



READY OR NOT...

July 2003

Findings and Recommendations of the APHL

Chemical Terrorism Project

ASSOCIATION OF PUBLIC HEALTH LABORATORIES

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APHL is grateful to the members of the Chemical Terrorism Project Steering Committee and Expert Panel. These individuals graciously contributed their time and expertise to ensure that this project reflects sound scientific principles to address chemical terrorism issues facing the nation's public health laboratories.

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EXECUTIVE SUMMARY

While federal funding to support the surveillance and control of infectious biological agents associated with bioterrorism began in the early 1990s, only in fiscal year 2003 did Congress provide resources to develop the most basic chemical terrorism response capabilities in *all* state public health laboratories. Federal bioterrorism funding was helpful to develop the Laboratory Response Network for Bioterrorism (LRN), a multi-tiered system of laboratories with the resources to detect and identify bioterrorism agents. But the LRN has limited capability for clinical testing of chemical weapons agents, and no capability whatever to handle environmental samples containing unknown chemical agents.

In light of these deficiencies, the Association of Public Health Laboratories (APHL) began a chemical terrorism project in the summer of 2002 to assess national laboratory readiness for a chemical terrorism attack. Based on state laboratories' experience responding to the anthrax attacks of 2001, during which APHL members conducted two-thirds of all testing performed nationwide, APHL members had three main concerns about the laboratory response to a chemical attack: how to assure the safety of laboratory workers and others, how to conduct tests on environmental samples, and how to provide surge capacity when funding, workforce, and other critical laboratory assets are stretched thin on a normal day.

Safety: Those who weathered the anthrax attacks understand the consequences of accepting samples that are meant to harm—particularly environmental samples of chemical agents that may be in highly concentrated form. A powder in a threatening letter may contain multiple hazards: a biological agent in an explosive powder, or a mixture of radioactive and flammable compounds, for example.

APHL members handled all manner of hazards during the anthrax attacks. The public health laboratory community seeks to offer a credible response to terrorist threats, but understands that doing so means more than just saying, "no anthrax detected." It means being able to determine what *is* present in a sample, without having lost life or limb, or having to shut down the laboratory in the process. At this time, public health laboratories are being asked to evaluate chemical terrorism threats, but are not equipped to do so safely.

Environmental Testing: Most of the analyses done during the anthrax attacks were not performed on specimens from attack victims, but from environmental samples such as powders and wipes of surfaces in buildings. Methods are quite different for each. While the environmental testing burden was not anticipated, APHL members now know that in a chemical terrorist event, as during the anthrax attacks, hundreds of decisions to evacuate or reoccupy buildings and to determine affected areas will have to be made based upon environmental tests.

The Centers for Disease Control and Prevention (CDC) began development of methods to test for chemical weapons agents in clinical samples (those from human victims) in 1999, and is transferring this technology to states, to assure competent testing, adequate nationwide capacity, and good geographic coverage for the nation in a terrorist event. APHL is concerned that similar

methods and certification standards have not been developed for environmental testing, and that state public health laboratories will be left in the lurch if the homeland were attacked today.

Surge Capacity and Workforce Shortage: The anthrax attacks taught that laboratory testing in an event ramps up to levels ten-fold greater, or worse, than routine. Public health laboratories have faced workforce shortages for years. Funding for public health activities is typically bare bones, and state salaries are not competitive with the private sector or the federal government. Further, preparing and running a laboratory in response to terrorist events demands that a portion of the workforce be highly-skilled. Governments have not made the requisite investment in public health laboratories. There is simply no reserve workforce available to help states cope with chemical testing in the aftermath of a terrorist attack.

Lack of appropriate safety measures, validated test protocols for chemical agents in environmental samples, and sufficient trained personnel in state laboratories represent a significant gap in homeland security. Other government laboratory assets, including the Department of Defense's Edgewood Laboratory and federally funded Weapons of Mass Destruction Civil Support Teams, are insufficient to respond to a serious chemical attack without substantial support from state and local public health laboratories.

The APHL Chemical Terrorism Project

In November 2002, APHL members from 49 states, two territories and the District of Columbia responded to a survey to assess laboratory preparedness for a chemical terror attack. In January 2003, public health laboratory representatives from the 50 states and the District of Columbia attended a workshop in Atlanta, Georgia. Based on survey findings, site visits, expert consultations, and personal experience, attendees developed 46 recommendations, spanning a variety of topics. Recommendations are directed at federal agencies, Congress, state governments, state public health laboratory workers, and APHL. When implemented, these recommendations will assure that public health laboratories can respond to a chemical terrorism event, provide reliable testing, meet testing burdens in a timely manner, assure the safety of the public and all members of the responder community, including the laboratorians themselves, and minimize impacts on essential governmental and commercial activities.

In February 2003, APHL released preliminary project findings and wrote a letter to members of Congress asking that certain activities be funded in the forthcoming appropriations process.¹ This final report presents comprehensive project findings, including all recommendations.

¹ APHL, "Study Finds Public Health Laboratories Not Ready for Chemical Terrorism," February 5, 2003. Available at <http://www.aphl.org/docs/ChemT%20brief%20Feb-05-03.pdf>, accessed June 6, 2003. APHL letter to members of Congress, February 5, 2003, available at http://www.aphl.org/documents/chem_t_ltr_to_congress_feb03.pdf, accessed June 6, 2003.

Survey Highlights

When asked to rate their laboratories for their overall ability to respond to a chemical terrorism event, on a 1-10 scale, with 1 being “poor” and 10 being “excellent,” HALF of state public health laboratory directors rated their laboratories at “3” or less. (See erratum below.²)

Directors based their pessimism on a number of specific readiness gaps:

- Only eight (8) state public health laboratories reported having a chemical terrorism response plan in place.
- Most states reported that they knew of stockpiles of industrial and agricultural chemicals in their state, but most also responded that they *did not know* if there were stockpiles of chemical weapons agents in the state.
- Thirty-nine (39) states reported that their laboratories were not prepared to safely accept samples that might contain multiple hazards (e.g., a chemical and a biological agent).
- Twenty-five (25) of the 45 states that conduct chemical analyses reported that personal protective equipment was “*not very adequate*.” Only 6 reported that personal protective equipment was “adequate” or “very adequate.”
- When asked about adequacy of staffing to conduct testing during a chemical terrorism event, 38 states reported that they were either, “*not at all adequately staffed*,” or, “*would require a lot of help, and experience significant delays*.”
- While most states have experience testing for a variety of common, or industrial, chemicals, very few report having expertise to test for chemical weapons agents, in either clinical or environmental samples.

Recommendations - How to Prepare Laboratories for Chemical Terrorism

APHL Project workshop participants developed 46 recommendations for state public health laboratory capability and capacity to respond to chemical terrorism. Recommendations were developed in the following topical areas, with a subset of recommendations in each designated as priorities:

- Create an Integrated, All-Hazards National Laboratory Network
- Expand National Laboratory Analytical Capability and Capacity
- Develop Standardized Protocols for Routine Operations and Emergency Response
- Strengthen Partnerships

² Erratum: Due to a data management error, APHL reported in February 2003, that “half of state public health laboratory directors rated their laboratories at ‘2’ or less.” The correct median on the 1-10 scale is actually 3, hence the statement should read, “half of state public health laboratory directors rated their laboratories at ‘3’ or less.”

Project Conclusions, January 2003

Testing Capability: The nation lacks needed laboratory capability because environmental testing methods for chemical weapons have not been developed, or are not available to the states. CDC has developed and delivered clinical testing methods, but APHL has been unable to identify a lead civilian federal agency responsible for developing methods for environmental testing to be used during a chemical weapons attack. The *Federal Response Plan* and the *White House National Strategy for Homeland Security* appear to delegate this responsibility to EPA, and EPA has the most relevant expertise to support it. Yet, APHL has been unable to identify any EPA office, program, or activity currently developing environmental test protocols for use by state laboratories, with the exception of the "Guidance Document, Module for Chemical Analysis of Drinking Water," released in June 2003. In addition, while APHL understands the difficulty of ramping up a new federal agency, the association has been unable to identify any individual or program area at the Department of Homeland Security responsible for recognizing and addressing this gap.

Worker Safety: The safety of laboratorians and others is not assured under current circumstances. A number of recommendations address the development of protocols and strategies for sample collection in the field and transport to the laboratory to assure the safety of law enforcement personnel and other first responders, as well as preserving sample integrity for forensic and epidemiologic investigations. Once at the laboratory, a sample must be handled, eventually, if it is to be analyzed. Since the workshop, an interagency workgroup has formed to begin responding to the project recommendation for safe and secure sample screening and processing facilities to handle unknown or mixed samples. The group has explored design standards for a modular facility, which may include robotics to perform some of the most hazardous aspects of sample preparation. APHL has asked that Congress fund this activity and that the Department of Homeland Security designate a lead federal agency for its implementation.

