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Standard Guide for Operational Guidelines for Initial Response to Suspected Biological Agents and Toxins[1]

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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 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.

NIMS 2008 National Incident Management System[4]

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 2009[4]

NRF 2008 National Response Framework[4]

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 2008[5]

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, 2012[7]

DHS – Framework for a Biothreat Field Response Mission Capability, April 2011[8]

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

[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.

[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-anthracis.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**