System Assessment and Validation for Emergency Responders

Summary

May 2005

Guide for the Selection of Biological Agent Detection Equipment for Emergency First Responders, Guide 101–04, Volume I and II

The Office of Law Enforcement Standards (OLES) at the National Institute of Standards and Technology (NIST), supported by the Department of Homeland Security (DHS), the Technical Support Working Group (TSWG), the U.S. Army Edgewood Chemical and Biological Center (ECBC), and the Interagency Board for Equipment Standardization and Interoperability (IAB), has developed chemical and biological defense equipment guides. The guides focuse on chemical and biological equipment in areas of detection, personal protection, decontamination, and communication. This document focuses specifically on biological agent (BA) detection equipment and was developed to assist the emergency responder community in the evaluation and purchase of BA detection equipment. The information contained in the guide was obtained through literature searches and market surveys. Vendors were contacted multiple times during the preparation of the guide to ensure data accuracy, and information is supplemented with test data from other sources (e.g., Department of Defense) if available. The guide is a follow-up document to An Introduction to Biological Agent Detection Equipment for Emergency First Responders, NIJ Guide 101-00, published in December 2001.

The guide is intended to be more practical than technical and provides information on a variety of factors to be considered when purchasing detection equipment, including, but not limited to, sensitivity, specificity, startup and response times, power requirements, cost, durability, and portability. Volume I represents the actual guide and Volume II serves as a supplement to Volume I since it contains the detection equipment data sheets only.

Introduction to Biological Agents

The September 11, 2001, terrorist attacks against the United States, coupled with the havoc caused by the intentional dispersal of anthrax spores directed at highly visible targets, has attracted renewed attention to the potential for BAs to be used as weapons of terror. The use of BAs as weapons is a serious threat for several reasons. In contrast to their chemical counterparts, they have the ability to multiply in the human body and significantly increase their effect. Many BAs are highly virulent and toxic; they have an incubation period (their effects are not seen for hours to days after dissemination), which gives the perpetrators a chance to escape, and some can be transmitted from person to person. Significant advances in the areas of molecular biology and biotechnology over the past quarter century have made the tasks of detection and treatment of BAs all the more difficult.

Several other characteristics make BAs uniquely appealing to terrorist states, groups, or individuals. Biological agents can be grown in facilities that are inexpensive to construct or facilities that resemble pharmaceutical, food, or medical production sites that provide no detectable sign that such agents are being produced.

The Centers for Disease Control and Prevention (CDC) has classified potential agents of bioterrorism into three, high-priority categories.

- Category A includes BAs that could easily be disseminated or transmitted from person to person, and may result in high mortality rates. They have a potential for a major public health impact, causing panic and social disruption that requires special action for the public health system.

- Category B includes BAs that are moderately easy to disseminate, result in moderate morbidity and low mortality rates, and require specific

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For more information on Biological Agent Detection Equipment please see the SAVER website or contact the SAVER Program Support Office.

enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

- Category C includes emerging pathogens that could be engineered for mass dissemination in the future because of availability, ease of production and dissemination, potential for high morbidity and mortality rates, and major public health problems.

Possible methods of dissemination, incubation period, symptoms, and treatment for the common bacterial agents, rickettsiae, viral agents, and biological toxins are listed in the guide: A more in depth discussion is provided for the agents of highest concern.

