NATIBO Biological Detection System Technologies
Technology and Industrial Base Study

A Primer on Biological Detection Technologies

Executive Summary

In April 1999, the North American Technology and Industrial Base Organization's (NATIBO) Steering Group commissioned a study of the biological detection system technologies and industrial base. This report, based on information received prior to December 1, 2000, addresses technical, business, and policy information related to biological detection technology research efforts and industrial capabilities in the U.S. and Canada. Based on this analysis, the study team reached the following conclusions and provided the outlined recommendations.

Conclusions

Biological Warfare Agent Threat

- The biological warfare agent threat has emerged as one of today's foremost security challenges due to a number of reasons:

  1. The increasing availability and sophistication of biological weapons technology,
  2. The widespread proliferation of ballistic and cruise missiles,
  3. The changing global environment, and
  4. The tremendous lethality of biological agents.

- The U.S. and Canada were ill-prepared for countering the chemical and biological (CB) threat during the Gulf War, and readiness is only marginally better today.

- Biological warfare agents require relatively low levels of scientific and technological support and can be produced using common commercial processes.

- Limited financing and training are needed to establish a biological weapons program.

- Biological weapons have low visibility and can be deployed through a rather simple means of delivery.

- Biological and chemical warfare agents affect humans in different ways. Effects of exposure to chemical agents is almost immediate. But, effects of exposure to biological agents might not be manifest for several days and can affect wider areas because of increased toxicity.

- Both governments are concerned about the potential of terrorists to try to use new, genetically-engineered agents that might escape detection through current detection system capabilities and might defeat conventional methods of treatment.

- Crucial to eliminating or reducing the number of casualties and the spread of contamination is how quickly the release of warfare agents can be detected.

Biological Warfare Agent Detection Technology Challenges

- No single sensor detects/identifies all biological agents of interest. Several different technologies may be needed as components of a layered detection network.

- It is difficult to discriminate and measure biological warfare agents from naturally occurring background materials. Real-time detection and measurement of biological agents in the environment is daunting because of the number of potential agents to be identified, the complex nature of the agents themselves, the countless number of similar microorganisms that are a constant presence in the environment and the minute quantities of pathogen that can initiate infection. Potential biological agents can disguise themselves in apparently benign entities.

- Because of the makeup of biological warfare agents, approaches for detecting these agents differ somewhat from those technologies that are employed to detect chemical warfare agents. While biological agents are extremely complex and large in comparison to chemical warfare agents, they are only made up of a very limited number of unique building blocks. This means the detection systems have to either:

    1. Exploit the 2- and 3- dimensional configurations of biologics (e.g., using antibodies, gene probes/primers, and possibly chromatography),
    2. Use fairly generic detection/identification technologies like fluorescence, or
    3. Process the supra-molecular biological warfare agents into more manageable sizes to allow generic detection/identification by chemical warfare-type technologies (e.g., ion mobility spectrometry and mass spectrometry).

- The lethality of biological warfare agents heightens the requirements for detection system sensitivity, which can lead to increases in cost, size, weight and power requirements with present day technology. On a per-mass basis, biological warfare agents can be more lethal than chemical warfare agents. Hence, the farther the detector is from the agent release line or point, the more sensitive the system must be.

- There continues to be a large gap between the lethal threat aerosol concentration and the limits of detection of current equipment.

Current Systems

- Biological detection technologies are in a much less mature stage of development than chemical detectors. Most available systems are point detection systems that are either in the field testing stage or still in the laboratory. Stand-off biological agent detection systems are in early stages of development and will not be ready for deployment for several years. Current biological agent detection systems are large, complex, expensive, and subject to false alarms. They can detect only a limited number of biological agents and only after exposure. Sensitivity, selectivity and durability of these detection technologies are not proven.

- Cost is a major impediment to both military and non-military adoption of biological warfare detection systems. However, funding for biological detection systems has been on the rise. Even so, the cost to the military must decrease before military users can create networks of sensors. And, the cost of these systems will need to come down substantially before domestic preparedness operations and commercial users could afford to buy the systems in the quantities that they would require to be effective.

- The small particle size of biological agents requires a complex identification process and detectors. The generic model for a biological point detection system includes a collector, a trigger, a detector, and an identifier.

- Most biological detection systems have significant support requirements, due to the use of wet chemistry and expensive and sensitive reagents. The use of expensive and sensitive reagents is a huge logistics burden on the user. Some currently fielded systems must be manned continuously by specialized personnel and identification depends on having the correct reagents.

- Current biological detection devices/systems require substantial power for operation. Some systems require the use of dedicated generators.