Federal Support for States: APHL is encouraged that in May 2003, the Department of Health and Human Services and the CDC announced that for the first time, all 50 states would receive funds to build basic chemical terrorism preparedness activities at their public health laboratories.³ Previously, CDC had been able to support only five states in developing **clinical** testing capability. With this year's announcement, all states can now begin building chemical terrorism into their response plans, develop the ability to accept and refer samples, and institute preliminary safety measures. However, current funding is inadequate to support analytical capability in all states.

APHL remains concerned that other federal agencies have not provided support for the development of environmental testing capability or comprehensive worker safety upgrades, and calls upon the Department of Homeland Security to evaluate these gaps and delegate responsibility appropriately.

³ Centers for Disease Control and Prevention, Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism-Budget Year Four Program Announcement 99051, May 2, 2003, available at <http://www.bt.cdc.gov/planning/continuationguidance/index.asp>, accessed on July 9, 2003.

Laboratory Workforce Shortage: Finally, as APHL has noted before with regard to bioterrorism preparedness, chronic shortages of skilled laboratory workers severely hamper readiness efforts.⁴ This shortage also impacts chemical testing. In fact, 40 of 48 respondents to the chemical terrorism survey who have tried to recruit chemical laboratory staff said that recruitment was “somewhat” or “very” problematic. **As long as state public health laboratories are expected to provide frontline national response capability in an emergency, the federal government must work with states and with APHL to develop a comprehensive national strategy for laboratory workforce development**

⁴ APHL, Public Health Laboratory Issues in Brief: Bioterrorism Capacity. October 2002. Available at <http://www.aphl.org/docs/BTIssuebrief1.pdf>, accessed June 6, 2003.

BACKGROUND

When spores of the bacterium *Bacillus anthracis* were disseminated through the United States Postal Service in the fall of 2001, the nation's public health laboratories had the rudimentary systems in place to respond to the crisis. Had the terrorists chosen arsenic, sarin, strychnine or any of the other chemical agents listed in Table 1 instead of a biological pathogen, the laboratory response could not have been as swift. By almost any meaningful measure^{3/4} funding, validated test protocols, safety of facilities^{3/4} laboratory readiness for a chemical terrorism event lags far behind readiness for bioterrorism.

Table 1. CDC-Identified Categories of Chemical Agents

Categories of Agents	Examples of Agents
Biotoxins	Ricin, strychnine
Blister Agents/ Vesicants	Mustards and mustard gas, lewisites, phosgene oxime
Blood Agents	Cyanides, arsine
Caustics (acids)	Hydrofluoric acid
Choking/ Pulmonary Agents	Chlorine, phosgene, phosphine, chlorine
Incapacitating Agents	BZ, opioids, phenothiazines, LSD
Metals	Arsenic, mercury, thallium
Nerve Agents	Sarin, cyclosarin, VX
Organic Solvents	Benzene
Riot Control Agents/ Tear Gas	Chloropicrin, chloroacetophenone
Toxic Alcohols	Ethylene glycol
Vomiting Agents	Adamsite, diphenylchloroarsine, diphenylcyanoarsine

(Source: <http://www.bt.cdc.gov/agent/agentlistchem-category.asp>, accessed on May 26, 2003)

Environmental laboratory capacity exists for several of the categories of agents above, but there is no capacity for environmental testing of chemical warfare agents in the state public health laboratories.

UNDERSTANDING THE GAP^{3/4} CLINICAL VERSUS ENVIRONMENTAL TESTS

To understand the biggest gap in America's chemical terrorism preparedness, it is useful to consider how a terrorism event would unfold from the laboratory perspective and the kinds of testing that would be needed.

In a chemical terrorism event, public health laboratories will likely be asked to perform the initial identification of the chemical agent used. They will be asked to assess individuals, including those obviously exposed and ill, but also those who may have been exposed but are not overtly ill. Results of **clinical laboratory tests**—tests of human blood, urine, saliva—may be used to identify those with low-level exposures who may benefit from antidotes; to identify those with negligible exposures to avoid unnecessarily administering antidotes, which may themselves

have adverse effects; and to assess population-wide exposure levels and track long-term health outcomes.

Public health laboratories would likely also be pressed into service to conduct **environmental tests**—tests of samples from non-human sources such as food, soil, air, or water—to determine whether buildings, water supplies or other infrastructure are safe or must be removed from service and when they can be reoccupied or put back into service. Environmental testing is also crucial to support the criminal investigation that would accompany any terror attack. Discussions relating to food testing were beyond the scope of this project, but APHL understands and acknowledges the existing gaps and the need for a coordinated state and federal effort for chemical analysis of food products.

It may sound like laboratory arcana, but **the distinction between these two types of testing, clinical and environmental, is so important from safety, analytical, regulatory and jurisdictional perspectives, that it is key to understanding the biggest gap in national chemical terrorism preparedness.**

- **Safety Issues:** There are few chemical weapons agents for which the levels of chemicals in blood or urine samples (even from victims whose intoxication was fatal) pose an extraordinary safety hazard for laboratorians conducting testing.

In contrast, environmental samples containing military chemical weapons agents are likely to pose substantial risk to those handling them, especially when the presence of the agent in a sample is not yet known. As with many of the bioterrorism agents, gram or milliliter amounts of chemical agents may be sufficient to cause hundreds or thousands of casualties. Considerable effort was made by participants in the APHL Chemical Terrorism Project to determine who should collect, handle and analyze these samples, and how the safety of the responders and the public can be protected during these activities.

- **Analytical Issues:** As a practical matter, the levels of chemical agents and metabolites present in the blood or tissues of victims will be relatively low compared with the levels in the environment in which the victim was exposed. It is not always possible for a single detection instrument to operate reliably in both measurement ranges. Even when the instrument range is broad, analyzing highly concentrated environmental samples contaminates the instrument and the laboratory. Both must be thoroughly cleaned and decontaminated before valid testing for trace amounts of the agent (in clinical samples) can resume. Thorough breakdown and cleaning may require days to complete.

Instrumentation and systems intended for clinical testing generally must remain dedicated to that purpose, and cannot be used for environmental testing, either concurrently or intermittently, without potentially compromising readiness for clinical testing.

- **Regulatory Issues:** Clinical testing is generally conducted to guide health care decision-making. In an effort to assure quality testing, all clinical and hospital laboratories must comply with the Clinical Laboratory Regulations for the Medicare, Medicaid, and Clinical Laboratories Improvement Act of 1967 (CLIA) and are subject to regulation by the Centers

for Medicare and Medicaid Services. CLIA certification is a mature and objective benchmark of consistent laboratory standards.

In contrast, national laboratory quality standards and certification pathways for environmental testing are largely absent. The Environmental Protection Agency (EPA) maintains a certification program for water testing laboratories, but there is no oversight mechanism for testing of soil, air, surface swabs or other types of environmental testing that would be required in a chemical terrorism emergency.

The states, the federal government, and the private sector are working to develop and implement a national environmental laboratory accreditation program. Standards for the program have been adopted by a state-federal partnership named the National Environmental Laboratory Accreditation Conference (NELAC). These standards are implemented primarily by state agencies, which serve as accrediting authorities. EPA supports this effort by accrediting state accrediting authorities. To date, 11 states have become accrediting authorities under the NELAC program, and many others recognize NELAC accreditation. In addition to the NELAC program, the international standards community has developed laboratory accreditation standards (ISO 17025) applicable to chemical terrorism emergency testing activities. In addition, at least one United States national accrediting body (the American Association for Laboratory Accreditation) accredits laboratories against these standards.

- ***Jurisdictional Issues:***

The Centers for Disease Control and Prevention (CDC) has a clear mission to support state and local public health activities, and a long history of developing and transferring technologies for laboratory testing of public health importance. Blood lead testing and serological tests for West Nile virus are an historical and a recent example, respectively, of methods developed by CDC experts and delivered to states to meet public health needs. The CDC program to develop and transfer methods for clinical testing of chemical agents is consistent with the agency's mandate and expertise.

In contrast, APHL has been unable to identify a lead civilian federal agency responsible for developing methods for environmental testing to be used during a chemical weapons attack. The *Federal Response Plan* appears to delegate this responsibility to EPA, and EPA has the most relevant expertise to support it. The *White House National Strategy for Homeland Security* states that, "The Environmental Protection Agency will continue to provide a laboratory diagnostic surge capacity for environmental samples during a crisis."⁵ Furthermore, the *EPA's Strategic Plan for Homeland Security* notes that the agency will "undertake research, development, testing and communication/ implementation of *enhanced* (emphasis added) methods for detection and containment of ...chemical warfare agents," in buildings and in drinking water.⁶

⁵ National Strategy for Homeland Security, White House Office of Homeland Security, July 2002, p. 44. Available at <http://www.whitehouse.gov/homeland/book/index.html>, accessed June 4, 2003.

⁶ U.S. Environmental Protection Agency Strategic Plan for Homeland Security, September 2002, p. 29. Available at http://www.epa.gov/epahome/downloads/epa_homeland_security_strategic_plan.pdf, accessed on June 4, 2003.