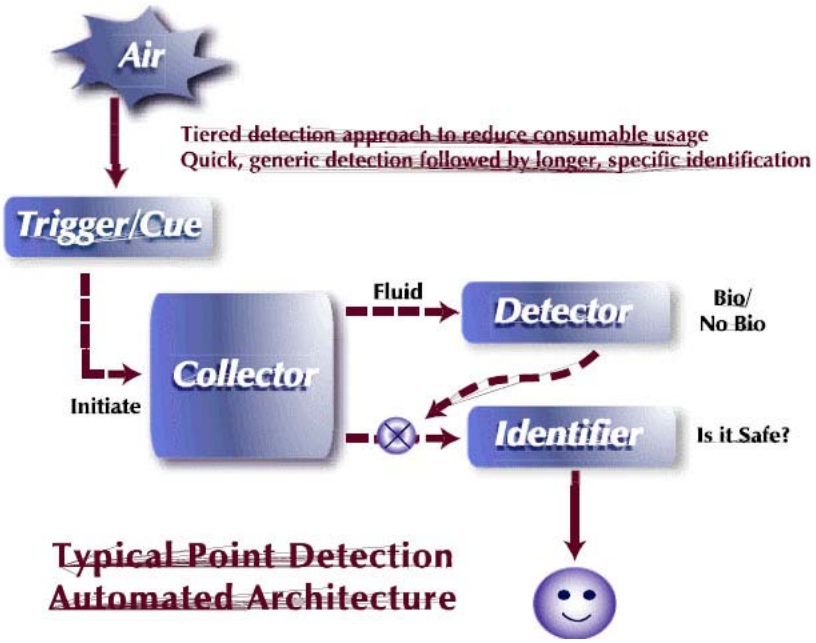

Figure 1. Typical point detection automated architecture (with a combined trigger/cue).

Challenges of Biological Agent Detection

Biological agents are infectious in very low doses. Therefore, BA detection systems need to exhibit high sensitivity (i.e., be able to detect very small amounts of BAs). The complex and rapidly changing environmental background also requires these detection systems to exhibit a high degree of specificity (i.e., be able to discriminate BAs from other harmless biological and nonbiological material present in the environment). A third challenge that needs to be addressed is speed or response time. Ease of use of a biological detection system (i.e., sample preparation requirements) is a fourth challenge needing attention. These combined requirements provide a significant technical challenge.

The guide identifies some of the major challenges associated with BA detection, specifically challenges associated with the ambient environment, specificity, sensitivity, and sampling.

Biological Detection System Components

Because of the need for high-efficiency collection and concentration of the sample, and high specificity and sensitivity during detection and identification, biological detection systems are necessarily complex devices consisting of various subunits. Each subunit performs a specific collection, detection, and signal transduction task. As a result, in its truest form, a biological detection system consists of a sampler, a probe (detection), and a signal transducer.

The effective detection of BAs in the environment requires a multi-component analysis system because of the complexity of the environment. Other variables contributing to the effectiveness of detection of BAs include the detection process itself and the efficient use of consumables in the field. Biological agent detection systems generally consist of four components: the trigger/cue, the collector, the detector, and the identifier. Figure 1 shows a flow diagram for a typical point detection automated architecture system.

Sampling Equipment

Environmental sampling is the first critical step in determining the nature and scope of the threat from a BA. The decision to sample should be based on the extent and location of any suspected contamination, the potential for the contaminant to migrate, the matrix to be sampled (air, water, or soil), the direction and speed of prevailing winds, and other factors. For example, in a point collection/detection scenario, sampling for BA particulates in the air is especially difficult due to the low effective doses of these agents. To sample BAs effectively, samplers are used that pass large volumes of air through the sampler, dispersing the small amount of agent contained in the large volume of air into a small volume of water or other liquid reagent, thereby forming a concentrated mixture of particulates. By concentrating the biological particulates, current detection systems that are not able to detect BAs at very low levels can detect these agents in the concentrated mixture.