- Current detectors available are stand-alone systems that lack connectivity to military command and control networks. Successful integration of command and control systems with CB sensors is considered essential for the battlefield.

- No adequate means exist today to detect biological agents within containers or packages non-intrusively or remotely.

- Personnel responding to, managing or investigating a biologically contaminated scene cannot sufficiently detect, characterize, and delimit the extent of hazardous materials in the environment.

Research and Development (R&D)

- The development of biological warfare agent detection and identification systems is one of the most intense research activities in defense R&D.

- Biological detection technologies research emphasis is aimed at:

    1. Improvements to biological detection and identification capability, ideally moving towards detect-to-warn capability,
    2. Emphasis on reduced weight, automation, and field-portability,
    3. Integration of components into a single, rugged system that optimizes power while retaining modularity to support upgrades, and
    4. The ability to protect valuable fixed assets such as a field hospital or airfield.

- A number of different candidate technologies are being researched for possible use in next generation detection systems, dependent upon their ease of use and level of logistical support requirements. Developing dry technologies for these systems would reduce the logistical burden.

- More investment in fast, sensitive and accurate bio-weapon detection is needed.

- Further research into sample collection and processing is required.

- Greater cooperation between military and civil authorities and a closer relationship between U.S. efforts and those of other friendly countries are needed. Military and civil R&D programs conduct R&D in similar areas as well as in support of similar user communities. They pursue many of the same capabilities, target the same types of technologies, and contract with many of the same laboratories to perform the R&D work. However, participation in formal and informal coordination mechanisms has been cited as inconsistent.

- One challenge facing the community is to ensure the effective integration of new and emerging sensor technologies into current and future detection programs.

Future Biological Detection System Requirements

- Detection systems need to be deployable and supportable across the entire spectrum of military operations and for the full duration of those operations. Continuous, long term monitoring may be required for high priority fixed sites.

- Systems must have low false-positive rates.

- The ability to detect biological warfare agents in water supplies is also needed. At many of the military fixed sites, troops draw potable water supplies from uncontrolled civilian sources.

- Power components must be reduced and more efficient power sources (batteries, generators, etc.) developed/integrated into biological detection systems to reduce the size and weight of the system, to reduce supportability requirements and to increase system utility.

- Desired biological detection features include:

  - operable with minimal supporting infrastructure
  - operable in a variety of terrain
  - must interface with existing and planned command and control systems
  - robust equipment that can withstand vehicle transport and environmental extremes
  - man-portable
  - high-volume automated throughput
  - inexpensive
  - disposable or decontamination-capable
  - minimal requirement for specialized training
  - operable for long periods of time with minimal maintenance
  - long shelf-life
  - broad-ranged and able to add new threat agents rapidly
  - sensitive to civilian population susceptibility
  - low false positive alarm rates that reflect specific mission requirements
  - rapid detection and identification

- One need of future enhancements to current detection systems is to incorporate technologies that enable better characterization and portrayal of background interference for point and standoff biosensors.

- Systems capable of non-specific identification, e.g., determining the presence of bacteria, toxins and viruses by targeting generic factors, are highly desirable. Broad based detection may provide a means for detecting biologically engineered threats with signatures that are different from the agents current systems are programmed to identify.

- Improved sample collection systems for air, surfaces, water and soil are needed. DNA based detection/identification is feasible for military field detection requirements only after a sample has been collected, contaminants have been removed from the sample, and a "clean" sample (inhibitors removed) has been presented to the identification component (e.g., polymerase chain reaction, mass spectrometry). Speed of detection using DNA-based detectors could be accelerated with the development of improved sample preparation systems.

- Another needed capability is for non-intrusive detection of biological agents (e.g., screening cargo, mail, packages, etc.).

Technology and Industrial Base

- The biological agent detection technology industrial base sector is primarily supported by small and medium sized companies.

- Many of these companies are in the development stages of technological maturity, with very small scale manufacturing capabilities.

- Most of the companies involved in this arena have already formed or are actively forming teaming arrangements in order to be able to fulfill requirements.

- Smaller companies are teaming with larger companies, who would act as system integrators in assembling the detection system and make use of flexible manufacturing lines.

- Companies involved in development of technologies for detection systems are not solely focused on biological detection system applications, but rather for use in a variety of commercial applications as well. A number of marketplace factors influence a company's success including, among others, its ability to:

    1. Successfully commercialize a broad range of products,
    2. Keep pace with rapidly changing technology,
    3. Remain competitive,
    4. Fund R&D programs,
    5. Manage the patent process,
    6. Protect the company's trade secrets,
    7. Capitalize on collaborative opportunities and strategic partnerships,
    8. Develop products that are in demand in the marketplace, and
    9. Invest in needed capital equipment/facilities.

