collect and send a sample to a LRN reference laboratory based on level of risk determined during field assessment.

6.2.5 Training.

6.2.6 Sample collection methods and materials including sampling kits.

6.2.7 Screening/detection technologies and analysis.

NOTE 1—Field screening methods may have limits of detection inadequate for material identification.

6.2.8 Packaging.

6.2.9 Decontamination procedure.

6.2.10 Transportation.

6.2.11 Documentation, including:

6.2.11.1 Standardized or uniform sample submission and chain-of-custody forms.

6.2.11.2 Contact information for responder, public health and law enforcement on-scene and on-call coordination representatives.

7. Training Program Development

7.1 Responders tasked with the initial response to an incident involving a suspect biological agent or toxin, including sample collection and field screening must be trained according to recognized training standards.

7.2 A training program shall be developed through coordination between the initial responder organization, which may be the hazardous materials response unit, LRN reference laboratory, local law enforcement, the FBI, and other agencies as defined by planning participants.

7.3 A training program shall include a curriculum similar to the training required to receive certification as a Hazardous Materials Technician, meeting the standards of the National Fire Protection Association standard, NFPA 472, on responder competencies.

7.4 An alternative training level may be necessary for certain jurisdictions that may include training personnel at the level of Operations Level Responder under NFPA 472 with additional mission specific competencies. Hazardous Materials Technician Training meeting the NFPA 472 standard is highly preferred; less training should only be employed for jurisdictions and agencies where the responder does not have other HAZMAT responsibilities that require technician level training. Where lesser trained responders are utilized, operations should provide for consultation with a Hazardous Materials Technician. Responders should possess the knowledge, skills, and abilities as described in NFPA 472:

7.4.1 Chapter 5: Core Competencies for Operational Level Responders.

7.4.2 Chapter 6: Competencies for Operations Level Responders Assigned Mission-Specific Responsibilities.

7.4.2.1 Section 6.1: General.

7.4.2.2 Section 6.2: Mission Specific Competencies: Personal Protective Equipment.

7.4.2.3 Section 6.4: Mission Specific Competencies: Technical Decontamination.

7.4.2.4 Section 6.7: Mission Specific Competencies: Air Monitoring and Sampling.

7.4.2.5 Annex B: Competencies for Operations Level Responders Assigned Biological Agent-Specific Tasks.

7.5 Additional training courses, professional conferences, and standards may include:

7.5.1 DHS Office of Domestic Preparedness Course – “Public Safety Response – Sampling Techniques and Guidelines” (PER – 222).

7.5.2 DHS Office of Domestic Preparedness Course - “Advanced Chemical and Biological Integrated Response – Technician Level” (PER – 226).

7.5.3 Implementation of Practices **E2458**.

7.5.4 National conferences on environmental sampling and detection for biological agents and toxins.

7.5.5 Biosafety in Microbiology and Biomedical Laboratories (BMBL).

7.6 Training program components shall include but may not be limited to:

7.6.1 Understanding biological agents.

7.6.2 Defining the emergency response teams for threats with biological agents and toxins.

7.6.3 Proper coordination with emergency response team members for threats with biological agents and toxins.

7.6.4 Purpose, operation, and limitations of screening technologies

7.6.5 Threat evaluation procedures.

7.6.6 Screening technology purpose and operation.

7.6.7 Risk communication.

7.6.8 Methods for isolation and containment.

7.6.9 Personal protection equipment.

7.6.10 Aseptic technique.

7.6.11 Proper sample collection methods.

7.6.12 Sample packaging, decontamination, and transportation procedures.

7.6.13 Documentation.

7.6.14 Incident termination procedures.

8. Responder Competency Assessment

8.1 A competency assessment is recommended to assess proficiency of emergency response personnel across the range of knowledge, skills, and abilities identified in the training program as related to performing duties associated with response to suspected biological agents and toxins.

8.2 Successful completion of a training program demonstrates responders' role to protect the LRN reference laboratory from unknowingly receiving hazardous samples, which could injure laboratory personnel or cause damage to this critical facility.