At the time of APHL's 50-state meeting in January 2003, the association was unable to determine an EPA office, program or activity developing or enhancing such methods, with the exception of drinking water protocols, for use by state laboratories. Since that time, APHL has learned that EPA does possess *limited* capacity and capabilities to address *conventional* chemicals used as a weapon. Though it can analyze some samples, it is constrained in what it can accept if confronted with a total unknown or a sample with a suspected warfare agent. Moreover, the agency lacks safety procedures and medical protections necessary to ensure the safety of its employees. Only a very select group of laboratories, which support military missions, are capable of handling, sampling, storing and disposing of chemical warfare agents.

To date most of EPA's work in identifying and responding to chemical agents focuses on contamination of water. The agency is developing an expert system to help analysts make decisions when considering known or unknown water contaminants. Additionally, it is updating the National Environmental Methods Index (NEMI) to include methods relevant to water security and, under the auspices of its new Homeland Security Research Center (HSRC), has embarked on an expedited program to develop and evaluate testing protocols and analytical procedures to rapidly determine if a drinking water system has been attacked and contaminated. A draft analytical guide has been prepared and is under review prior to field-testing.

EPA has, however, undertaken several initiatives to address the larger issue of testing environmental samples in the event of a terrorist attack. Its National Homeland Security Research Center (NHSRC), in Cincinnati, OH, was created to develop methods for detecting and containing chemical warfare agents in buildings as well as water systems. It is slated to develop a compilation of related procedures and detection levels. Further, EPA's Homeland Security Laboratory Capability Workgroup is collecting and evaluating available methods and standard operating procedures for testing environmental samples in a terrorist incident. The agency also is compiling methodology for determining whether an unknown sample can be handled in a normal environmental/public health laboratory (i.e., is not an acutely hazardous material); whether the material contains constituents of concern at significant concentrations (i.e., sample is likely to have been contaminated); and what constituents of concern are present in the sample and at what concentrations.

No resources have been provided to EPA to carry out the activities specified in the Homeland Security Strategic Plan for laboratory capability and capacity. EPA's role, as defined in the National Homeland Security Strategic Plan, is to continue to provide laboratory surge capacity for environmental samples during a crisis. Christine Todd Whitman, EPA's former Administrator, notified the Secretary of the Department of Homeland Security (DHS) that EPA's role was limited to providing surge capacity for conventional samples, not warfare agents. She indicated that EPA could not fulfill this role without a specific mission directive and appropriate resources. While a Homeland Security Council Policy Coordinating Committee has been asked to address this need, DHS has made no decision as to what agency is responsible for providing laboratory capability to analyze warfare agent samples.

To resolve this issue, and others that will undoubtedly arise among the various federal and state actors involved in emergency preparedness and response, it is critical that one federal agency assume the lead role for inter-jurisdictional planning and coordination of chemical terrorism activities.

CATCHING UP WITH BIOTERRORISM READINESS

In many ways, the United States is about a decade behind in building a national system for laboratories responding to chemical terrorism, compared with national bioterrorism activities. While federal funding to support the surveillance and control of infectious biological agents began in the early 1990s, only in fiscal year 2003 did Congress provide resources to develop the most basic chemical terrorism response capabilities in *all* state public health laboratories.

A federal focus on biological pathogens began in earnest in 1994 when the CDC initiated an effort to build basic public health infrastructure with the release of its prevention strategy for emerging infectious diseases. While not specifically mentioning bioterrorism, the strategy articulated the surveillance, applied research, prevention and control, and infrastructure goals needed to maintain “a strong defense against infectious diseases that affect, or threaten to affect, the public’s health.”⁷ The strategy provided for the creation of several federal funding mechanisms to restore a robust infrastructure at state and local public health agencies.

The emerging infections strategy was updated in 1998, and a separate funding source was established for state health departments specifically to build bioterrorism response capacity. This bioterrorism grant program was intended to complement other CDC funding sources, with the premise that the nation’s best defense against bioterrorism was achieved by assuring that public health programs for infectious disease control were in generally good shape across the nation. Still, funding was not adequate to provide resources to all states each year.

At about the same time, CDC announced the availability of funds for state public health laboratories to develop analytical capability to test clinical samples for chemical weapons agents. The CDC announcement stated that “in the event of a known or suspected chemical terrorist incident, personnel would be deployed from a Laboratory Response Team at CDC within a few hours to the site to collect initial blood and urine samples for analysis using CDC’s Rapid Toxic Screen ... [to] determine the chemical agent(s) used and the exposure level of persons sampled.” But, because the CDC would probably not be able to provide all the laboratory services necessary during a serious chemical terror attack, the agency would establish additional laboratories in the U.S. with the ability to measure chemical agents in blood and urine. Together, these laboratories and the CDC would function as a chemical terrorism response network.⁸

CDC made awards to four states to build public health laboratory infrastructure for analysis of chemical weapons agents in clinical specimens: California, Michigan, New York and

⁷ Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States, Centers for Disease Control and Prevention 1994, available at ftp://ftp.cdc.gov/pub/infectious_diseases/emergplan/pdf/emergplan.pdf, accessed May 1, 2003

⁸ CDC Program Announcement 99051, Public Health Preparedness and Response for Bioterrorism, Notice of Availability of Funds, Spring 1999.

Virginia. In 2000, New Mexico was added. The five states have received annual funding and serve along with CDC/NCEH as sites for national surge capacity during a chemical terrorism event, after initial agent identification at CDC.

In the fall of 2001 Congress provided an additional \$918 million in emergency supplemental appropriations to build state and local capacity to respond to terrorism. For the first time, all states were eligible to receive some funding for bioterrorism and general preparedness activities. But funding for Focus Area D—Laboratory Capacity for Chemical Agents—was not included. States and territorial public health laboratories received \$146 million from that appropriation, but were restricted to spending the money on bioterrorism preparedness activities, leaving only the existing five states able to respond to chemical threats in a limited fashion by testing clinical samples.

In fiscal year 2003, Congress again provided \$940 million to build state and local public health infrastructure. In this funding cycle, CDC announced a critical benchmark for Focus Area D, meaning that every state must apply for funding to acquire at least the ability to safely collect and ship samples in a chemical terrorism event, and to coordinate response activities with CDC and the Federal Bureau of Investigation (FBI) and across all neighboring jurisdictions.⁹

The Laboratory Response Network for Bioterrorism. The funding dedicated to bioterrorism preparedness in the past decade yielded meaningful results. When the first case of anthrax was suspected in the fall of 2001, laboratories were ready and able to perform the necessary clinical tests and, although somewhat problematic, to devise a working test for environmental samples that might contain anthrax.

In 1999, a CDC workgroup proposed the creation of a national network of laboratories to respond to bioterrorism, stating, “CDC and its partners will create a multi-level laboratory response network for bioterrorism (LRNB). That network will link clinical labs to public health agencies in all states, districts, territories, and selected cities and counties and to state-of-the-art facilities that can analyze biological agents. As part of this effort, CDC will transfer diagnostic technology to state health laboratories and others who will perform initial testing. CDC will also create an in-house rapid-response and advanced technology (RRAT) laboratory. This laboratory will provide around-the-clock diagnostic confirmatory and reference support for terrorism response teams. This network will include the regional chemical laboratories for diagnosing human exposure to chemical agents and provide links with other departments (e.g., the U.S. Environmental Protection Agency, which is responsible for environmental sampling).”¹⁰

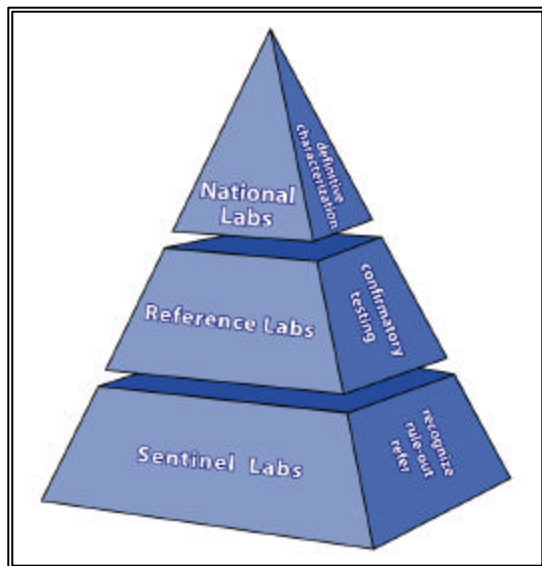
The LRN, in place when the anthrax attacks occurred, encompasses:

- Hospital and clinical laboratories, which are likely to be the first to recognize the use of a bioterrorism agent as individuals fall ill.

⁹ Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism – Budget Year Four, CDC, May 2003, available at <http://www.bt.cdc.gov/>, accessed May 26, 2003.

¹⁰ Biological and Chemical Terrorism: Strategic Plan for Preparedness and Response: Recommendations of the CDC Strategic Planning Workgroup. MMWR 49 (RR04), 1-14, April 21, 2000.

