InterAgency Board (IAB) Biological Issues Group: Gap Analysis of First Responder Response to an Environmental Biological Threat Incident

1. *Credible Threat Assessment*

Gap:

a. There is a lack of standard policies, procedures and SOPs to assess threat and determine credibility of samples.

b. A decision matrix is needed for all responders and partner agencies to determine the level of risk associated with a hazardous substance. This would include a formal template that would assist law enforcement and health agencies in determining if there is a need for sample collection. This matrix is not limited to communication and notification but also includes the appropriate use of field screening, sampling, and testing, and the use of equipment and interpretation of this data in a risk assessment.

c. There is a need for procedural guidance for dealing with exposed personnel at a scene suspected of containing a biological threat agent once a credible threat has been established.

2. *Equipment.*

Gap: Currently, there is a lack of standards to which available biological detection equipment can be validated. Standards are also lacking for field screening, sampling collection and detection and identification.

Desired requirements for such technology must enable the first responder to determine if the environment is contaminated to a level considered to be hazardous. Detection equipment used for emergency response or bought by facilities to protect public places must be:

- Able to detect to the level of a health hazard for each agent (minimal infective dose)
- Inexpensive for initial cost and maintenance
- Third party tested and validated against recognized consensus standards
- Able to test multiple threat agents from one sample
- Proven to have minimum cross reactivity
- Easy to use and maintain

- Ideally able to time stamp results
- Proven to have a high degree of specificity and sensitivity
- Be able to archive data and sample

This will require that Limits of Detection (LOD) are established so that the end user understands the advantages and limitations of the equipment being used. The goal of the LODs should be to assist a responder in determining the level of the hazard.
A process to address the lack of standards in the entire chem./bio detection area is just getting under way from the DHS Office of Science and Technology Policy . There is currently an interagency working group on standards.

3. *Standards, policies and procedures*

Gap:

a. A decision matrix and procedure for first responders to conduct field sampling and testing is needed. In addition, standards governing sample collection procedures for bulk powders, aerosols, and surfaces are also lacking. There are no nationally vetted policies and procedures available for response to suspect biothreat agents.

b. A tiered level approach for response must be developed that is based on the capabilities of a responding agency. If an agency responds that does not have the appropriate equipment or training, there should be a plan in place for a neighboring county etc to assist in screening, or collection of samples for testing. This tiered approach would allow regions to organize resources.

c. Define and develop the roles and responsibilities of first responders and collaborating agencies such as public health and Laboratory Response Network (LRN) laboratories. A guidance document with tactical objectives would ensure a baseline safety level for all parties.

4. *Training and competency requirements*

Gap: There are no standards and regulations available for training and competency of first responders and the use of equipment in the field. A nationally recognized curriculum should be developed and established along with the details of what constitutes end user ongoing proficiency and competency.

5. *Develop bioremediation standards and thresholds*

Gap:

a. Policies and standards are lacking to determine “how clean is clean” and who has responsibility for securing “dirty buildings” that have been determined to be “contaminated”. Guidance needs to be developed that states that an emergency responder agency is not responsible for determining the status of building re-entry by the public.

b. Polices and standards are lacking to determine on what basis a building is declared safe for re-entry and occupation and when this can occur once a sample has been collected and submitted for analysis. These policies should include what types of testing are used to make this decision and when this decision should be made.

6. *Autonomous detection systems*

Gap: Interim guidance is needed to develop a template for legislation or city ordinance that details the requirement for using/installing biomonitoring devices in public or private establishments/venues is needed. (Homeland Security Council is working on this topic). Biomonitoring equipment should have the capability to time stamp results and archive samples.

7. Sampling Mission

Gap: Further education and awareness is needed for first responders conducting public safety sampling on how their actions may impact evidentiary requirements.

Additional Background Information
Introduction

Since the intentional release of a biological threat agent in 2001, lack of appropriate technologies for the detection of biological agents has been a major issue and roadblock for emergency services. Many departments and agencies have acquired equipment without the proper research or available validation of such equipment. Additionally, the necessary educational training component is non-existent or inadequate for many agencies. Currently, the lack of national doctrine or polices for an effective response to a suspected biological release has led to abstract response plans that are regional or nonexistent in some areas. Regional doctrine and policies are often not available in written form and are not vetted for downstream flaws or by partners involved in biological response. There is a critical need for a comprehensive plan that addresses the responder's needs in terms of philosophy, consensus standard development, appropriate use of detection and screening systems,(Conops) and incorporation of imbedded administrative/engineering controls in biothreat detection systems.

An effective response to a suspect biological threat agent should incorporate partner agencies including the traditional responder (Fire, Law Enforcement and EMS) with health services which should include the LRN labs as well as county and state health departments. Many components necessary for an effective response are available but have been segregated into subcomponents and have not been integrated and included in response planning. One must remember that the first step in any emergency response, taught across this county regardless of the discipline is to identify the hazard. This is a resounding principle whenever one considers a response issue. A national response doctrine is necessary to provide a practical approach that all responder agencies can utilize. This response doctrine must encompass all disciplines.

The development of a consensus standard that can be used by all responder disciplines and agencies nationwide in response to a suspect biological threat event is a critical gap identified by the IAB. This standard or set of standards must ensure that the following requirements:

- Credible Threat or Risk Assessment
- Appropriate Use of Validated Equipment
- Standard Procedures and Policies
- Training and Competency Programs
- Mission Roles and Responsibilities for all disciplines
- First Responder and Family, Critical Infrastructure, and Community Prophylaxis trigger points

In general standards which address these issues must be established in order to ensure a consistent level of response in all applicable agencies. These standards should encompass these issues vetted through Subject Matter Experts, with current established resources within communities to produce policy driven Standard Operating Practices for the first responder.