8.3 Competencies evaluated include:

8.3.1 Risk assessment coordination/performance.

8.3.2 Photography (if applicable) of on-scene observations.

8.3.3 Proper sample collection including proper use of standard methods and selection of collection tools.

8.3.4 Proper field screening based on threat evaluation/sample quantity.

8.3.5 Field screening capabilities:

8.3.5.1 Explosives screening for elimination.

8.3.5.2 Flammability screening.

8.3.5.3 Radiological screening.

8.3.5.4 Corrosive screening.

8.3.5.5 Additional chemical screening may be utilized.

8.3.6 Completion of sample submission documentation, including:

8.3.6.1 Field screening report.

8.3.6.2 Sample submission form.

8.3.6.3 Chain of custody form.

8.4 A competency assessment program should include:

8.4.1 Hands on competency assessment (proficiency panels) performed annually. Proficiency panels should be designed in coordination with the receiving LRN reference laboratory. ISO/IEC Guide 43 on proficiency testing program development can serve as a guide for developing proficiency testing programs for field response programs.

8.4.2 Field exercises or drills; conform to HSEEP program where appropriate.

8.4.3 Competency evaluation shall be performed in coordination with the receiving LRN reference laboratory and the FBI.

8.4.4 Competency evaluated on an annual basis.

9. Initial Response Best Practices

9.1 An initial response to a suspected biological hazard involves local hazardous materials response teams, fire departments, law enforcement, the FBI Field Office Weapons of Mass Destruction Coordinator and other federal agencies, and notification of the receiving LRN reference laboratory. The vast majority of calls for responses are received in public safety dispatch centers on the 911 lines. When an incident occurs, local fire or police officers, or both, are sent to the scene of the reported hazard. As stated in the coordinated FBI-DHS-HHS/CDC guidelines for responders to suspicious letters and packages, the role of Incident Commander (IC) will be assumed by the appropriate authority, as designated by state or local responders. In many cases, the incident will be managed by a Unified Command. Unified Command is an Incident Command System application used when more than one agency has incident jurisdiction or when incidents cross political jurisdictions. Agencies work together through the designated members of the UC, often the senior persons from agencies or disciplines participating in the UC, or both, to establish a common set of objectives and strategies and a single Incident Action Plan.

9.2 The purpose of this section is to provide guidance on establishing a standardized protocol for hazardous materials response teams, and other properly trained emergency responders, for conducting initial scene assessments and responses to incidents of suspected biological agents and toxins.

9.3 In situations where biological agents and toxins are suspected, a secondary objective is to provide the information gained during the initial response, sample collection and field screening to local authorities to assist them in making short-term tactical decisions pending the confirmatory analysis at the LRN reference laboratory.

9.4 Response document development should specify a limited mission for the emergency responders. It is intended to guide the development of a response protocol for:

9.4.1 Actions to mitigate the consequences of an emergency for human health and safety, quality of life, the environment and property.

9.4.2 Initial response where there is no intelligence available at the time of dispatch to suggest that the incident will require more than a limited response of specialized resources.

9.4.3 Emergency response teams with the purpose of examining specific items or visible substances that caused the public to call a public safety access/dispatch center.

9.5 It is beyond the scope of the guidance provided here to address development of a protocol where evidence collection or large area sampling missions are required.

9.6 Additional upgraded response protocols should be designed to address situations where there are credibility factors present such as:

9.6.1 Reports of victims.

9.6.2 Dissemination devices.

9.6.3 Confirmed presence of biological agents and toxins (for example, public health reports).

9.7 An initial response protocol should include guidance for the emergency response team to properly conduct:

9.7.1 A risk assessment, including but not necessarily performed in this order:

9.7.1.1 Hazard assessment.

9.7.1.2 Threat evaluation.

9.7.2 Field screening operations.

9.7.3 Sample collection and packaging.

9.7.4 Tactical actions and decision making aids.

10. Risk Assessment

10.1 Once on-scene, emergency responders should begin a risk assessment, which includes both a hazard and threat assessment. If the assessment indicates the potential for a biological threat exists, responders should immediately notify local law enforcement, the FBI and the receiving LRN reference laboratory.

10.2 A risk assessment provides an indication of the probability of suffering harm or loss. Risks cannot be eliminated but can be managed. Factors that influence the level of risk include the nature of the hazardous material, level of the threat, quantity of the material, if the material is enclosed in a container, the containment system and type of stress applied to that system, proximity of exposures, and level of available resources.

10.3 Risk assessment is an ongoing activity. Risk assessment activities should include initiating coordination with law enforcement so that law enforcement can begin conducting a threat credibility evaluation to evaluate if a credible threat exists. Changes in the environment and intelligence information may result in a reevaluation of priorities; the risk assessment should be reevaluated appropriately.