- State public health laboratories, which would provide confirmatory testing and support epidemiologic investigations.
- National laboratories, including those at the CDC and the Department of Defense, which would conduct sophisticated analyses of bacterial agents suspected in terrorist events, supporting the most effective public health and law enforcement response possible in these situations.



These three tiers of laboratories, the clinical or sentinel laboratories within the healthcare system, the public health or reference laboratories in states, territories and major metropolitan areas, and the national laboratories with high-level pathogen characterization methods, work together to detect and identify bioterrorism agents. Thousands of sentinel laboratories perform initial screening of potential pathogens. When they cannot rule out the presence of an agent of bioterrorism, they refer specimens and isolates to state public health laboratories (SPHLs) and other reference laboratories for rule-out or confirmation. If a serious outbreak or terrorist event is suspected, national laboratories are involved in analysis and investigation.

APHL, CDC and the FBI are founding partners of the LRN. More than 100 state, local and federal laboratories provide reference testing. The LRN provides uniform testing methods; geographic coverage for states and regions; a known chain of command to report results and manage consequences; and coordinated national reporting and data sharing. Laboratories at CDC and the U.S. Army Medical Research Institute of Infectious Diseases provide safe and sophisticated analysis of the most dangerous or perplexing pathogens in their Bio-Safety Level 4 laboratories.¹¹

CDC has begun delivering methods for clinical tests for chemical weapons agents to the LRN, for use by the five currently funded states. The LRN will remain the mechanism for coordination of all state public health laboratories as they develop protocols for accepting and referring samples, and devise methods for analysis of certain types of chemical weapons agents.

The lesson from the anthrax attacks is clear: the LRN model works for bioterrorism, providing known capability, surge capacity, and good geographic coverage. But the LRN has limited capability for clinical testing of chemical weapons agents, and no capability whatever to handle environmental samples containing unknown chemical agents. Lacking a civilian program

¹¹ "CDC Responds: Coping with Bioterrorism—The Role of the Laboratorian," Public Health Training Network Satellite/Internet Broadcast, originally aired on November 9, 2001, transcript available at <http://www.bt.cdc.gov/Agent/anthrax/webcast/110901/index.asp>, accessed July 9, 2003. Perkins, B.A. et. al. Public Health in the Time of Bioterroris m. Emerging Infectious Diseases, Vol 8(10), Oct 2002, available at <http://www.cdc.gov/ncidod/EID/vol8no10/02-0444.htm>, accessed on July 9, 2003.

to develop environmental testing methods, state health officials have no good options if a terrorist were to strike today.

Bioterrorism Testing and Safety. Standard practices for safe handling of microbial agents have been in place for many years. The fourth edition of the CDC - NIH publication “Biosafety in Microbiological and Biomedical Laboratories” (BMBL), provides consensus recommendations for standards and microbial practices, safety equipment and facilities for working with infectious agents in the laboratory.¹² BMBL explains the familiar BioSafety Levels 1-4 for handling of a variety of agents. A recently published revision of its laboratory security and emergency response guidelines provides updated information on preventing infectious disease hazards that could result from intentional, illegal acts.¹³ Guidelines of comparable scope for safety and security in chemical testing laboratories are lacking. The Occupational Safety and Health Administration requires laboratories to develop Chemical Hygiene Plans to address specific hazards and their management,¹⁴ and a framework for chemical safety levels has been proposed.¹⁵ One of the recommendations from the APHL project is the development of a comprehensive “BMBL equivalent” for chemical laboratory testing.

THE BIG PICTURE—GOVERNMENT ROLES AND LABORATORY ASSETS IN A CHEMICAL ATTACK

A review of the roles of the major government entities that would mobilize to respond to a chemical attack on the homeland reveals two important points. First, state public health authorities retain the major responsibility for assuring public health in the aftermath of a terrorist attack. Second, current federal laboratory resources are insufficient to respond to a serious chemical attack without substantial support from state and local public health laboratories.

A domestic chemical attack would elicit responses from a host of health, safety, and law enforcement personnel representing local, state and federal government actors from a variety of agencies at each level. The challenge in this situation is to assure that all available resources exist and are fit to respond in a coordinated fashion. Neither is true for national chemical terrorism preparedness in 2003.

The Federal Response Plan (FRP) is premised on the understanding that the initial response to any emergency is local. The public health response to a chemical terrorism event, aimed at treating the ill and injured and preventing further exposure and illness, depends on service delivery by local health departments for victim identification, assessment of individual exposures, dissemination of antidotes, evacuation and closure of premises to prevent further

¹²The BMBL 4th edition, May 1999, is available at <http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm>, accessed Jul 9, 2003.

¹³Richmond, J.Y. and Nesby-O’Dell, S.L., Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents. MMWR 51(RR19): 1-8, Dec. 6, 2002

¹⁴ See <http://www.osha.gov/SLTC/laboratories/index.html>, accessed on Jul 9, 2003.

¹⁵Hill, R. et. al., Chemical Safety Levels (CSL's): A proposal for chemical safety practices in microbiological and biomedical laboratories. July-Aug 1999, available at <http://www.cdc.gov/od/ohs/new%20publications.htm>, accessed on Jul 9, 2003.

exposures, follow-up of long-term complications of exposure, and related activities. Police powers for public health, those authorities required to compel evacuation and closure of businesses, the restriction of travel, case follow-up and such, generally reside at the state rather than the federal level.

In Homeland Security Presidential Directive 5 (HSPD-5) issued February 2003, President Bush announced plans to establish a National Incident Management System, to replace the FRP, and designated the Secretary of Homeland Security as the principal federal official coordinating domestic incident management.¹⁶ HSPD-5 states that, “The Secretary shall coordinate the Federal Government’s resources utilized in response to or recovery from terrorist attacks, major disasters, or other emergencies if ...the resources of State and local authorities are overwhelmed and Federal assistance has been requested by the appropriate State and local authorities, (and/or) more than one Federal department or agency has become substantially involved in responding to the incident.”

While public health authorities are largely state-based, domestic terrorist acts are considered federal crimes, and their investigation and prosecution are the responsibility of the Attorney General. State public health officials worked closely with the FBI to respond to anthrax attacks in the fall of 2001.

State health officials and the FBI hold the leadership roles in assuring public health and safety in the prevention and response to domestic terrorism incidents. Understanding these principals and their interaction with each other and with other local, state and federal agencies in an event is essential for coherent pre-event planning and for coordination during and after an attack. This theme was articulated in the President’s *National Strategy for Homeland Security*, July 2002, noting “the tenth amendment makes clear that each state retains substantial independent power with respect to the general welfare of its populace.”¹⁷

Department of Defense Capabilities. The U.S. Army Soldier, Biological and Chemical Command maintains a military chemical weapons testing laboratory in Edgewood, MD. The facility is not designed for civilian use, but can be used as a response asset in declared emergencies. In addition, Army personnel have provided assistance to public health laboratory directors on many occasions when suspicious substances required identification in non-emergency situations.

The Edgewood laboratory is not designed to handle large volumes of testing (surge capacity) that would be required in a terrorism event. During the few months following the anthrax attacks in 2001, the LRN conducted more than one million analyses for anthrax, most of them on environmental samples. These test were distributed among more than 75 laboratories in the network, but still strained the system to its limits. It is inconceivable that the Edgewood laboratory could provide this service to the nation in a comparable chemical terrorism event.

¹⁶ HSPD-5, Management of Domestic Incidents, Feb 28, 2003, is available at www.whitehouse.gov. The Department of Homeland Security was created under PL 107-296, signed on Nov 25, 2002.

¹⁷ The National Strategy for Homeland Security, White House Office of Homeland Security, July 2002, available at www.whitehouse.gov/homeland.

National Guard Weapons of Mass Destruction Civil Support Teams. In 1998, in an effort to improve national readiness for biological and chemical attacks, Congress authorized the formation of 10 Weapons of Mass Destruction Civil Support Teams (CSTs). CSTs are unique in that they are federally-funded through the Department of Defense, but report to civil authorities via the governor in each state. They function as state emergency response assets. Each unit is made up of full-time National Guard members providing high-priority response capabilities in an emergency. Additional CSTs have been added, creating a total of 32 teams, with home bases distributed to provide optimal response coverage for the majority of the United States population.¹⁸

Each team is equipped with a mobile analytical laboratory for field analysis of potential biological and chemical weapons agents. Yet there has been little national coordination of activity between CSTs and LRN laboratories. This is due in part to the brief history of CSTs, the fact that they are based regionally rather than in state capitals, as state laboratories usually are, and because they are not active unless deployed in an emergency. In many cases CSTs have functioned as sentinel LRN laboratories for bioterrorism, bringing suspicious samples from their mobile response positions to the fixed-location LRN laboratories for confirmatory testing.

