



REPLY TO
ATTENTION OF

DEPARTMENT OF THE ARMY
PROGRAM EXECUTIVE OFFICE
FOR CHEMICAL AND BIOLOGICAL DEFENSE
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This white paper is in response to the July 19, 2002 memorandum from the Executive Office of the President Office of Science and Technology Policy (OSTP) for Federal Mail Managers and First Responders to Federal Mail Centers. The OSTP memorandum discusses the use of commercially available detection and identification technologies for use in determining if unknown substances resembling *Bacillus anthracis* powder do in fact contain this agent. It advises that actions taken for the procurement of such commercial technologies should cease. The memorandum states that the only valid method for the detection and identification of *Bacillus anthracis* is to transport suspect samples to an accredited Centers for Disease Control (CDC) Laboratory Response Network (LRN) Laboratory for microbiological culture. The policy memorandum addresses only *Bacillus anthracis* detection. It does not address any other threat agents. The memorandum also appears to focus on single technology testing with no context to the deployment of that technology. However, the memorandum also states that the Department of Defense (DOD) will continue to procure capabilities in addressing DOD requirements.

While this memorandum is clearly directed towards the detection of *Bacillus anthracis* in mailrooms and not directing the DOD to alter its current detection and identification strategies, it does raise questions about the capability of several technologies that the DOD currently employs. Specifically, the memorandum is directed towards Polymerase Chain Reaction (PCR) and Hand Held Assay (HHA) technologies. It is the intent of this document to put some context to the employment of these technologies and to succinctly describe how these multiple pieces fit into the overall detection strategy.

The DOD has recognized since the inception of its Biological Warfare (BW) Detection program that the lowest risk methodology for the detection and identification of BW warfare agents involves a layered, multi-technology strategy. Each of those single technologies has its strengths and limitations. The choice of how and when those technologies are employed involves many factors that must be taken into account through command risk analyses. These multiple technologies are fielded to the user community along with adequate training and information about their capabilities. It is then command responsibility to define how and when these capabilities are employed, based on the operational situation and what actions can be taken based on their results.

HHAs and PCR play vital roles in the DOD biodetection strategy. HHAs are effective when employed as part of a systematic, layered detection approach supported by additional levels of confirmation and with a variety of technologies. PCR is an integral piece of that laboratory confirmation. The OSTP recommends an integrated response with threat assessment protocols, which the DOD has adopted as military doctrine and put into effect.

HHAs can be properly employed to provide information in an expedient fashion when they are used as intended and are supported by additional technologies. HHAs were designed to provide data quickly, to enhance early command assessment and response to a given scenario. To improve upon

HHA generated data, the DOD has invested aggressively in fielding other technologies such as freeze-dried ECL immunoassays and DNA-based PCR assays, the results of which can be combined with other data to produce supporting evidence of the presence and identification of a biological agent and increase the confidence in the data generated. These investments in new technologies are being fielded and integrated into the overall biodetection strategy and will further enhance our ability to protect the warfighter and contribute to the Homeland Defense effort.

HHAs provided the first indication of the presence of *Bacillus anthracis* in the letter sent to Senator Daschle. Command decisions were made based on the high probability that the substance in question was *Bacillus anthracis*. These decisions did not include immediate medical treatment but did include movement of personnel from potentially contaminated areas, the shutting down of the building ventilation system to prevent more wide-spread contamination and the notification of medical personnel that there may be an incident. Furthermore, HHA test results prompted expedient sample transport to USAMRIID for laboratory based testing that included PCR, ECL, and traditional microbiological culture analysis.

The DOD investment in fielding new technologies such as advanced immunological assays and PCR is focusing on the highest standards of quality testing, from reagent manufacture, to Quality Control and Assurance testing, to proper operator training and certification. The DoD acquisition, scientific and testing communities, to include the the Program Executive Office for Chemical and Biological Defense (PEOCBD), US Army Medical Research Institute of Infectious Disease (USAMRIID), the Armed Forces Institute of Pathology (AFIP), the Naval Medical Research Center (NMRC), the AF Institute of Environment, Safety and Occupational Health Risk Analysis (AFIERA) the US Army Chemical School (USACMLS) and the Soldier Biological Chemical Command (SBCCOM) are working towards a common technological and procedural approach to BW agent testing and surveillance. Improved ties with additional CDC certified laboratories and proper fielding and implementation of advanced testing technologies will further enhance first response with HHAs.

The DOD has instituted an operationally tested and suitable biological warfare agent detection strategy consistent with countering BW threats. When used properly, the use of immunological and PCR assays are valid and necessary tools to provide first tier, presumptive agent identification information as part of this overall detection strategy. For more information please contact either Dr. David Cullin at dave.culling@peocbd.army.mil or Dr. Peter Emanuel at peter.emanuel@us.army.mil .

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