10.4 In the event of multiple hazards, the results of a risk assessment can be used to establish priorities so that the most dangerous situations are addressed first and those less likely to cause major problems can be considered later. The outcome of a risk assessment can be used to request and assign resources.

NOTE 2—Within states or local jurisdictions, or both, there may be additional resources available that are designed to provide guidance and equipment in support of the mission.

10.5 NFPA 1600 provides guidance on performing a risk assessment; Annex A.5.3 of NFPA 1600 provides steps for a comprehensive risk assessment. Additional guidance documents developed by state, county, and local public health should be referenced as available.

10.6 Steps in a risk assessment include:

10.6.1 Identify potential hazards, threats or perils to the responding organization, the infrastructure and the surrounding area.

10.6.1.1 Field screening can assist in determining the nature of the hazard and aid in the threat credibility evaluation and hazard categorization.

10.6.2 Determine the potential impact of each hazard, threat or peril.

10.6.2.1 Determine whether the probability is high, low, or no apparent risk that the source will actually cause damage.

10.6.2.2 Estimate the severity, relative frequency and vulnerability to the hazard, threat, or peril.

10.6.2.3 Determine whether the seriousness of a risk to life, property, and the environment of such a hazard would be high, low, or no apparent risk.

10.6.3 A risk assessment may also include both a “what-if” analysis to identify specific hazards and hazardous situations and a checklist of known hazards. “What-if” questions should include an evaluation of what could go wrong if hazardous consequences are identified.

11. Hazard Assessment

11.1 The physical and chemical properties of a material can provide insight into the nature of the hazard. Some of these properties can be determined through field measurements known as field screening.

11.2 All field screening and on-site biological assessment capabilities chosen to support the response, as well as the associated performance criteria, should be communicated well before an event with the receiving LRN reference laboratory and local and federal law enforcement, including the FBI Field Office Weapons of Mass Destruction Coordinator or other representative agencies that contribute to response planning activities.

11.3 If there is indication a low or high risk exists, personnel (for example, HAZMAT response teams, law enforcement, FBI) conducting the risk assessment may determine field screening is warranted. Field screening consists of examining a material or object for the presence of explosives, radiological, corrosive and volatile organic hazards by the HAZMAT response team as is defined in the coordinated FBI-DHS-HHS/CDC guidelines for responders to suspicious letters and packages.

11.4 Methods of analysis that minimize sample consumption should be used when performing field screening on suspicious substances, conserving as much of the sample as possible for laboratory confirmation and law enforcement evidence collection. Field screening is different from the initial visual and physical assessment of a package for indications of explosive materials and acute chemical hazards.

11.5 In the case of response to a possible biological agent or toxin, or both, field measurements of the physical and chemical properties of the material aid in the risk assessment and help to protect the responders, the public, and the receiving LRN reference laboratory.

11.6 Currently, the only definitive tests for identifying biological agents and toxins are those performed by the LRN reference laboratory; confirmatory testing by the LRN reference laboratory is necessary to make public health decisions.

11.7 Jurisdictions choosing to integrate on-site biological assessment into response procedures should do so in accordance with Practices E2458, method A or methods A & B,

which provides a method for use of the residual powder when the primary source and bulk powder sample have been collected and packaged for transport to the LRN reference laboratory.

11.8 Jurisdictions choosing to integrate on-site biological assessment into response procedures should ensure that personnel and test methods are supported by training and proficiency testing programs defined in sections 7 and 8 of this document. It is recommended that assessment methods have been validated by nationally recognized consensus standards (for example, AOAC International, Stakeholders' Panel on Agent Detecting Assays (SPADA) performance specifications¹¹) and supported as defined in this document.

11.9 All field measurements results, including on-site biological assessments, should be documented and made available to the receiving LRN reference laboratory and to responding local and federal law enforcement. Documentation should be included in the sample package or sent directly to the receiving LRN reference laboratory by fax transmission. Alternatively, field screening and on-site biological assessment results can be communicated by telephone to the LRN reference laboratory staff and appropriate written documentation submitted later.

11.10 Field screening and on-site biological assessment should be conducted downrange with basic detection and monitoring equipment, thereby reducing the risk of spreading contamination outside of the hot zone.

11.11 Samples collected for purposes of field screening and on-site biological assessment should not be opened beyond the decontamination line.