Since there is, at this time, no national strategy nor a national network of laboratories to analyze environmental samples for chemical weapons agents, the CSTs, with their rapid tests for a variety of chemical weapons, may serve as the only analytical assets available in the first days of an attack. The scope of their capabilities, and the reliability and validity of the methods they use, are poorly understood by the public health laboratory community. Strengthening this partnership is essential and is a recommendation from this project. Expecting CSTs to operate in a *de facto* confirmatory role because the appropriate national assets are lacking raises concerns among the public health community. Having weathered the national response to the anthrax attacks, state public health laboratory directors understand the consequences of false positive and false negative results. The means to backstop field assays with solid confirmation exists for bioterrorism testing. It does not for chemical testing.

LABORATORY WORKFORCE SHORTAGE

The specific gaps in readiness for chemical terrorism—spanning safety, testing, regulatory and jurisdictional issues—must be viewed in the broader context of an ongoing and likely worsening shortage of trained laboratory workers. Laboratory staff are stretched thin on a routine day. Yet the anthrax attacks taught that laboratory testing during a terrorist event ramps up to levels ten-fold greater, or more, than routine.

A 2001 U.S. General Accounting Office report on bioterrorism confirmed what is well-known within the public health laboratory community: that “reductions in public health

¹⁸ Testimony of Raymond F. Rees, United States Army Acting Chief, National Guard Bureau, before the Subcommittee On Terrorism, Unconventional Threats and Capabilities, House Armed Services Committee, March 13, 2003, at <http://armedservices.house.gov/openingstatementsandpressreleases/108thcongress/03-03-13rees.html>, accessed on Jul 9, 2003.

laboratory staffing and training have affected the ability of state and local authorities to identify biological agents.”¹⁹ Since this conclusion was published, state public health labs have had the benefit of supplemental funds to boost emergency preparedness, and some states labs have since created new positions for bioterrorism coordinators. But, as discussed above, until recently funds were not available for staff positions, equipment, or activities specific to chemical terrorism preparedness, and, even now, funding for chemical terrorism preparedness is quite limited.

Preparing and running a laboratory in response to terrorist events demands that a portion of the workforce be highly skilled. Yet, while staffing problems exist at all levels within the public health laboratory system, highly skilled workers are in particularly short supply. A recent APHL study found that state laboratory directors anticipate that an average of 13 vacancies in state public health laboratory director positions will emerge by 2007, with a replacement pool that current directors describe as either “not adequate” or “only marginally adequate” in size to meet future demands.²⁰

According to current directors, perhaps the most important barrier to recruiting and retaining laboratory workers is the inability to offer salaries competitive with the private sector and the federal government. Governments have not made the requisite investment in public health laboratories. There is simply no reserve public health laboratory workforce available to cope with chemical testing in the aftermath of a terrorist attack.

THE REAL STORY OF UNKNOWN HAZARDS³/₄ LABORATORIES IMPROVISING ON THE EDGE

The following actual incidents illustrate how under-resourced laboratories must improvise to respond to unknown hazards. They also show how public health laboratories are linked to public safety. Though each incident ended well, even humorously, the results could have been drastically different had the agent been toxic rather than benign. However skilled, resourceful and dedicated, laboratory professionals cannot compensate for absent or inadequate infrastructure, equipment and personnel.

Bomb at Government Building: Laboratory Workers Assume Risk

In a Western state, a bomb was left outside a government building. The bomb was safely disposed of by the HazMat team on site, but attached to it was a little vial labeled “biochem.” It appeared to contain oily water. Without knowing the identity of the liquid, safety officials didn’t permit people to re-enter the building. One state laboratory could not handle the sample; its chemical hoods were not adequate for handling potential chemical agents, such as Sarin or VX. Another state laboratory accepted the sample, but did not have, or have access to, any standard protocols or training for handling potential chemical weapons agents. Taking a great risk, that

¹⁹ Bioterrorism: Federal Research and Preparedness Activities GAO-01-915, U.S. General Accounting Office, September 2001, p 21.

²⁰ Who Will Run America’s Public Health Labs? Educating Future Laboratory Directors, Association of Public Health Laboratories February 2002, p. 22-23.

laboratory ran a preliminary screen of the sample and was able to rule out standard military agents.

If this laboratory had not been willing to risk the analysis, the FBI would have resorted to shipping the sample to the East Coast for analysis at the Army's Edgewood laboratory in Maryland.

Situations like this play out every day across the nation, and usually go well in the end because the samples are rarely found to contain chemical weapons agents. On the day that a sample is positive, laboratory workers and others may find that the risks they have taken will not have been acceptable. We have to have a better system.

Unknown Chemical: ID Via Google

A state courthouse was evacuated when a strong odor overcame a number of the occupants. A maintenance worker found an open vial of an unknown liquid in a ventilation duct, and within the hour was hospitalized with a variety of symptoms. The vial was taken to the state public health laboratory for analysis. The liquid was run on the lab's mass spectrometer, yielding a pattern describing the chemical, but the pattern didn't match any recognized at the laboratory. The state public health laboratory does not yet have access to patterns of potential chemical weapons agents, and thus could not compare the unknown chemical to any of them. Eventually the laboratory was able to identify the chemical by finding its pattern through a Google™ search on the Web. The liquid was a commercially available, concentrated skunk scent used by hunters, and apparently also by pranksters. The maintenance worker was nauseated by the strong odor but was not otherwise harmed.

This story, with its amusing outcome, could well have been different. Laboratory workers hope that on the day when the unknown vial contains the real thing, a Google™ search will not be the only national security asset at their disposal.

Unknown Hazard at Airport: Restaurant Sample Gets Results

Late one afternoon Norman Crouch, director of the Minnesota public health laboratory received an urgent call from the FBI regional coordinator for weapons of mass destruction. An incident was developing at the Minneapolis-Saint Paul International Airport, part of which was now closed due to a possible terrorist threat. An airport employee had developed a rash immediately after her skin came into contact with an oily substance leaking from an unclaimed suitcase left on a baggage carousel. A HazMat team was already on-site. The suitcase had arrived on a flight from Ethiopia and its owner, who had been quickly tracked down by the FBI, identified the creamy material as Ethiopian curry butter. Could the state lab confirm this claim? A sample of the substance was rushed to the state laboratory for analysis. Yet, while chemists could rule out the presences of certain toxicants, they could not definitively identify it; that is, until Paul Swedenborg, supervisor of the lab's organic chemistry unit, procured his own sample of curry butter from a local Ethiopian restaurant. Comparative analyses proved that the two samples were identical. Although the incident had cost the airport and its customers significant inconvenience, no one's health was at risk—this time.

PROJECT METHODS

In the fall of 2002, APHL awarded a contract to RTI International to conduct an assessment of state public health laboratory capability and capacity to respond to chemical terrorism. Logistical and technical oversight for the project was provided by a steering committee composed of APHL members, and an expert panel composed of APHL members in addition to representatives from the CDC, EPA, FBI and the Department of Defense (DoD).

In order to identify the current level of state public health laboratory preparedness for chemical terrorism, an RTI field team conducted site visits to state laboratories in Kansas, Maryland, Michigan, Utah and Washington. Information from a literature review and input from chemical/environmental chemistry experts informed development of interview and observational protocols conducted during the site visits to assess readiness gaps.

Qualitative data gathered during site visits were used to develop a Web survey of APHL's active members—the 50 states, the District of Columbia, U.S. Virgin Islands, Puerto Rico, and Guam. RTI chemists and members of the steering committee and expert panel provided substantive guidance for survey development. Topics included equipment and facilities, personnel and training, safety and security, procedures and communications, and partnering. Survey respondents included 49 states, three territories and the District of Columbia, for a 98 percent response rate.

On January 6 and 7, 2003, laboratorians from 50 states, 2 territories and the District of Columbia met in Atlanta, GA, to develop consensus recommendations for state public health laboratory preparedness for chemical terrorism. Twenty-nine laboratory directors were in attendance, as were representatives of the CDC, EPA, FBI, DoD, the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), and the Agency for Toxic Substances and Disease Registry.

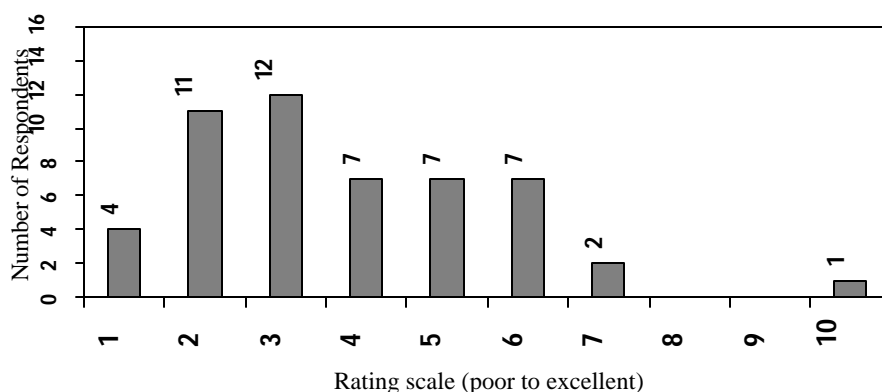
The workshop format involved an iterative process in which attendees participated in one of six facilitated topical breakout group discussions, receiving periodic updates from each of the other groups during which they could offer comments. The topics for these discussions included *Equipment and Facilities*, *Personnel and Training*, *Safety and Security*, *Procedures and Communications*, *Partnering*, and *Other (including foodborne and radiological agents)*. Each group was asked to develop a set of actionable recommendations for laboratory preparedness for chemical terrorism in their issue area. Expert panelists representing the CDC, EPA, DoD, and FBI visited each group on a rotating schedule to answer questions. At the conclusion of the workshop, the facilitators of each group presented their recommendations, and all workshop participants were given a final opportunity to ask questions and provide comments. Finally, members of the expert panel discussed, augmented and organized the recommendations, and developed a model for their integration.