- A number of companies who manufacture laboratory equipment for other markets are also tracking developments in this field, looking at the potential to tailor their technologies and/or instruments for future detection systems.

- CB detection technologies have dual use potential in a number of different fields, including pharmaceutical and medical diagnostics, and monitoring air pollution and air quality in plants, noxious fumes inside enclosed areas, and municipal water supplies.

- The biological detection arena reaps the benefits of advances in other high growth technology areas, including biotechnology, computer technology, display technology, micro electronics, nano technology, communications technology, and low level signal recovery technology.

- The military forces are not the only government entities that have detection system requirements. Detection systems are needed for first responders, the U.S. Secret Service, the Federal Bureau of Investigation, fire departments, airports, embassies, and hospitals.

- There currently is not enough demand for any single biological detection system that would allow companies to make a realistic business case decision on production. Systems developed should be based on dual use technologies because the military is too small a segment of the market.

- Both the U.S. and Canadian military forces have low inventories of some biological detection equipment.

- In the U.S., detection equipment currently fielded would not be adequate to fulfill current major theater of war requirements.

- The U.S. Department of Defense (DoD) and the Canadian Department of National Defence (DND) have striven to communicate with industry on their nuclear, biological and chemical procurement plans for the future through annual Advance Planning Briefings for Industry (U.S.) and Industry Days (Canada). Both countries' defense departments are also receptive to briefings from industry on their different technologies.

Program Implementation/Fiscal Considerations

- CB defense efforts of each of the four U.S. Services are coordinated through the Chemical and Biological Defense Program, which has led to a number of Joint Service projects.

- However, each of the U.S. Services also has unique, specific requirements for biological detection systems to meet their needs. Meeting the needs of all Services using common equipment is sometimes

difficult, hampering the effectiveness of joint programs. For instance, whereas the U.S. Air Force can handle a 900-pound detector, the U.S. Marine Corps wants a detector that weighs just nine pounds. U.S. inter-service disagreements hamper the DoD's efforts to deploy advanced detectors in the field. This has contributed to a lack of preparation in the technology base.

- Canada's research arm for biological detection is centralized at Defence Research Establishment Suffield. The U.S. research efforts are more decentralized, more complex, and broader ranging. Many different research components of the U.S. government are involved in U.S. biological detection R&D. Research in this area is conducted by the four Services laboratories, as well as within Department of Energy and Defense Advanced Research Projects Agency.

- Challenges faced by the DoD and DND are the rapid turnover of promising Science and Technology products and technologies, shortening acquisition times, and lowering total ownership costs. This necessitates the need to continually track new and emerging technologies and ensure an effective technology transfer/integration process.

- The U.S. funding process is very involved and lengthy, and sometimes hampers the military's ability to move forward with a promising technology or fund a new program. The U.S. players must defend their programs through the Program Objective Memorandum process every year. This can cause fluctuations in funding of programs. The Canadian DND has a shorter, more streamlined decision process in which very few decision-makers are involved and, as such, its funding is much more stabilized.

- The U.S. spends more money than Canada to fund a number of different research programs and system development initiatives in the biological detection area. This is a reflection of the size difference between the U.S. and Canadian defense R&D budgets. Given these funding constraints, DND has made considerable progress in technology development.

Communications

- There are many new players in the biological defense arena, and improvements in communication are needed. Though there is formal and informal program coordination between the agencies sponsoring R&D, it is inconsistent and does not ensure that potential overlaps, gaps, and opportunities for collaboration are addressed. The Joint Program Office for Biological Detection has cited three challenges:

    1. The ability to leverage mission requirements for Domestic, Reserve, and National Guard requirements,
    2. Overcoming the instability of Service requirements, and
    3. Leveraging international collaboration.

- Information is lacking on the military forces' operations' prioritized needs, CB defense equipment requirements and how programs relate R&D projects to these needs. The requirements process needs to be defined. Competing priorities of a very complex management and oversight bureaucracy can dilute program focus. The DoD is working to alleviate this situation and intends to submit the needed information to Congress in 2001. To accomplish this, the DoD is in the process of developing performance goals and performance measures. These goals and measures will be stated along with the development of the Chemical Biological Detection Program Strategy Guidance and incorporated into key planning, programming, and budgeting documents. A Performance Plan will be completed during calendar year 2000 and included in the next annual report to Congress. DND has published a revised concept for Canadian Forces Operations – Nuclear, Biological and Chemical Defence, and is presently maturing a concept of operations for biological agent detectors.