First Responder Needs and Current Gaps

1. *Credible Threat Assessment* – Historically, this form of risk assessment has been from a human exposure vs. significant structure/target. This will require an expansion of the credible threat assessment into the above mentioned disciplines, with a defined method of use and development of a specific set of criteria. Credible Assessment is not just an identification of threat based upon signature profiles but also includes communication and notification between responders, law enforcement intelligence, LRN laboratories and public health epidemiologists. This would include a formal template that would assist local law enforcement and health departments in the establishment of the need for sample collection as well as the need for isolation and quarantine actions for affected individuals (building quarantine/decontamination). Models that have already been developed that have been vetted by responders and public health in a community can be utilized by other responder agencies. Coordination between local agencies that are involved in the response to a suspect biological agent needs to be established in standard development to ensure an integrated response. This is not limited to communication and notification but also includes the appropriate use of field screening equipment and interpretation of this data for use in a risk assessment.

2. *Equipment* – The majority of instrumentation presently on the market has not been appropriately validated nor have detection limits for biological agents been established. This has proven to be problematic within response systems and with response personnel. These issues are compounded by the fact that vendors are often providing little to no in-depth education to the end users of the equipment and the lack of available data to support or disprove the claims of an equipment vendor/manufacturer. Additionally, detection technology is driving the response goals of an agency. The reverse must occur, in that the response objective must be established through standard development to drive response profiles. The current underlying problem is that the equipment that is being used in the field has not been properly validated for the performance of the equipment under a variety of conditions. This would include independent third party validation of equipment purchased by either first responders or facilities. Once equipment standards have been developed and adopted, and validated equipment is available for use, operator training must occur and include the development of detailed guidance documents and policies, and include the limitations of the equipment. This may include legislation or city ordinance, much like electrical codes or sprinkler systems ordinances/laws, for autonomous detection systems located in private facilities.

   Detection equipment used for emergency response or bought by facilities to protect public places must be:

- Able to detect to the level of a health hazard for each agent (minimal infective dose)
- Inexpensive for initial cost and maintenance
- Third party tested and validated against recognized consensus standards
- Able to test multiple threat agents from one sample
- Proven to have minimum cross reactivity/sensitivity
- Easy to use and maintain
- Ideally able to time stamp results
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- Be able to archive data and sample

This will require that Limits of Detection (LOD) are established so that the end user understands the advantages and limitations of the equipment being used

3. *Procedures and policies* – There are no nationally vetted policies and procedures available for response to suspect biothreat agents. States such as Massachusetts, Rhode Island and New York have within their own communities developed localized procedures and are working towards established policies; however these concepts are not broadly used across the country.

   Procedures and policies transcend the equipment, training, decision making and SOPs. Although there are issues within each of these topic areas, the issues will require integration between the above and across disciplines. As an example, a hierarchy of sample movement and procurement (testing priority levels of prescreening for chemical, radiation and explosive hazards before entering a lab for biological analysis/further identification).

   An effective response to suspect biological agents must include procedures for:

   Training plan for equipment operation and test result interpretation
   Quality Assurance plan and action plan
   Notification action plan
   Pre-event action plan
   Independent evaluation of these plans

4. *Training and competency consistency* – Although standards and regulations are presently available, a developed training program that is nationally recognized is lacking, along with the details of what constitutes end user ongoing proficiency and competency. It is identified that the majority of the training that is produced has not been vetted nor established to cover the details of a biological response. Because of this, consistency of training, proficiency and competency is not presently institutionalized within the emergency response community.

   Standardized training has been embedded within the emergency services since the early 1960's and before. It is recognized that establishing a standard training

regimen gives the responder a baseline of education, on which they can build – continuing their training based upon local needs and requirements. Currently available education is weak, and does not afford the responder training in the necessary science to mount an effective response or to necessarily interpret test data to the point of making a well informed, scientifically sound decision making process. In the mid 60's as a nation emergency medicine was identified as a community problem. The success of EMS is the standardized training that was established. Presently in biological response no national established education or proficiency standards exist. If we follow the structure of EMS training over the years and use this model as a template for educational development, working against a training standard would ensure the constancy of response across the nation. As with equipment validation, training also must have a vetting process along with a quality assurance program.

5. *Mission Roles and responsibilities* – Specific roles and responsibilities along with trigger points involved in suspect biological agents across discipline lines are nonexistent. The additional issue is that without defined roles and responsibilities, the cause and effect between disciplines are not considered or identified.

   Mission Roles and responsibilities require a cross discipline approach along with a detailed scientifically defined method. Although we have minimal guidance based on chemical standards that are physiologically based, the details of these roles and responsibilities have not been identified in detail. Each discipline requires a standard for operations which ensures consistency between traditional emergency responders (Fire, Law Enforcement, EMS, and LRN labs) but also ensures consistency with nontraditional responders such as health departments and LRN's

6. *Community prophylaxis trigger points* – Although some states have identified in general trigger points for community health actions, along with points when other agencies become involved, a consistent plan for local, state, and national response are not detailed enough to provide the street responder enough information to activate such resources.

Summary

The issues and gaps identified need to be addressed at a national level. The IAB has identified the need for a well-vetted consensus set of standards along with accompanying policies, guidelines, and procedures that are founded and supported by scientific evidence and data including sampling and WMD response. Each standard must be followed by supportive documentation identifying the goals and objectives of the responders within the context of holistic emergency response. Within this is a range of educational requirements and validation of techniques and detection equipment.