SURVEY FINDINGS

When asked to rate their laboratories for their overall ability to respond to a chemical terrorism event, on a 1-10 scale, with 1 being “poor” and 10 being “excellent” . . .

HALF of state public health laboratory directors rated their laboratories at “3” or less.
(See erratum below.²¹)

Figure 1. Self-Rating of Laboratory Readiness for Chemical Terrorism



Below, other findings from the November 2002 survey of state public health laboratory (SPHL) directors are presented, which explain the basis for the pessimism reflected above, and reveal opportunities for improved readiness. Unless otherwise noted, there were 51 respondents, representing public health laboratories in 49 states, one territory and the District of Columbia (for simplicity, referred to as “states”).

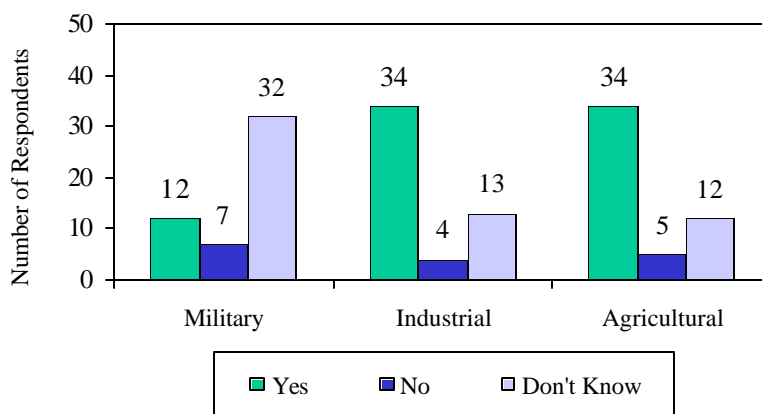
OVERVIEW

- Only eight (8) states reported having a chemical terrorism response plan in place.
- Forty-five (45) states reported that they conduct some chemical analyses on environmental samples.
- Thirty-five (35) states reported that they conduct some chemical analyses on clinical samples.
- Five (5) states reported that they do not conduct chemical analyses on either clinical or environmental samples.

²¹ Erratum: Due to a data management error, APHL reported in February 2003, that “half of state public health laboratory directors rated their laboratories at ‘2’ or less.” The correct median on the 1-10 scale is actually 3, hence the statement should read, “half of state public health laboratory directors rated their laboratories at ‘3’ or less.”

- While all states are members of the Laboratory Response Network for bioterrorism and conduct confirmatory testing for biological agents, six (6) state laboratories reported that they would rather not conduct any testing for chemical agents, but would prefer to refer all samples known or suspected of containing chemical agents to the CDC, EPA, or other agencies for testing.
- Most respondents reported that they knew of stockpiles of industrial and agricultural chemicals within state borders, but most also responded that they *did not know* if there were stockpiles of chemical weapons agents in the state. (See Figure 2.)

Figure 2. States Reporting the Presence of Chemical Stockpiles in the State



SAFETY

- Thirty-nine (39) respondents reported that their laboratories were not prepared to safely accept samples that might contain multiple hazards (e.g., a chemical *and* a biological agent).
- Twenty-five (25) of the 45 state labs that conduct chemical analyses reported that personal protective equipment is “not very adequate.” Only 6 reported that personal protective equipment is “adequate” or “very adequate.”
- Thirty-one (31) of the 45 state labs that conduct chemical analyses on environmental samples reported that staff are not trained to safely accept and handle environmental samples potentially containing unknown chemical hazards.
- Twenty-six (26) of the 35 state labs that conduct clinical specimen analysis said that staff are not trained to safely accept and handle specimens that may contain unknown chemical hazards.

WORKFORCE

- When asked about the adequacy of staffing to conduct testing during a chemical terrorism event, 38 respondents reported that they were either, “not at all adequately staffed,” or, “would require a lot of help, and experience significant delays.”
- Ten (10) states reported having five or fewer full-time chemical laboratorians on staff.
- Eighteen (18) states reported having *no* doctoral-level chemists on staff. Eleven (11) states reported having only one.
- Forty (40) of 48 respondents who have tried to recruit chemical laboratory staff said that recruitment was “somewhat” or “very” problematic.

CHEMICAL ANALYSIS

As shown in Table 2, while most states conduct chemical testing on clinical and/or environmental samples, their methods and expertise are based on those types of analyses that have traditionally had public health importance. Examples include testing for lead and certain pesticides. While most states have experience testing for a variety of these traditional, or industrial, chemicals, very few report having expertise to test for chemical weapons agents, in either clinical or environmental samples.

Table 2. State Public Health Laboratory Capabilities for Analysis of Chemical Agents

CHEMICAL AGENT	LAB ANALYZES CLINICAL SPECIMENS FOR AGENT (N=35)	LAB ANALYZES ENVIRONMENTAL SAMPLES FOR AGENT (N=45)
INDUSTRIAL CHEMICALS		
Heavy metals	28	44
Arsenic	21	41
PCBs	13	36
Pesticides (e.g. organophosphates)	10	38
Organic chemicals (e.g. VOCs)	10	40
CHEMICAL WEAPONS AGENTS		
Vesicant agents (e.g. mustards and lewisite)	4	5
Blood agents (e.g. hydrogen cyanide)	7	12
Choking agents (e.g. chlorine and phosgene)	1	7
Incapacitating agents (e.g. BZ and opioids)	3	1
Nerve agents (e.g. sarin and VX)	5	4

PROJECT CONCLUSIONS

APHL and its members, in consultation with federal experts, have developed recommendations to address its members' primary readiness goals: that state laboratories have the ability to conduct testing; that the safety of their workers and all others is assured in the process; and that states receive the funding and support they need to carry out this national security activity.

Testing Capability: The nation lacks needed laboratory capability because environmental testing methods for chemical weapons have not been developed, or are not available to the states. CDC has developed and delivered clinical testing methods. But APHL has been unable to identify a lead civilian federal agency responsible for developing methods for environmental testing to be used during a chemical weapons attack. The *Federal Response Plan* and the *White House National Strategy for Homeland Security* appear to delegate this responsibility to EPA, and EPA has the most relevant expertise to support it. In addition, while APHL understands the difficulty of ramping up a new federal agency, the association has been unable to identify any individual or program area at the Department of Homeland Security responsible for recognizing and addressing this gap.

Worker Safety: The safety of laboratorians and others is not assured under current circumstances. A number of recommendations address the development of protocols and strategies for sample collection in the field, and transport to the laboratory, to assure the safety of law enforcement personnel and other first-responders, as well as preserving sample integrity for forensic and epidemiologic investigation. Once at the laboratory, a sample must be handled, eventually, if it is to be analyzed. Since the workshop, an interagency workgroup has formed to begin responding to the project recommendation for safe and secure sample screening and processing facilities to handle unknown or mixed samples. The group has explored design standards for a modular facility, which may include robotics to perform some of the most hazardous aspects of sample preparation. APHL has asked that Congress fund this activity and that the Department of Homeland Security designate a lead federal agency for its implementation.

Federal Support for States: APHL is encouraged that in May 2003, the Department of Health and Human Services and the CDC announced that for the first time, all 50 states would receive funds to build basic chemical terrorism preparedness activities at their public health laboratories.²² Previously, CDC had been able to support only five states in developing clinical testing capability. With this year's announcement, all states can now build chemical terrorism into their response plans, develop the ability to accept and refer samples, and institute preliminary safety measures. However, current funding is inadequate to support analytical capability in all states.

APHL remains concerned that other federal agencies have not provided support for the development of environmental testing capability or comprehensive worker safety

²² Centers for Disease Control and Prevention, Continuation Guidance for Cooperative Agreement on Public Health Preparedness and Response for Bioterrorism – Budget Year Four Program Announcement 99051, May 2, 2003.

upgrades, and calls upon the Department of Homeland Security to evaluate these gaps and delegate responsibility appropriately.