- Department of Energy and Defense Advanced Research Projects Agency sponsored programs do not formally utilize user requirements in planning their R&D goals. These government offices have not

instituted program performance requirements to measure program performance against desired goals, as required by the Government Performance and Results Act (GPRA). The GPRA required adherence to an overall strategic plan, explicit program goals and measurable performance benchmarks.

- Civilian biological detection domestic preparedness programs lack performance measures and measurable goals. Domestic preparedness needs are not as clearly defined and not specified in as great a detail as the military has defined their requirements. No detailed equipment performance specifications or mission and threat analyses documentation has been prepared. A 1999 General Accounting Office report stated that "rapid growth is taking place in the domestic preparedness programs for responding to terrorist attacks and public health initiatives, though no sound threat and risk assessments to establish program requirements and prioritize and focus the nation's investments has been accomplished."

Testing

- There are insufficient test sites in the U.S. to accommodate all the required testing. In fact, currently there is a backlog of testing of different detection technologies.

- The Joint Field Trial (JFT) process is being standardized between primary U.S. and Canadian test facilities. Standard test methodologies, processes and procedures are in place based on previous JFT and the tri-national Test and Evaluation Working Group work. This will allow U.S. and Canadian researchers to compare data based on the same reporting results criteria.

- Additional work must be accomplished in developing and implementing new test methodologies to appropriately test emerging point and standoff technologies.

Additional Concerns

- There are different decision-makers involved in determining military and domestic response issues. How to coordinate requirements and program initiatives between these communities and determine what role the DoD and DND should play in civilian biological defense needs is a real challenge.

- For the U.S., considering that the funding for Department of Energy and Defense Advanced Research Projects Agency R&D programs have been increasing and combined are projected to be greater than the non-medical R&D funding for DOD's Chemical and Biological Defense Program for FY 2001, mechanisms for coordination need to be established to ensure that funding is used most effectively, redundant efforts are avoided, and similar requirements are handled jointly.

Recommendations

The recommendations resulting from this study are designed to overcome the technical, policy, market and testing considerations addressed in the conclusions presented above. The recommendations define specific actions that should be undertaken to foster the advancement of current biological detection system technology and fielding of systems.

Based on the conclusions reached as a result of this analysis into the technology and industrial base for biological detection systems, the NATIBO Biological Detection Technologies Working Group has outlined the following recommendations. These recommendations fall into two categories: those that address technology considerations and those that address policy considerations. These recommendations highlight a roadmap of actions that the U.S. and Canadian governments should embark upon to help ensure that the future biological detection system needs of the military forces are met.

Technology

- **DoD/DND should target joint R&D and biological detection system programs of mutual interest. Full use should be made of the programs in place in both countries – the U.S. Advanced Concept Technology Demonstration, the U.S. Technology Transfer Program, the Canadian Defence Industrial Research (DIR) Program, the Canadian Technology Investment Fund, and the Canadian Technology Demonstration Program - to fast track those technologies that demonstrate best value into programs.** By jointly developing biological detection systems, interoperability and supportability can be better ensured. In addition, the military forces can develop and field cutting-edge biological detection capabilities needed now, while pooling scarce resources and ensuring that there are no unnecessary duplicative efforts. The DoD has used the U.S. programs to focus on (in the near term):

  1. Collector/Concentrators – The goal is to develop a high efficiency, low power consuming collector/concentrator capable of delivering a detectable level from a low concentration aerosol.
  2. Generic Detectors – non-wet chemistry – high performing, small, low power consuming dry detectors are key to ensuring that the military forces don't miss an unorthodox biological warfare agent attack. They are also key to reducing the overall size and logistics burden of the entire detection system.
  3. Dry Detection Technologies – optical stand off technologies like LIDAR, fusing radar signals with an intelligent warning algorithm, improving methodologies for analyzing physical aerosol signatures, miniaturizing and ruggedizing detectors, and exploiting the power of networked systems. There is a big push to examine how to integrate optical standoff with other technologies.
  4. Reagents – Antibody and gene-based identification systems are the current state-of-the-art but there is also focus on developing reagents for new and emerging threat agents and in exploiting cutting edge molecular engineering techniques to improve the current reagent sets to make them more sensitive, faster reacting and more specific.

- **Alternative concepts for biological agent detection and active defense should continue to be explored**. At present, there is no silver bullet for universal detection of biological warfare agents. No one method or technique exists today that is capable of detecting all agents. Potential alternatives to currently employed technologies, perhaps discovered through technology breakthroughs achieved as a result of research being conducted in other scientific fields, could advance the capabilities of existing systems. For example, an individual-sized air purification unit based on plasma pyrolysis could be a powerful component of an overall system of active and passive biological warfare defense.