The guide covers sampling procedures, sampling equipment for five sampling techniques—air sampling, liquid sampling, solid sampling, surface sampling, and bulk material sampling—and microbiological considerations and

Location	Perpetrator(s)	Disease(s)	Number of cases/deaths	Dissemination	Year
Eastern USA	Unknown	Anthrax	22/5	Mailed envelopes	2001
Texas	Individual	Dysentery	12/0	Foodborne	1996
Oregon	Rajneeshee cult	Salmonellosis	751/0	Foodborne	1984
South Africa	Apartheid regime	Several	Unknown	Various	1980s
Sverdlovsk, USSR	Escaped from a lab	Anthrax	96/64	Air	1979
London	Bulgarian authorities	Ricin toxicity	2/1	Pellet in an umbrella tip	1978
Toronto	Individual	Intestinal roundworm	4/0	Foodborne	1971
China	Japanese military	Several	Unknown	Various	1932 - 1944
Europe	German agents in the U.S.	Anthrax	Unknown	Infected animals destined for the Allied Forces in Europe	1915
N. America	British soldiers	Smallpox	Unknown	Distributed infected blankets	1754
Kaffa, on the Black Sea	Tartar warriors	Plague	Unknown	Catapulted infected bodies	1346
Assyria, Middle East	Assyrians	Ergotism	Unknown	Poisoned enemy wells	600 B.C.

Historical incidents related to biological agents and toxins.

human factors (e.g., training, personnel safety, decontamination, and record keeping and chain of custody) associated with sampling equipment.

Biological Detection Technologies

Many technologies are currently being used or explored for detection of BAs and toxins. The guide discusses each of the technologies that were identified through the combined experience of an expert panel and emergency responders, through available literature searches, and through a market survey of biological detection equipment. The identified technologies include molecular techniques, immunochemical-based techniques, optical detection techniques, physical techniques, ligand-based techniques, biosensor-based techniques, standard culture applications, and hybrid techniques. While not all of these technologies are applicable or available for the emergency responder community, the information is designed to provide background material for making sound decisions. Currently, the predominant detection methods that are being used by the emergency responder community are molecular (real-time polymerase chain reaction [PCR]), immunochemical (lateral flow immunochromatography [LFIC]), and screening (Fourier transform infrared [FTIR] spectrometry), and are thought to be the most appropriate systems at this stage.

Biological Agent Detection Equipment Selection Factors

The guide recommends the emergency responder community consider 19 selection factors when selecting and purchasing BA detection equipment. The selection factors were compiled by a panel of scientists and engineers with multiple years of experience and relevant expertise in the areas of BA detection, identification and analysis, domestic preparedness, and identification of emergency responder needs. The factors have also been shared with the emergency responder community in order to obtain their thoughts and comments. The factors are start-up time, response time, sensitivity, specificity, forms detected, type of output, data interpretation, ease of use, sample preparation, support equipment needed, alarm capability, portability, durability, power requirements, environmental requirements, skill level, availability, cost and technical support and warranty.

Equipment Evaluation

The 19 selection factors were developed so that BA detection equipment could be compared and contrasted in order to assist with the selection and purchase of the most appropriate equipment. It is important to note that the evaluation conducted using the 19 selection factors was based upon vendor-supplied data and no independent evaluation of equipment was conducted in the development of the guide. The 19 selection factors are as follows: start-up time; response time; sensitivity; specificity; forms detected; type of output; data interpretation; ease of use; sample preparation; support equipment needed; alarm capability; portability; durability; power requirements; environmental requirements; skill level; availability; cost; technical support and warranty. The vendor-supplied data can be found in its entirety in Volume II of the guide.

In order to display the evaluation results in a meaningful format, the detection equipment items were grouped into four categories based on the prospective manner of usage by the emergency responder community. It is important to note that many of the equipment items could be grouped into one of several usage categories, but an attempt was made to group them based on intended use by the emergency responder community. The usage categories include the following: handheld detection equipment, mobile laboratory detection equipment, fixed-site detection systems, and standoff detection systems. The definitions for the four usage categories were extracted from the 1998 U.S. Army Chemical and Biological Defense Command's Final Report on the Assessment of Biological Agent Detection Equipment for Emergency Responders.

The evaluation results for the BA detection equipment are presented in Volume I for the 143 biological detection items identified at the time of the writing of the guide. Ninety-six of the items are considered for biological detection and identification applications, nine are considered for biological screening purposes, and the remaining are either biological samplers (26 items) or biological reagent kits (9 items).