Laboratory Workforce Shortage: Finally, as APHL has noted before with regard to bioterrorism preparedness, chronic shortages of skilled laboratory workers severely hamper readiness efforts.²³ There is no reason to expect this problem to be any different for chemical testing. In fact, 40 of 48 respondents to the chemical terrorism survey who have tried to recruit chemical laboratory staff said that recruitment was “somewhat” or “very” problematic. **As long as state public health laboratories are expected to provide frontline national response capability in an emergency, the federal government must work with states and with APHL to develop a comprehensive national strategy for laboratory workforce development.**

²³ APHL, Public Health Laboratory Issues in Brief: Bioterrorism Capacity. October 2002. Available at <http://www.aphl.org/docs/BTIssuebrief1.pdf>, accessed June 6, 2003.

CONSENSUS RECOMMENDATIONS FOR CHEMICAL TERRORISM PREPAREDNESS IN STATE PUBLIC HEALTH LABORATORIES, JANUARY 2003

Recommendations from the APHL Consensus Workshop are grouped into the following categories:

Create an Integrated, All-Hazards National Laboratory Network

Expand National Laboratory Analytical Capability and Capacity

- Methods and Equipment
- Personnel

Develop Standardized Protocols for Routine Operations and Emergency Response

- Worker Safety
- Laboratory Security/ Law Enforcement
- Emergency Response
- Routine Operations

Strengthen Partnerships

- Coordination
- Training

Recommendations are numbered sequentially, across categories. The first few recommendations in each section are priority recommendations, noted in bold, and also listed separately at the beginning of this section. Following each recommendation, in parentheses, are the parties to whom the recommendation is directed. These may include Congress, federal agencies, states, and APHL.

Two terms used in the recommendations have specific meanings in the context of laboratory preparedness. *Capability* denotes the ability to perform a specific service, while *capacity* denotes the quantity or volume of a service that a laboratory can carry out within a defined period of time.

PRIORITY RECOMMENDATIONS FOR LABORATORY PREPAREDNESS, JANUARY 2003

Create an Integrated, All-Hazards National Laboratory Network

1. Support the current Laboratory Response Network tiered system and expand it to include sampling, analysis, and reporting for chemical, biological and radiological testing of clinical, environmental, drinking water and food samples. (Federal, state, local governments; APHL)

Expand National Laboratory Analytical Capability and Capacity

Methods and Equipment

4. Assure that personnel in all states are able to safely conduct prescreening, packing, shipping, and referral of unknown samples, or those samples they choose to refer, for analysis by another laboratory. (Federal, state, local governments; APHL)

5. Develop national *capability* and *capacity* for chemical testing of *environmental samples*, excluding food. EPA or another lead agency designated by the Department of Homeland Security (DHS) must begin this activity. Assets to be developed include validated analytic methods, training, proficiency testing, and technology transfer to laboratories able to provide surge capacity. As recommended in #1, the existing LRN is the recommended mechanism to provide national surge capacity. (EPA, DHS, Congress)

6. Expand national *capacity* for chemical testing of *clinical specimens*, now supported by CDC in five state public health laboratories. Transfer technology for analysis of more agents to more states to assure sufficient national capacity in an event. Bolster support for methods development and technology transfer programs at CDC, including enhanced staffing. (CDC, SPHLs, Congress)

7. Expand EPA's evaluation program for field and rapid screening devices, and communicate findings to public health laboratories and other stakeholders. (EPA, Congress)

Personnel

11. Designate a chemical terrorism laboratory coordinator in each state, with expertise in safety and security; sample collection and preservation methods; incident command; relevant state and federal laws and regulations, including certification standards for the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and hazardous materials, Department of Transportation and the International Air Transport Association shipping regulations; and media and public relations. (SPHLs, with federal support)

Develop Standardized Protocols for Routine Operations and Emergency Response

Worker Safety

16. Treat *all* unknown samples as mixed hazards until proven otherwise. (Federal, state, local governments; APHL)
17. Provide all state public health laboratories with safe and secure sample screening and processing facilities to handle unknown or mixed samples. Modular or freestanding facilities should be considered. Facilities must provide all-hazards worker protection, prevent radiological, bacterial or chemical contamination of the laboratory, and protect personnel and the laboratory in the event of an explosion. Federal funds for construction of these facilities must be made available to states. (DHS, Congress)
18. Develop national guidance for chemical laboratory safety and security for state and local laboratories, comparable to the manual *Biosafety in Microbiological and Biomedical Laboratories* for handling microbial agents. (CDC)

Laboratory Security/ Law Enforcement

22. Determine restrictions on facility access based on the threat posed by unauthorized access to protocols and equipment, and theft of reagents and samples. Relevant federal agencies should work in consultation with states to develop and define levels of access in laboratories conducting analyses on agents of chemical terrorism. (FBI, CDC, EPA, states)

Emergency Response

28. Determine and document chains-of-command and triggers for emergency response to a chemical terrorism event; determine what events result in a response action, and which party is in charge of specific components of the response. Local and state public health officials, law enforcement personnel, HazMat personnel, National Guard Civil Support Team officials and other parties should draw up memoranda of understanding prior to events. (States and FBI, in consultation with other agencies and APHL)

Routine Operations

31. Establish relationships and develop protocols for sample collection and handling among public health workers, first responders and law enforcement personnel, to assure safe sample handling, preservation of forensic and epidemiologic evidence, and documentation of chain-of-custody. (Federal, state, local governments, APHL)

Strengthen Partnerships

Coordination

36. Assure funding support for inter-jurisdictional planning and coordination activities for chemical terrorism. Funding should be dedicated and kept separate from corresponding administrative, epidemiologic, and other coordinating activities. Assure that planning and coordination activities operate horizontally (i.e., among first responders, SPHLs, hospital laboratories) and vertically (i.e., among local, state, federal partners). (Congress, CDC, EPA, state governments, APHL)

Training

44. Train first responders in the roles, responsibilities and resources of all local, state and federal partners involved in a laboratory response, and on the policies and procedures governing the deployment of the Laboratory Response Network. (SPHLs, with federal support, APHL)

45. Train first responders and law enforcement personnel in field sample collection and transport protocols, taking into account safety of personnel all along the sample route, preservation of sample integrity, preservation and documentation of the chain-of-custody, and other relevant matters. (SPHLs, with federal support, APHL)

46. Train first responders and law enforcement personnel in the uses and limitations of field-testing devices, including quality assurance and quality control principles, results of any federal evaluations or certification of field technologies, risk assessment and other guidance documents, and other relevant matters. (SPHLs, with federal support, APHL)

COMPLETE LISTING OF RECOMMENDATIONS FOR LABORATORY PREPAREDNESS, JANUARY 2003

Create an Integrated, All-Hazards National Laboratory Network

- 1. Support the current Laboratory Response Network (LRN) tiered system and expand it to include sampling, analysis, and reporting for chemical, biological and radiological testing of clinical, environmental, drinking water and food samples.** (Federal, state, local governments; APHL)
2. Include in the LRN all federal agencies that support laboratory capability for response to a hazard. (CDC, EPA, FDA, USDA Food Safety and Inspection Service, DoD, FBI, national laboratories)
3. Collect and maintain relevant information on all laboratories in the network, including analytical capabilities, capacity, type and level, location, routine and emergency contact information, etc. (LRN Working Group)

Expand National Laboratory Analytical Capability and Capacity

Methods and Equipment

4. **Assure that personnel in all states are able to safely conduct prescreening, packing, shipping, and referral of unknown samples, or those samples they choose to refer, for analysis by another laboratory.** (Federal, state, local governments, APHL)
5. **Develop national capability and capacity for chemical testing of environmental samples, excluding food. EPA or another lead agency designated by the Department of Homeland Security must begin this activity. Assets to be developed include validated analytic methods, training, proficiency testing, and technology transfer to laboratories able to provide surge capacity. As recommended in #1, the existing LRN is the recommended mechanism to provide national surge capacity.** (EPA, DHS, Congress)
6. **Expand national capacity for chemical testing of clinical specimens, now supported by CDC in five state public health laboratories. Transfer technology for analysis of more agents to more states to assure sufficient national capacity in an event. Bolster support for methods development and technology transfer programs at CDC, including enhanced staffing.** (CDC, SPHLs, Congress)
7. **Expand EPA's evaluation program for field and rapid screening devices, and communicate findings to public health laboratories and other stakeholders.** (EPA, Congress)
8. Support FDA and USDA efforts to expand *capability* and *capacity* for chemical testing of foods. (Congress, FDA, USDA Food Safety and Inspection Service)

9. Provide, in conjunction with technology transfer programs, appropriate ancillary support to states, including quality assurance, proficiency testing, and expert consultation programs. (Congress, DHS, CDC, EPA, FBI, national laboratories)
10. Develop accreditation programs for laboratories conducting military chemical weapons testing. (CDC, EPA, in consultation with states, APHL)

Personnel

- 11. Designate a chemical terrorism laboratory coordinator in each state, with expertise in safety and security; sample collection and preservation methods; incident command; relevant state and federal laws and regulations, including certification standards for the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and hazardous materials, Department of Transportation and the International Air Transport Association shipping regulations; and media and public relations.** (SPHLs, with federal support)
12. Assist public health laboratories in meeting personnel needs. Federally supported grants, scholarships, fellowships and service agreements are means to expand the available state laboratory chemistry workforce. Federally supported continuing education opportunities and full-time equivalent homeland security positions in state laboratories are means to retain qualified staff. (Congress, DHS, other federal agencies, APHL)
13. Designate a communications lead for chemical terrorism events in each state. (SPHLs)
14. Build additional chemical terrorism capability and capacity in some states with personnel skilled in analytical chemistry, medical technology, liquid chromatography/ mass spectroscopy, manufacturing and preventive maintenance, good laboratory practices, and other skills as methods are developed. (SPHLs, with federal support)
15. Maintain staffing levels necessary to provide critical mailroom, shipping and administrative functions. (SPHLs, with federal support)

Develop Standardized Protocols for Routine Operations and Emergency Response

Worker Safety

- 16. Treat all unknown samples as mixed hazards until proven otherwise.** (Federal, state, local governments, clinical laboratorians, first responders, APHL)
- 17. Provide all state public health laboratories with safe and secure sample screening and processing facilities to handle unknown or mixed samples. Modular or freestanding facilities should be considered. Facilities must provide all-hazards worker protection, prevent radiological, bacterial or chemical contamination of the laboratory, and protect personnel and the laboratory in the event of an explosion.**

Federal funds for construction of these facilities must be made available to states.
(DHS, Congress)

- 18. Develop national guidance for chemical laboratory safety and security for state and local laboratories, comparable to the manual Biosafety in Microbiological and Biomedical Laboratories for handling microbial agents.** (CDC)
19. Develop national guidance for field triage, screening and handling of suspected chemical terrorism samples, including proper procedures to screen for or protect against radiation, biological, chemical, toxic, explosive, and flammable hazards, as well as for transport, handling and storage of samples in laboratories. (LRN Working Group)
20. Develop state-specific procedures and algorithms for field triage, screening and handling of suspected chemical terrorism samples, as above, expanded and tailored to each state's specific needs and circumstances. (SPHLs, with federal and APHL support)
21. Develop state-specific written procedures for sample intake. Sample intake procedures should address risk and vulnerability assessments from the point of collection through receipt at the laboratory. Those assessments should include knowledge of the screening tools used at the point of collection. (SPHLs, with federal and APHL support)

Laboratory Security/ Law Enforcement

- 22. Determine restrictions on facility access based on the threat posed by unauthorized access to protocols and equipment, and theft of reagents and samples. Relevant federal agencies including FBI, CDC and EPA should work in consultation with states to develop and define levels of access in laboratories conducting analyses on agents of chemical terrorism.** (FBI, CDC, EPA, states)
23. Conduct criminal background checks on employees with access to restricted areas. Deny unescorted access to other parties. (States, with FBI support)
24. Provide federal "secret" clearance to at least two state laboratory employees who have access to the laboratory conducting analyses on agents of chemical terrorism. (DHHS)
25. Develop written chain-of-custody procedures for handling suspected threat items in all laboratories. Have procedures reviewed by relevant law enforcement officials. (SPHLs, in consultation with federal, state and local law enforcement agencies, APHL support)
26. Coordinate activities of FBI with CDC, EPA, and states in developing risk assessment protocols for a spectrum of situations. (FBI, CDC, EPA, states, APHL)
27. Perform facility security risk assessments using qualified consultants/ evaluators. (SPHLs)

Emergency Response

28. **Determine, document and agree on chains-of-command and triggers for emergency response to a chemical terrorism event; determine what events result in a response action, and which party is in charge of specific components of the response. Local and state public health officials, law enforcement personnel, HazMat personnel, National Guard Civil Support Team officials, and other parties should draw up memoranda of understanding prior to events.** (States and FBI, in consultation with other agencies and APHL)
29. Develop written procedures with local police/fire/HazMat on the level of response to the facility in the event of natural disasters or intentional acts, including fire, explosion, collapse, or contamination. Local first responders must be familiar with building layout and storage of all potentially hazardous materials, including biological and chemical weapons agents, and reagents and supplies that may be volatile, explosive, toxic, or otherwise hazardous. (SPHLs, local first responders, with APHL support)
30. Amend current state emergency preparedness and response plans to reflect laboratory involvement, including: 1) a pre-event risk communication plan designating a trained public information officer, a process of clearance and communication of laboratory results to specific parties, a means of secure communications, and protocols for production of audience-specific communications materials; 2) a contingency plan for continued chemical terrorism testing if the laboratory is disabled, relying on a neighboring state or other suitable laboratory for back-up; and 3) a personnel management plan to provide round-the-clock analytical support. (SPHLs, with APHL support)

Routine Operations

31. **Establish relationships and develop protocols for sample collection and handling among public health workers, first responders and law enforcement personnel, to assure safe sample handling, preservation of forensic and epidemiologic evidence, and documentation of chain-of-custody.** (Federal, state, local governments, APHL)
32. Develop algorithms to guide activities in all stages of laboratory response: pre-analytical (field evaluation, sample collection and delivery), analytical (sample intake, analysis, storage and disposal) and post-analytical (reporting of results, follow-up). Create flowcharts and other tools to support educational activities. (LRN Working Group)
Algorithms must consider:
 - Worker safety
 - Sample integrity, sample volume and analytical needs (when multiple testing is required, including forensics and higher-level chemical characterization)
 - Chain-of-custody and evidence handling
 - Screening and confirmatory testing schemes to rule out and rule in agents
 - Qualitative vs. quantitative analysis
 - Reflex testing

- Turnaround time
 - Surge capacity, contingency plans and continuity of operations
33. Periodically assess state public health laboratory capability and capacity for chemical terrorism preparedness and response according to existing recommendations, guidance and benchmarks. (APHL, CDC)
 34. Develop consistent specifications for each type and level of laboratory, addressing: facilities, methods, equipment, proficiency testing, safety, security, design, containment, storage and disposal. (States, with support from APHL and federal agencies)
 35. Develop consistent standards for secure electronic data management including formatting, storage, transport, and communication. (States, with support from APHL and federal agencies)

Strengthen Partnerships

Coordination

- 36. Assure funding support for inter-jurisdictional planning and coordination activities for chemical terrorism. Funding should be dedicated and kept separate from corresponding administrative, epidemiologic, and other coordinating activities. Assure that planning and coordination activities operate horizontally (i.e., among first responders, SPHLs, hospital laboratories) and vertically (i.e., among local, state, federal partners).** (Congress, DHS, CDC, EPA, state governments, APHL)
37. Coordinate chemical terrorism preparedness plans and activities across state and national borders, and with sovereign entities, such as American Indian tribal nations. (States, with APHL support)
38. Define relationships between SPHLs and first responders (HAZMAT, CST, and other field response personnel) in a chemical terrorism event, and incorporate first responders' activities in the state's chemical terrorism response plan. (States, with APHL support)
39. Consider the role of hospital, clinical, environmental and other laboratories in chemical terrorism response. Develop policy and agreements governing these labs' role in providing elements of surge capacity as deemed appropriate. (States, with APHL support)
40. Leverage chemical terrorism preparedness activities with existing assets, such as National Guard Civil Support Teams and the National Laboratory Training Network. (States, with APHL support)
41. Designate and assign a liaison position to APHL to facilitate planning and coordination of activities that require inter-state consistency, such as deployment of the Laboratory Response Network, in a chemical terrorism event (DHS).

42. Define the roles, responsibilities, resources and contact information for key federal partners involved in a laboratory response to a chemical event. Document and disseminate this information to key stakeholders. Expand this activity over time to reflect the laboratory response to all hazards. (LRN Working Group)
43. Develop a tool for state public health laboratory directors to document roles, responsibilities, resources and contact information for key state and local partners involved in a laboratory response to a chemical terrorism event. Expand this effort over time to reflect the laboratory response to all hazards. State public health laboratory directors, serving as Laboratory Response Network gatekeepers for all non-federal laboratory assets in their state, are the leaders in coordinating these in-state assets during a laboratory response. (APHL)

Training

- 44. Train first responders in the roles, responsibilities and resources of all local, state and federal partners involved in a laboratory response, and on the policies and procedures governing the deployment of the Laboratory Response Network.** (SPHLs, with federal support, APHL)
- 45. Train first responders and law enforcement personnel in field sample collection and transport protocols, taking into account safety of personnel all along the sample route, preservation of sample integrity, preservation and documentation of the chain-of-custody, and other relevant matters.** (SPHLs, with federal support, APHL)
- 46. Train first responders and law enforcement personnel in the uses and limitations of field-testing devices, including quality assurance and quality control principles, results of any federal evaluations or certification of field technologies, risk assessment and other guidance documents, and other relevant matters.** (SPHLs, with federal support, APHL)