- **Some promising technologies are being developed by small companies that do not have the internal resources to participate in the Joint Field Trials**. Funding should be established in the Government technology base to support the participation of selected small businesses in their field demonstration of potentially valuable technologies and systems. Selection criteria would need to be developed to determine what constituted a promising technology.

Policy

- **Requirements and standards for biological detection systems and how these relate to R&D projects should be better defined.** More detailed information about user needs, CB defense equipment requirements, and how user needs relate to R&D projects may allow more effective coordination to be achieved. If the biological detection community had access to specific data in order to compare the specific goals and objectives of R&D projects, the researchers could better assess whether overlaps, gaps, and opportunities for collaboration exist. Performance measures could also be implemented to help track progress toward goal achievement.

- **A formal process to coordinate areas of research that are supported by multiple agencies and nations should be instated and managed in the U.S. by the Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense.** This coordination process could reduce potential

redundant efforts, ensure different agency requirements/concerns are addressed, provide a mechanism to share insights on technology advances/drawbacks, and enhance opportunities for collaboration.

- **The DoD/DND should sponsor bi-annual Biological Detection Conferences.** As demonstrated by the success of the First Joint Conference on Point Detection for Chemical and Biological Defense held in October 2000 and the recent Defence Research Establishment Suffield Chemical/Biological Industry Day, these types of fora provide an invaluable opportunity for the CB communities to share ideas, discuss potential technological advances, and collaborate on possible joint opportunities. Conferences of this nature could help to foster improved dialogue between companies possessing the different pieces of a biological agent detection system as well as with the military organizations. It could prove to be a catalyst to bring electro, mechanical, optics, electronics, and bio-technology firms together.

- **The JFT process should continue to be supported/funded. Work should continue to improve existing test methodologies and procedures as well as develop new methodologies to support emerging technologies.** Improved standards will allow U.S. and Canadian researchers to directly compare data from different testing sites and analyze the effectiveness of different technologies in order to gauge what programs and technologies should be targeted for transition. In fact, it is conceivable that, in the future, with these guidelines, industry could have their technologies tested at different testing sites and their data submitted to the JFT Joint Abbreviated Analysis for analysis. The military services should take full advantage of the JFTs to objectively evaluate potential technologies for inclusion in biological warfare agent detection systems. These tests provide materiel developers with opportunities to conduct field and chamber testing on their technologies while gaining performance data early on in their programs that they wouldn't otherwise be able to afford. It is an excellent opportunity for them to showcase technologies that have great potential, but lack strong sponsorship. These reports are also open to other appropriate government agencies for their uses. The JFT process has been touted as setting the standards for domestic and international biological detection test methodologies and has been adopted by Canada and the United Kingdom, and set the baseline for the International Field Trials completed this year in Canada.

- **A bottom-up review of future biological detection requirements and operational concepts with emphasis on integration, interoperability, and operational utility should be considered.** Earlier research was focused on specific technologies like state-of-the-art power systems, collection systems, and communications and information technologies, but these were carried out without emphasis on the larger system requirements. The current point detection systems all deal with detection of agents after people have already been exposed, and the next step is medical rather than operational. Future systems should develop a "system of systems" concept that could maintain operational effectiveness in a biological warfare environment.

- **Much more emphasis and sustained, stable funding is needed over a period of time long enough to allow the DoD and DND to research new technologies, move things out of the R&D base, ensure effective command and control communications with other systems, and field them.** Heightened focus and research dollars should be devoted to the biological detection program. There is a clear need for new technologies, especially with the demanding requirements of biological agent detection and identification. Traditional hardware systems and/or immuno-assay approaches may be less effective in dealing with complex environments such as cities and populated areas. And, greater investment in technologies like state-of-the-art power systems, collection systems, and communications and information technology programs for integration into warning and reporting networks is needed. This would allow systems to be reduced in size, be more fully automated and ensure that interoperability requirements are met. Incorporation of these supporting technologies into new/advanced platforms could allow for the use of robotics, unattended ground sensors, and unmanned aerial vehicles. Key to this is ensuring funding stability. A good rapport with industry cannot be established if funding needed for a multi-year program is subject to fluctuations. Industry makes business decisions based on the total level of funding budgeted for that program. On the U.S. side especially, funding provided for a program that has suddenly been stripped has led to the disruption of ongoing industrial programs and caused friction with industry partners.