11.12 Responders should consider the potential for resuspension or cross contamination of material.

11.13 Additional provisions recommended for a field screening location are:

11.13.1 Protected from wind and weather.

11.13.2 Adequate lighting.

11.13.3 Adequate bench space for equipment.

11.13.4 Containment from sample release.

11.13.5 Negative pressure with HEPA and activated charcoal (or appropriate NIOSH-certified CBRN) filtration.

11.13.6 Decontamination and temporary storage of hazardous waste.

11.14 An alternative would be utilization of a deployable shelter or purpose built vehicle or trailer with negative pressure HEPA and activated charcoal filtered glove box. All Hazards Receipt Facility Screening Protocol¹² provides requirements for a field screening facility capability.

12. Threat Evaluation

12.1 A critical aspect of assessing the risk of a given situation includes an evaluation of the threat. A threat credibility evaluation assesses indicators of possible violence, harm, or

danger and may include an indication of intent and capability. A threat evaluation may be initially performed by state or local authorities.

12.2 If the result of the threat evaluation concludes that there may be reasonable belief that a bio-terrorism crime has occurred, an FBI-led threat credibility evaluation must be conducted on-scene.

12.3 Whether a credible threat exists is determined by evaluating all available information on scene including law enforcement interviews, intelligence information, hazard results, and communication with public health and the receiving LRN reference laboratory.

12.4 An FBI threat credibility evaluation is coordinated by the local FBI Field Office Weapons of Mass Destruction Coordinator via a conference call with FBI Headquarter elements (Weapons of Mass Destruction Directorate and the Laboratory Division) and on-scene personnel.

12.5 Once it is determined that a credible threat exists, a course of action should be initiated to collect any evidence and bring it safely to the nearest LRN reference laboratory and, in certain circumstances, partner laboratories as specified by the FBI. All credible samples are immediately sent to the LRN reference laboratory for confirmatory testing.

12.6 A threat evaluation performed on-scene may be used to support an FBI-led threat credibility evaluation. To assist in performing a threat evaluation, the following guidance is provided:

12.6.1 Reference the National Terrorism Advisory System, which is in use at the federal, region, tribe, territory, and state levels. The Homeland Security threat advisories combine threat information with vulnerability assessments and provide communications to public safety officers.

12.6.2 Develop a list of credible threat factors agreed upon by the responders, LRN reference laboratory, state and local law enforcement agencies, and the FBI Field Office Weapons of Mass Destruction Coordinator.

12.6.3 The following are suggested indicators that increase suspicion and add to the credibility of the threat:

12.6.3.1 An articulated threat, written or verbal.

12.6.3.2 Dissemination device or mechanism of dispersal.

12.6.3.3 Profile of the recipient or target, or both.

12.6.3.4 Political affiliations.

12.6.3.5 Social indicators that may include schools, churches, health care providers.

12.6.3.6 Public media.

12.6.3.7 Known item or watch list.

12.6.3.8 Event indicated by public safety/health channels.

(1) Confirmation of a biological agent or toxin, or both

(2) Reports of human illness

12.6.4 Responders may take into consideration guidance from the FBI, CDC, and US Postal Service in the FBI-DHS-HHS/CDC Coordinated Document as well as the guidance from IAFC to identify indicators of a threat incident involving a biological agent or toxin, or both. This guidance describes the characteristics of a "suspicious" package as follows (note that these are not recommendations that apply specifically to the assessment of potential biological threats):

¹¹ SPADA specifications are available at www.aoac.org.

¹² Available from nepis.epa.gov and www.epa.gov/emergency-response/erln-activities-details.

- 12.6.4.1 Excessive postage.
- 12.6.4.2 Handwritten or poorly typed address.
- 12.6.4.3 Incorrect titles.
- 12.6.4.4 Title, but no name.
- 12.6.4.5 Misspelling of common words.
- 12.6.4.6 Oily stains, discoloration, or odor.
- 12.6.4.7 No return address.
- 12.6.4.8 Excessive weight.
- 12.6.4.9 Lopsided or uneven.
- 12.6.4.10 Protruding wires or aluminum foil.
- 12.6.4.11 Excessive security material such as masking tape, string, etc.
- 12.6.4.12 Visual distractions.
- 12.6.4.13 Unusual sounds.
- 12.6.4.14 Sealing of seams with tape.
- 12.6.4.15 Physical touch of the package suggests that a powder might be present.
- 12.6.4.16 Powder spilling from package.

12.6.5 Along with these factors, it is recognized that emergency response personnel have a great deal of response experience and should use their judgment and experience to determine if there are additional factors at the scene that would cause them to upgrade the threat.

12.6.6 It should be noted that hoaxes (for example, letters that contain a threat about a dangerous substance with or without visible substance present) will be considered credible threats because these cases may be prosecuted under the false information and hoaxes statutes (18 USC 1038), even if later the substance is determined to have posed no hazard.

13. Tactical Actions and Decision Making Aids

13.1 Recommendations should be developed during the planning efforts to address incidents involving biological agents and toxins that will assist emergency responders in determining an appropriate level of action based on the risk assessment and the threat credibility evaluation. These recommendations should be developed with the LRN reference laboratory and the FBI Field Office Weapons of Mass Destruction Coordinator and other representative agencies that contribute to response planning activities.

13.2 An example to accommodate such recommendations may include three categories: No Apparent Risk, Low Risk, and High Risk. Indicators and actions for each risk category are described below.

13.2.1 *No Apparent Risk Indicators:*

13.2.1.1 The presence of powder, particulate matter, or liquid material not associated with a threat and an obvious explanation for the item at the given location is determined.

13.2.2 *No Apparent Risk Actions:*

13.2.2.1 Responders (for example, HAZMAT) should communicate with the LRN reference laboratory and local and federal law enforcement including the FBI Field Office Weapons of Mass Destruction Coordinator or other representative agencies upon arrival at the scene as to that there is no apparent risk.

13.2.2.2 The decision is made to clear the scene.

13.2.3 *Low Risk Indicators:*

13.2.3.1 The presence of powder, particulate matter, or liquid material not associated with a threat but no obvious explanation for the item at the given location.

13.2.3.2 Example: An envelope that contains an unexplained substance, but not accompanied by a threat.

13.2.4 *Low Risk Actions:*

13.2.4.1 Responders (for example, HAZMAT) should communicate with the LRN reference laboratory and local and federal law enforcement including the FBI Field Office Weapons of Mass Destruction Coordinator or other representative agencies upon arrival at the scene.

13.2.4.2 Through coordination with the FBI, law enforcement will initiate a threat credibility evaluation for all threats potentially involving biological agents (low or high risk designation) and toxins.

13.2.4.3 The LRN reference laboratory is provided with the contact information for the on-scene responders (for example, HAZMAT) and the submitting party.

13.2.4.4 The decision to collect and submit a sample to the LRN reference laboratory for testing is made at the local level through communication among on-scene responders, including the FBI and the receiving LRN reference laboratory.

13.2.5 *High Risk Indicators (Including Credible Threats):*

13.2.5.1 A sample associated with a verbal or written threat.

13.2.5.2 A sample associated with specific intelligence.

13.2.5.3 Public official, government building.

13.2.5.4 Casualties.

13.2.5.5 Any unusual event that is determined by public safety or public health officials, or both, to be of high risk.

13.2.5.6 Human illness associated with the situation.

13.2.6 *High Risk Actions:*

13.2.6.1 Responders (for example, HAZMAT) immediately contact the FBI to initiate a threat credibility evaluation.

13.2.6.2 Responders (for example, HAZMAT) immediately call the LRN reference laboratory, which will coordinate testing with the responding unit and the submitting party.

13.2.6.3 LRN reference laboratory is provided with contact information for on-scene personnel including the following:

(1) Emergency Responders.

(2) Submitting party.

(3) Site operator or property/facility owner.

13.2.6.4 Emergency response team conducts a risk assessment and determines if the threat should be treated as a potential credible threat.

13.2.6.5 Emergency responders perform field screening for radiation, explosives, and corrosives for all samples according to federal recommendations in the joint FBI-DHS-HHS/CDC Coordinated Document guidelines for responders to suspicious letters and packages.

13.2.6.6 Emergency responders collect and package the samples for transport to the LRN reference laboratory as described in Method A of Practices [E2458](#).

13.3 As a result of the initial risk assessment, it may be determined that there is sufficient indication of a credible threat to take immediate tactical actions to contain the threat and mitigate the potential effects until the LRN reference laboratory receives the sample and can perform rapid presumptive and then confirmatory analysis. Such tactical actions include: