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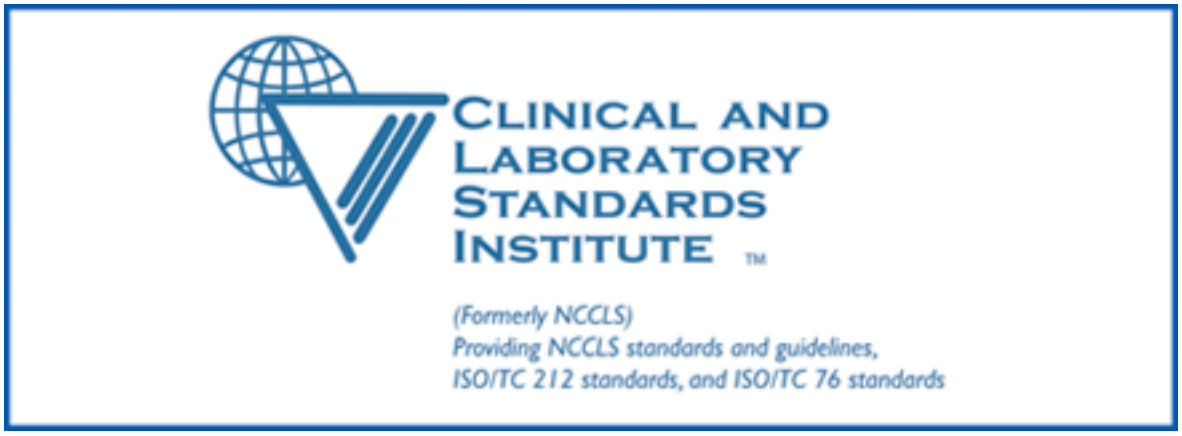
Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report



This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency.

An NCCLS report for national application.

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Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

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Abstract

NCCLS document X4-R—*Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report* was written for use by laboratory managers, directors, and supervisors, and is intended to provide a checklist of considerations to be used to assess preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations. Emergency situations that are associated with large numbers of injured or dead (which will require an acute demand for laboratory services) may also result in catastrophic disruptions in laboratory services. The emergency may be associated with a variety of very different causes: natural, accidental, or terroristic. In each case, emergency operational procedures are necessitated by loss or degradation of infrastructural elements, upon which routine laboratory operations are dependent. Sample infrastructural insults include: interrupted access to utilities (electrical power, clean water, and refuse disposal), climate control, transportation of clinical specimens, and electronic test ordering and reporting. In both natural and man-made disasters, including events such as hurricane, flood, earthquake, and explosion, it is likely that more than one infrastructure element will be lost. In other instances, including accidental or terroristic exposure to infectious, chemical, or radiological agents, it is likely that utility infrastructure will remain operational, but there may be breakdowns in system components, possibly including quality assurance for clinical specimen testing and reporting, as well as reporting public health issues. All of these issues are complicated by the possibility that some laboratory staff may be unable or unwilling to report to work.

This report is written in an expanded checklist format. It outlines the important considerations laboratory professionals must make to identify infrastructure and systems that may be at risk of failure during natural and man-made disasters.

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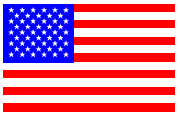

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Report

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Contents

Foreword

Recent events have dramatically worsened our perceptions of the likelihood, severity, and types of emergencies to which our communities and healthcare resources may be susceptible. While the laboratory capacity to perform emergency clinical and public health testing has received considerable attention, proportionately little guidance has addressed the logistical, nonanalytic challenges of laboratory operation during large-scale disasters. This document seeks to reasonably balance concepts and completeness, in an effort to urgently field information specifically addressing logistical (nonanalytic) challenges of laboratory operations during an emergency of very large scale. Users of this document are apprised that the challenges it seeks to address are, above all, evolving. National, state, local, and facility emergency response plans and infrastructures are presently under intense scrutiny and revision. Given the complexity of the "emergency response" topic, deficiencies in this limited report are inevitable. The authors and reviewers hope the contents are found useful to laboratorians in considering and planning for these challenges wherever they live and work.

Key Words

Communications, disaster, local emergency operations plan, preparedness, public health, terrorism

Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report

1 Scope

This guide provides direction for assessing nonanalytic (operational) system components of both clinical and public health testing that may be impaired or at risk of failure in various natural and man-made disasters. Although certain aspects of the report focus upon emergency operational challenges confronting hospital-based laboratories, guidance for clinical laboratories residing in physicians' offices, medical centers, and reference (independent) laboratories is also provided. With this document, these institutions have a framework to implement a team responsible for reviewing the infrastructures that support both clinical and public health laboratory testing and result reporting. System components that may be affected include:

- test ordering and receipt by the laboratory/phlebotomy team
- patient specimen acquisition and identification
- computer functions
- specimen transportation to the laboratory
- staffing
- analysis
- test result reporting
- reagents and supplies
- usual internal institutional partners for testing support
- test referral, specimen packaging and transportation, and communication to external reference laboratories
- reporting tests of public health importance
- transportation of isolates for public health testing
- communication with the public health laboratory for epidemiologic surveillance
- morgue operations

2 Introduction

Recent events have emphasized an urgent need to expand laboratory, facility, community, state, and national preparedness to include realistic considerations of the types and magnitudes of emergency incidents heretofore thought impossible. Although beneficial, intense planning is proceeding within the government, law enforcement, public safety, public health, and medical sectors, this document seeks to recognize and address those preparedness and operational challenges unique to the clinical laboratory. Both detrimental and beneficial potential effects related to the clinical laboratory's relationship with selected aspects of local community disaster planning are also explored.

Disaster planning and preparedness requires dedicated people, time, and money. Of these three, the first is by far of greatest importance. It is important to understand that much can be accomplished collaboratively and/or voluntarily without direct resource expenditures. For example, virtually expense-free backup emergency communications systems are possible in cooperation with local volunteer communicators using their own equipment. Networking among the participants and potential stakeholders (to be described in this document) during plan development ensures a robust and flexible plan, and also enhances aspects of routine clinical laboratory practice, such as relationships with local public health personnel.

Funding will be required at most facilities to achieve suitable preparedness. While the situation is evolving, funding for hospital and laboratory preparedness may be available through state health

departments (via the Centers for Disease Control and Prevention [CDC] and the Health Resources and Services Administration). All states have bioterrorism advisory committees and hospital planning and preparedness committees, which are currently active in interfacing community hospitals and clinical laboratories with their state health departments to help develop response plans and acquire funding. The future status of the Metropolitan Medical Response System, which has contracted to provide funds for emergency medical response enhancements to many cities where weapons of mass destruction could pose a threat, is uncertain at the time of publication. Local community businesses and other resources may also be available to help communities prepare for emergency medical response.

3 Definitions

Alternate care facility – A nonhospital facility which assumes the function of outpatient, urgent, or inpatient care during an emergency to promote expansion of community bed capacity.

Biosafety level 2 (BSL-2) – Practices, equipment, and facility design and construction that are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.[a]

Biosafety level 3 (BSL-3) – Practices, safety equipment, and facility design and construction that are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.[a]

Civil air patrol (CAP) – An organization congressionally charted to assist the Air Force and federal, state, and local agencies with emergency assistance; operations include humanitarian/disaster missions employing general aviation aircraft for transportation of important cargo, including medical supplies and blood; **NOTES:** a) The Air Force Auxiliary, Civil Air Patrol, is composed of 61,000 volunteers in 1,700 communities nationwide, organized as 52 Wings (states/territories) and Squadrons (local); b) CAP contact may be provided in the LEOP in your community; c) Information may be accessed at: www.capnhq.org.

Covert incident – An event intrinsically unrecognizable as life threatening at inception; **NOTE:** For example, an infectious bioterrorist attack is usually covert, thus denying the exposed population prophylaxis.

Critical incident stress management (CISM) – A product of the International Critical Incident Stress Foundation, Inc.; **NOTE:** ICISF is a non-profit, open membership foundation dedicated to the prevention and mitigation of disabling stress through the provision of: education, training and support services for all Emergency Services professions, which also provides consultation in the establishment of Crisis and Disaster Response Programs for varied organizations and communities worldwide. Information is available via: www.icisf.org.

Disaster – A state of a community threat to life and property of unusual magnitude; **NOTES:** a) For the purposes of this document it is assumed that the disaster is of great magnitude, likely to be associated with a large number of injured, contaminated, or dead; b) Synonymous with "incident" or "event" in this report.

Disaster mortuary operations team (DMORT) – A multidisciplinary forensic team which, with necessary support equipment, can be deployed to assist in the investigation of a mass fatalities incident;

[a] From *Biosafety in Microbiological and Biomedical Laboratories*. U.S. Department of Health and Human Services; Public Health Service, Centers for Disease Control and Prevention; and National Institutes of Health. 4th ed. May 1999 (Stock number: 017-040-00547-4).

NOTES: a) DMORT operates under the auspices of NDMS and can be activated under several legal authorities; b) DMORT is accessed by the local medical examiner/coroner through a request to their EMA.

Emergency alert system (EAS) – Created in 1994 to replace the Emergency Broadcast System, the EAS can be used by the President and others to warn the public about emergency situations; **NOTES:** a) The EAS is composed of broadcast networks; cable networks and program suppliers; AM, FM, TV broadcast stations; the National Weather Service, FEMA, and other entities and industries operating on an organized basis during emergencies at the National, State and local levels; b) The "This is a test of the Emergency Alert System" messages, occasionally heard on electronic media outlets, identify EAS test messages; c) Information may be accessed at: www.fcc.gov/eb/eas.

Emergency management agency (EMA) – Agency responsible for coordinating response to any type of emergency within its jurisdiction; county, state, or national (www.fema.gov).

Emergency operations center (EOC) – A community, county, or state command center which, when activated, centralizes and protects leadership responsible for coordinating a disaster response.

HIPAA – The acronym for the Health Insurance Portability and Accountability Act of 1996; **NOTE:** The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II) require the Department of Health and Human Services to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addresses the security and privacy of health data.

Hot zone – The site of an overt incident of any type.

Incident command system – A type of command structure specifically useful for management of emergency operations[b]; **NOTE:** A proven, useful resource for hospital incident planning is the Hospital Emergency Incident Command System (HEICS) which is in its third edition. Information may be accessed at: http://www.emsa.ca.gov/dms2/download.htm.

Local emergency operations plan (LEOP) – A plan outlining emergency response guidelines for relevant agencies and entities affecting a robust response to any emergency; **NOTE:** Response plans are integrated and identified by jurisdictional authority; e.g., State Emergency Operations Plan (SEOP). The LEOP may be available online, via the local government's website.

Memorandum of understanding (MOU) – A written agreement to provide cooperation between two agencies or entities during a disaster incident; **NOTE:** MOUs are very commonly made and updated between relief, public service, medical and other organizations to assist coordinated disaster community response.

National disaster medical system (NDMS) – A cooperative asset-sharing program among Federal government agencies, state and local governments, and the private businesses and civilian volunteers to ensure resources are available to provide medical services following a disaster that overwhelms the local healthcare resources.

Overt incident – An event intrinsically recognizable as life threatening at inception; for example, a bomb detonation or explosion.

[b] From the *Hospital Emergency Incident Command System (HEICS) Manual*, Version 3. Reprinted with permission from the California Emergency Medical Services Authority.

Strategic national stockpile (SNS) – Large (approximately 150,000 lbs.), strategically-located caches of medical supplies and pharmaceuticals, designed for rapid airborne deployment to domestic sites suffering a major disaster, within 12 hours of formal request; **NOTES:** a) Synonymous with "pushpack;" b) This term supercedes "National Pharmaceutical Stockpile." (http://www.dhs.gov/dhspublic/display?theme=15&content=327)

Surge capacity – In the context of this document, the reserve ability to conduct testing in a situation when normal laboratory functions are overwhelmed, so as to compromise testing accuracy and/or timeliness; **NOTES:** a) It is implied that such testing would be shifted to another site(s) outside the institution; however, surge capacity may also exist within the institution; b) For clarity, surge capacity is best used to define reserve ability for a specific test (or tests), but can also be used in the general sense; c) The term implies that there is mutual understanding between testing facilities such that specific conditions are defined, including the sharing of testing equipment, reagents, and/or testing personnel.

Surveillance – Systems or approaches to analyzing individual patient or collective laboratory or symptomatic data to permit early detection of an unusual type, number, or cluster of syndromes or diseases; **NOTE:** Approaches which rely upon symptoms are called "syndromic" surveillance, and those which rely upon agent identification, e.g., culture results, are "traditional" surveillance.

Terrorism – The unlawful use of force and violence against persons or property to intimidate or coerce a government, the civilian population, or any segment thereof, in furtherance of political or social objectives. (www.fema.gov/hazards/terrorism/)

Trunked communications system – A computer-controlled radio system which provides highly reliable, flexible, and often secure voice communications options to large numbers of governmental and public service users; **NOTE:** Such systems are current state of the art for local, regional, or state law enforcement, fire, and medical emergency communications.

Weapons of mass destruction (WMD) – Nuclear, biological, chemical, or radiological agents, capable of production of mass fatalities and casualties if effectively deployed.

4 The Environment of Response to Disasters

A disaster of any type typically inflicts community-wide disruptions, and requires, fundamentally, a community-level response. Because clinical laboratories are highly technical, communicative, and human resource dependent entities, any disaster may alter or disrupt the community relationships and services which ordinarily sustain daily operations. Some of the resulting operational challenges are unique to clinical laboratories, while others are not. Furthermore, the community response itself may inadvertently amplify the challenges of emergency operations, especially for the unprepared. Thus, it is important that laboratory leadership seek an understanding of the larger community and facility emergency response environment in which they coexist.

4.1 Categories of Incidents

Natural and terroristic disasters harm people and/or property through a limited number of mechanisms, which can be roughly simplified into two very different incident profiles. Correspondingly, the laboratory's and laboratorians' roles are very different in these different types of events:

- An *overt incident* manifests as a sudden catastrophic event, at a localized site or "hot zone." Property damage may occur, and the victims are immediately and obviously injured. An explosion or bomb detonation is a type of overt incident. Laboratory staff is principally responsible for supporting the

clinical medical response to trauma, chemical exposure, or other potential insults affecting a surge of presenting victims.

- A *covert incident* is classically represented by dispersal or spread of an infectious agent. Victims present over time, potentially at many geographically disparate sites. Early incident detection and epidemiology will be difficult. Laboratorians in this situation have a unique role in both incident recognition and agent identification.

Additional simplified attributes of overt and covert incidents are presented in Table 1.

Table 1. General Categories of Incidents

	Overt	**Covert**
Incident detection	Obvious	Difficult
Incident evolution	Minutes to hours	Days to weeks
Public health surveillance	Irrelevant for detection	Essential for detection
Early detection and response	Law enforcement, fire, rescue personnel	Laboratorians, healthcare workers
Weaponry may include	Explosive, chemical, nuclear detonation	Infectious agent, nuclear agent dissemination
Principal challenges	Immediate and large-scale victim extraction, potential decontamination, and immediate treatment. Psychological support to victims' families and the community.	Surveillance and detection, public health communications and prophylaxis, potential health system expansion for mass care for numerous victims.
Examples of recent incidents	World Trade Center, New York City; Alfred P. Murrah Federal Building, Oklahoma City; Hurricane Andrew; urban tornado; earthquake	Anthrax release, Washington, D.C.

4.2 The Responding Community

All laboratories exist within communities. Events directly and indirectly associated with the disaster will affect the community. Detrimental impact on routine laboratory operations may result.

Following a disaster declaration, the local emergency operations plan (LEOP) will be activated. The LEOP details central command and control authority and location (usually within an emergency operations center [EOC]), as well as myriad details describing cooperative agreements (memoranda of understanding [MOUs]) and responsibilities for responding agencies and entities, including medical facilities.

The effects upon routine laboratory operations will vary, depending upon the scale and nature (overt, covert, specific type) of the incident. Potential challenges and responses include:

- **Delay or inability of staff to report for work**

  Emergency responders or travel restrictions imposed by law enforcement bordering an incident site may disrupt usual traffic flows and transit services. Public transit resources may be redirected from routine operations by emergency management to service emergency transportation needs.

- **Disrupted ability to provide extra-facility services**

  Phlebotomy and courier services for nursing homes, clinics, and community may suffer interruption due to vehicular traffic restrictions. Furthermore, to permit community expansion of care, nursing homes may have MOUs with emergency agencies by which they alter routine operations and accept and care for appropriate transfer patients or casualties. Clinics may have MOUs agreeing to cease routine operations and convert to other functions, such as acute care facilities, to support the community disaster response.

- **Requests or direction to assist staffing in other facilities**

  Local facilities may request support from each other, either extemporaneously or in cooperation with preexisting local emergency plans. Local emergency medical operations may also direct and identify a single, central site to process assisting medical personnel — providing security clearance, identification, credentialing, and other staff support needs. State governments either have now, or are developing, authority to direct healthcare workers to care for the public during emergencies of large magnitude. State and health system facility credentialing is currently under national, state, and local review, with the intent of promoting seamless and legal interstate and cross-facility emergency professional support. These operational plans enable the personnel surge capacity necessary for support of a large-scale disaster response.

- **Requests or direction to share supplies with other facilities**

  The local community disaster plan may implement previously agreed upon staffing within emergency management (EOC) to direct optimized distribution of medical supplies in an emergency. Facilities with depleting supplies may make direct requests of other local facilities. Some facilities may have made arrangements for backup supplies. Refer to the facility emergency plan.

- **Requests or direction to provide assistance to first responders**

  Depending upon the nature of the disaster and the potential need to test for biological agents or indicators of chemical or radiological exposure among patients, the clinical laboratory may be called upon to provide advice, assistance, or supplies to responders in the field. Therefore, the clinical laboratory should have protocols in place for how to respond. For all ambiguous situations when specimen stability and transportation are unclear, the response plan should, at a minimum, include consultation by the clinical laboratory with the state public health laboratory before advice is shared with the field responders. The plan should also specify who it is that will communicate with the field; one source of information is preferred. The response plan could also include the option of directing the caller to the state public health laboratory for advice. The clinical laboratory may also elect to provide various levels of field assistance or possibly referral to a laboratory closer to the field response team. The state public health laboratory can locate the laboratory closest to the site using the National Laboratory Database.

- **Communications by pre-established wireless or Internet emergency systems**

  In a disaster, local community and facility emergency communications systems will be staffed. They will function during the emergency, and in the event of failure of routine communications systems, will shoulder substantial communications responsibilities for local facilities. The simplest emergency communications system model employs radio operators at a previously identified facility location to whom messages or inquiries can be directed verbally or in writing. Refer to Section 5. The Internet may work, especially if not dependent on telephone service. Public media or EAS systems may provide the community or responders with supplemental communication.

- **Facility cohorting**

  Public health and emergency authorities may direct persons with a specific disease to be cared for exclusively at selected local facilities. For example, one hospital may be designated as the principle care facility in a smallpox outbreak, permitting more effective patient isolation and care by previously vaccinated health personnel drawn from community-wide sites.

- **Mobilization and transfer of healthier patients before an influx of casualties**

  Emergency authorities may activate the National Medical Disaster System (NDMS) in order to assist in triage and transport, and to maximize bed capacity and care regionally or even nationally.

It is often stated, "All disasters are local." For the first 72 hours, the laboratory and local community are primarily on their own. One to three days following a major incident, national resources (potentially including medical [disaster medical action team]; pharmaceutical [Strategic National Stockpile]; and mortuary [disaster mortuary team], as well as other regional and national assets) will begin to arrive.

4.3 The Responding Hospital[c]

Hospital and medical personnel are invariably enveloped in any disaster, but especially those that involve mass casualties. The local hospital's routine facility operations will change dramatically to respond to the simultaneous challenges of potential mass care of the injured and sick; enhanced security and safety; triage; decontamination; continuation of baseline services; and possibly loss of utilities and communications, which may accompany a major disaster. While different facilities will respond in individualized ways, a common portrait can be offered.

- Facility control would assume a centralized command structure, and the facility disaster plan would be activated.

- Security assumes a principal role, to protect patients and healthcare personnel from uncontrolled and potentially contaminated public access, as well as the public from contagious hospitalized patients.

- Facilities could experience "lock down" with controlled access and designated triage areas for victim severity assessment and decontamination (usually proximate to emergency care areas). The latter is necessitated as many victims or potentially exposed (to chemical or infective agent) persons will self-transport and present for care or evaluation. The number of "worried well" (fearful but unexposed) persons would dwarf the number of true victims, constituting a substantial crowd management challenge.

- Public health messages directing the public to alternative evaluation sites would help alleviate crowd control problems. See: Definitions, "EAS" and Section 4.2.

- Ordinary employee access and parking may be obstructed or prohibited.

- Healthcare professionals from other facilities and communities could arrive to assist the local facility, and would require appropriate and timely completion of security identification, credentialing, and procedural training. See Section 4.2.

- Physical and mental health support of all staff assume importance in sustaining the emergency response and helping staff emerge holistically from it long term.

[c] From *Hospital Emergency Incident Command System (HEICS) Manual,* Version 3. Reprinted with permission from the California Emergency Medical Services Authority.

- Very early in the incident, the hospital will need to temporarily suspend routine clinic operations, in order to redirect healthcare personnel to the emergency response.

According to Joint Commission on Accreditation of Healthcare Organizations (JCAHO), components of the hospital emergency management plan should address four phases of emergency management activities: mitigation, preparedness, response, and recovery. These phases are specified in "Hospital Accreditation Standards," E.C.1.4 (Environment of Care).[d] These plans, paraphrased as follows, should include processes for:

- identifying hazard specific procedures;
- plan initiation;
- coordination with community plans;
- notification of external authorities and personnel;
- facility staffing;
- management of patients;
- management of staff (including housing, transportation, incident stress debriefing);
- management of public relations;
- assurance of critical supplies;
- alternative means of meeting essential hospital utilities (water, gas, electricity, ventilation, fuel sources, medical gas/vacuum systems);
- decontamination and isolation facilities for chemical or radiological agents;
- backup internal and external communications in the event of failure during emergencies; and
- alternate roles and responsibilities of personnel during emergencies, as well as an established command structure.

JCAHO stipulates there should be processes to manage facility evacuation and establishment of alternative care sites, with support of care processes at such sites. Also, orientation and education programs for participating personnel and ongoing monitoring of performance is stipulated.

Usually, all of these unique challenges of a hospital disaster response can be best met when leadership adopts the incident command system model. This command structure has been widely implemented by community fire and law enforcement. A version specifically addressing hospital response, the Hospital Emergency Incident Command System (HEICS) plan, now in its third edition, is an excellent reference, and has proven worth as a response asset. It provides: predictable and common command terminology, structure and roles; flexible and efficient deployment of personnel and resources as dictated by the scope of a given emergency; and prescripted job roles and checklists which describe duties and provide documentation and accountability. The HEICS plan specifically assigns laboratory personnel leadership roles, overseeing clinical laboratory and morgue support activities.
(www.emsa.cahwnet.gov/dms2/history.htm)

4.4 The Role of Public Health During a Disaster

In the event of a disaster, the duty of public health officials (potentially including state, city, and/or county or even Federal health officers and epidemiologists) will be to assure that the number of future casualties is limited. These officials may want to know details concerning individual patients and casualties, and in some cases they may want samples and microbial isolates for further testing. Interaction with these public health officials may be perceived as a distraction to laboratorians whose

[d] © Joint Commission Resources: *CAMPCLS: 2002 – 2003 Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services.* Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations. 2002:EC-9. Modified with permission.

priority it is to treat surviving patients. Their assistance, however, will be critical to protecting the public health.

In anticipation of this need, institutions should predesignate specific staff to interact with public health officials. Every laboratory should establish lines of communication with the appropriate institutional officials. The National Association of County and City Health Officers (NACCHO) and Centers for Disease Control and Prevention (CDC) have created a list of local public health departments through which laboratories can contact their local health officers. The Association of State and Territorial Health Officers (ASTHO) can assist on the state and territorial level. The Council of State and Territorial Epidemiologists (CSTE) can likewise help to pre-identify the state epidemiologist.

Every state public health laboratory is a member of the CDC-sponsored Laboratory Response Network (LRN) and can assist laboratories in all aspects of public health testing, especially in the context of biological and chemical terrorism. It is strongly recommended that each laboratory identify a contact within the respective state department of health who will be available to provide advice and technical assistance. Every state laboratory should have a laboratory program advisor, or equivalent who can advise about testing and specimen transportation for public health testing, including terrorism-related testing. The Association of Public Health Laboratories (APHL), a key partner of the LRN, is a source for contact information for state public health laboratories.

Useful Resources

National Association of County & City Health Officials (NACCHO)
http://www.naccho.org/; +202.783.5550

Association of State and Territorial Health Officials (ASTHO)
http://www.astho.org/; +202.371.9090

State Health Departments
http://www.astho.org/?template=regional_links.php&PHPSESSID=d6d945f38befe05f3c45b7e9af9a39e6

Council of State and Territorial Epidemiologists (CSTE)
http://www.cste.org/

State Epidemiologists
http://www.cste.org/members/state_and_territorial_epi.asp

Association of Public Health Laboratories (APHL
http://www.aphl.org; +202.822.5227

State Public Health Laboratories
http://www.aphl.org/Public_Health_Labs/index.cfm

5 Communications

5.1 Communication Systems

Communications failures are often cited as the single greatest challenge in large-scale disaster operations. For purposes of this discussion, "communications" means electronic modes of conveying verbal or readable information from point to point within the community, state, or nation.

Most types of communications which we use daily are wholly or in part dependent upon a nominally functioning community telephone system, which is vulnerable to service degradation or failure due to overload and/or physical damage.

Within the community, technical barriers commonly limit the capacity of emergency public service agencies to cooperatively respond to large-scale disasters. Community fire/rescue, law enforcement agencies, public utilities, relief organizations, and public health departments are commonly unable to intercommunicate directly at the field operational level. While this problem is being addressed as public service communications move to newer 800 MHz trunked technologies, even the latest public service communications systems may poorly support cross-jurisdictional operation. Existing systems for all agencies would likely be operating at maximum capacity.

5.2 Designating a Backup Communications System

The communications environment in which the laboratory and facility exist would be adversely affected during an emergency. Therefore, hospitals and health systems are increasingly seeking backup (wireless) communications capabilities that are independent of public phone systems, in addition to the radio communications, which are already common to emergency departments in support of paramedic/ambulance services. While hospitals may install communications equipment compatible with the public services/emergency management services agencies in the community, this option is expensive and usually not publicly funded. More commonly, hospitals establish relationships with pre-existing community groups, such as the Amateur Radio Emergency Service (ARES) (i.e., ham radio) or REACT (General Mobile Service). These groups regularly serve in disasters and are integrated with emergency services in most communities. Contact with such communicators can be initiated through the emergency management office of the community. ARES (through the American Radio Relay League) has had a signed memorandum of understanding with the American Red Cross since 1940. ARES supports both Red Cross disaster services and blood services during emergencies, and many Red Cross facilities are already equipped with amateur radio stations.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of blood-borne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document M29—*Protection of Laboratory Workers from Occupationally Acquired Infections.*

6 Challenges to Laboratory Operations During Disasters

6.1 Considerations for Disaster Planning

The underlying basis of this section is that a community may experience a disaster (natural or man-made) that will require unusual amounts of laboratory resources for an extended period of time. A disaster may require a laboratory to maintain, or even extend, its services under difficult, if not hardship conditions. While the laboratory is the focus of this document, during a crisis it will be part of the larger effort by the community to maintain services. Thus planning by the laboratory will be dependent on, and integrated with, the disaster plans of the community. To be part of the larger community response to a disaster, the laboratory needs to have a plan in place that will describe how it will respond to such an event. The plan should address, at a minimum, the elements listed in the following table.

Table 2. Elements of a Laboratory Disaster Plan

1. Implementing triage testing to ensure the most urgent testing is available
2. Maintaining resources
3. Maintaining supply links with manufacturers and alternative suppliers
4. Increasing surge personnel capacity
5. Maintaining a communication system
6. Maintaining links with reference laboratories
7. Ensuring security of the area

Implementing many aspects of the plan will require coordination with many elements of the immediate community, as well as elements outside the community that the laboratory may need to depend upon during a crisis. These include the elements listed in the following table.

Table 3. Relationships with Community Plans and Resources Potentially Critical to Sustained Laboratory Operation During an Emergency

1. *Manufacturers/suppliers.*
   MOUs outlining special operational relationships during an emergency may be appropriate. Alternate or backup communications systems may be required.
2. *Other neighboring or community institutions/clinical laboratories.*
   The community LEOP may outline medical resource coordination during a disaster. Otherwise, ad hoc laboratory-to-laboratory arrangements are appropriate as needed. Alternate or backup communications systems may be required.
3. *Emergency Management Agency.* Local EMA will attempt to coordinate assets and requests for transportation, security, compromised utilities, and public safety and support services. EMA will follow the LEOP as a guideline. Alternate or backup communications systems may be required.

Once these groups have been identified, the facility should meet with their representatives to discuss plans to coordinate activities during any future crisis. See Section 6.5.1.

When addressing the elements in Table 2, laboratory personnel might want to consider the following:

6.1.1 Laboratory Tests

- A menu of laboratory tests will be necessary for acute care and must be maintained during the crisis. These tests include the following:
  - Blood-gases and co-oximetry
  - Electrolytes
  - Hepatic and basic metabolic profiles
  - Hemograms and coagulation studies
  - Pseudocholinesterase, if available

- There may be laboratory tests not used for acute care, but ordered at an unusually high level or needed for longer-term care, such as:
  - Microbiological, serology

- Laboratory tests are most likely to be ordered for send-out to an appropriate referral laboratory (see Section 6.7), such as:
  - Microbiological, serology
  - Toxicological

6.1.2 Laboratory Instrumentation

- Laboratory instrumentation may need to be moved to a point of emergent care on very short notice. Examples include:
  - Blood-gases and co-oximetry, definitely
  - Electrolytes
  - Possibly hemoglobin and hematocrit

6.1.3 Laboratory Supplies

- If the disaster/crisis situation exists for more than 24 hours, the laboratory must maintain delivery of critically needed supplies (see Section 6.5.2). It is appropriate to consider and cooperate with community response plans (which may include resource-sharing) in the laboratory's own plan. The following are appropriate activities.
  - Working with vendors to prepare plans for resupply during a crisis.
  - Identifying other users of the laboratory's reagent/supplies within the community who could be called on during a crisis.
  - Speaking with vendors early on in the crisis to determine the impact on expected supplies or *re*-supplies (usage of reagents may go up in a disaster), as well as whether the prearranged plan needs to be put into effect.

6.1.4 Specimen Transport

- Backup plans for transporting specimens within the facility to the laboratory are needed. For example, if current system is mechanical/electrical (e.g., pneumatic tube), backup plans are needed in case of electric outage.
  - Individuals (e.g., laboratory staff, backup personnel, volunteers) providing transport will need to be identified. (See Section 6.2.)
  - A plan must be in place for transporting specimens to reference laboratories. (See Section 6.7.)

6.1.5 Laboratory Information System (LIS)

- A plan must be in place for tracking patient identification, specimens, and results if there is an interruption in LIS function or if there is insufficient time to enter information in the LIS.

- The hospital information system downtime plan should be reviewed and updated to address emergencies affecting the LIS system.

6.1.6 Reference Laboratories

A plan for utilizing reference laboratory services when required (e.g., if the disaster is the result of a biological or chemical toxin) must be in place. The reference laboratories may be private or public. (See Section 6.7.)

6.1.7 Control of Biological, Chemical, and Radiological Materials

Because it is difficult to predict the biological and chemical toxins and radiological materials that are likely to be encountered in a man-made disaster, the laboratory and institution should be prepared to seek outside guidance when such encounters do occur. There are a number of community and Internet resources available to help in this process (see table below). In situations where identification of chemical or biological toxins is necessary, the institution should have a list of laboratories that are available to perform the identification.

If radiation exposure is a concern for the laboratorian, radiation meters can be used to detect and measure radiation from clinical specimens. Consult the institution's radiation safety office to ensure that the appropriate meter is used for the radioactive source material occurring and that the proper personal protective equipment is utilized. For the laboratorian handling specimens, radiation rings, badges, and meters can be worn to detect and monitor radiation exposure.

The laboratory should have access control stations to monitor the ingress and egress of people coming into the area. All entering personnel should wear employee ID badges, be a member of the laboratory staff, or be accompanied by laboratory personnel at all time. Access points into the laboratory area should be minimized during a crisis, and the remaining access points should be staffed with a security review to permit only authorized laboratory personnel to have access. Institutions may want to consider placing locks on all laboratory doors on a routine basis.

Table 4. Resources to Create a Response to Biological and Chemical Toxins and Radiological Materials

Community resources: Local or state poison control centers (see www.aapcc.org - American Association of Poison Control Centers and http://npic.orst.edu/poison.htm) Local metropolitan medical response systems (see community or state websites) Internet resources: www.cdc.gov- Centers for Disease Control and Prevention http://www.bt.cdc.gov/agent/smallpox/index.asp - Centers for Disease Control and Prevention, Smallpox Section www.aapcc.org - American Association of Poison Control Centers http://npic.orst.edu/poison.htm - State and Regional Poison Control Centers http://www.bioterrorism.slu.edu/ - Center for the Study of Bioterrorism and Emerging Infections at Saint Louis University http://www.slu.edu/colleges/sph/csbei/bioterrorism/other.htm http://www.epa.gov/ - U.S. Environmental Protection Agency http://hazmat.dot.gov/ - Office of Hazardous Materials Safety http://toxnet.nlm.nih.gov/ -TOXNET, U.S. National Library of Medicine http://www.slu.edu/colleges/sph/csbei/bioterrorism/internet.htm - Listing government and non-government Internet resources for dealing with bioterrorism.

6.2 Human Resource Challenges

In an extended disaster, one of the major laboratory resources that must be managed is personnel. Plans must take into account the personnel immediately available at the beginning of a crisis as well as replacement personnel in an extended crisis. The laboratory will be challenged to develop plans that will enable its personnel to get to and/or respond to their facility.

6.2.1 Availability of Personnel

- While human resources for current shift will most likely be sufficient, the following shifts may be more difficult to staff. Staff needs to know *before* a disaster (through regular disaster planning) that:
  - They may be asked to remain in the facility during an active disaster response.
  - The above may be required by law, with possible penalties for noncompliance.
  - If there is an overriding need to leave the facility, this need must be brought to a supervisor as soon as possible.

- Arrangements must be made for additional personnel
  - Supervisors need to know the availability of public transportation and highways that feed into the institution. Communication with institutional and community command centers is critical.
  - Arrangements should be made with local law enforcement or emergency workers to facilitate bringing personnel into the facility. Escorts or permits may be needed.
  - Supervisors may need to call in personnel from other shifts, informing them of their need to come to the facility and provide information on access to public transportation and highways that feed into the institution (make sure lists are always current).

6.2.2 Supplementing Staff

- A staffing plan should be developed.

- If sufficient staff is not available, alternative personnel need to be considered where it is not precluded by state law or other agreements (such as union labor agreements). Possible options include:
  - Technologists serving as phlebotomists
  - Clerks assisting technologists by performing nonanalytical tasks
  - Using volunteers to supplement regular staff by performing clerical functions
  - Technical volunteers from other, possibly unaffected, institutions, working during a crisis (be sure to determine if there are any potential legal/insurance problems).

6.2.3 Care of Personnel

- The needs of personnel must be considered.
  - Staff will likely be worried about the disaster and the impact on their families; frequent status updates/bulletins should be provided to them.
  - During the period of increased stress, the number of hours of productive work may be reduced; the frequency of short breaks should be increased.
  - Personnel remaining in the facility should have ready access to:
    - Showers
    - Full meals
    - A proper bed
    - Toiletries
    - Medication
    - Change of clothing such as scrub suits

If necessary, prior arrangements (e.g., MOUs) with nearby restaurants and hotels should be made to have these comforts available to staff.

- Mental healthcare personnel should be available during and after a crisis to help laboratory personnel deal with the emotional aftershocks of the crisis. Information regarding the availability of counseling should be disseminated to all workers in a neutral manner. For those laboratory workers who desire to talk with mental healthcare personnel, provisions should be made for the meeting to occur away from the laboratory to protect the anonymity of the workers.

- There should be provision for incident stress management. The CISM approach has been widely implemented by law enforcement and fire personnel, and is available for use in healthcare facilities nationwide. A product of the International Critical Incident Stress Foundation, Inc., ICISF is a nonprofit, open membership foundation dedicated to the prevention and mitigation of disabling stress through the provision of education, training, and support services for all emergency services professions. ICISF also provides consultation in the establishment of crisis and disaster response programs for varied organizations and communities worldwide. They also provide services to hospital workers and there are likely to be trained counselors in the state and area. Personnel in the emergency department are likely to be familiar with CISM, and some may even be trained as counselors.

6.2.4 Protecting Staff

- The continuance of operations during conditions that are perceived to be dangerous to staff requires that systems are in place to assure safety from:
  - Radiation hazards
  - Exposure to infectious agents submitted for testing
  - Chemical agents
  - Electrical shock

- A comprehensive plan should be implemented and reviewed with staff to assure that they are as safe as possible and that no one's actions jeopardize their own safety or that of their coworkers. Protocols should be created and reviewed concerning immediate referral of suspicious powders, chemicals and/or potentially radioactive materials to the state public health laboratory or office of the Environmental Protection Agency.

- The laboratory director may consider disseminating to staff information to help prepare their families for a disaster, especially in case there is a critical interruption of communications such that staff members cannot communicate with loved ones. Information to assist families in disaster planning can be found at:
  - http://www.redcross.org/services/disaster/beprepared/familyplan.html
  - http://www.fema.gov/pdf/library/fdsk.pdf

6.2.5 Education of Personnel

Laboratory personnel must be well prepared to face the challenges to a clinical laboratory during a disaster in their community. Educating personnel prior to any crisis may enable them to better cope with the stresses of the experience and understand their part in the larger community's response to the crisis. Laboratory workers should know what is expected of them during a crisis, and why. Some elements that can be included in an educational plan are listed below; many have been discussed in greater detail in other sections.

- Discuss the need to make all reasonable efforts to report to work following a disaster, including communicating with supervisory personnel.

- Explain the backup plans that may be in place in the larger community for helping workers communicate with supervisors and getting to work.
- Discuss why (including the legal implications) many workers may not be released from work during the emergency, as well as what steps have been taken to ensure their comfort and well being during the enforced detainment.
- Review the possible types of disasters that might occur and how they might impact on the need for different laboratory services.
- Discuss the risks to workers in the event the community is exposed to radioactive, biological, or chemical attacks.
- Discuss the plans taken by the institution to protect the workers from the effects of different types of terrorist attacks, especially radioactive, biological, and chemical. For example, it can be made clear that normal hospital barrier clothing will provide satisfactory emergency protection for hospital personnel; after decontamination, no special clothing is indicated for medical personnel, as the patient presents no risk to medical care providers. (Given current sensitivities of radioactive, biological, or chemical attacks, it may be very important to spend considerable effort on this.)
- Discuss the possibility that workers from other institutions may be used to provide coverage during the crisis.
- Discuss unusual procedures that may become operative during a crisis, such as a chain of custody procedure.

Preparation of laboratory workers for a disaster should occur as a formal, documented, continuing education event. Open discussion of these and other points will be critical to placing the information in a professional context.

6.3 Communications Challenges

6.3.1 Laboratory Communications

Because clinical laboratories are "information centers," communications interruptions carry special concerns. There are numerous electronic communications pathways essential to routine, timely laboratory performance. Functionally, these can be thought of as systems which communicate with and among:

- laboratory personnel tactically supporting laboratory operations;
- internal (intraorganizational) users and supporting departments; and
- external (extraorganizational) users and logistical supporting services.

Those communications tactically organizing laboratory personnel tend to employ common public and internal voice (telephone, cell phone, paging) systems. Communications need to be immediate and reliable, but have likelihood of dependency upon vulnerable public communications networks, as discussed below. Systems supporting intraorganizational (intrafacility, intrasystem) users and departments implement voice and, in more cases, digital systems for diverse functions: test ordering, resulting, billing, and numerous other ancillary interactions. These systems are usually distinguished by a relative lack of direct dependency upon more vulnerable public networks. Systems supporting external (extraorganizational) users and logistical supporting services, use digital and voice systems which tend to carry substantial dependency upon more vulnerable public communications networks. The Internet may remain functional.

6.3.2 Communications Assessment

It is a mistake to assume that phone service will remain suitably functional for use. It is prudent to expect that telephone or cellular service will NOT function in the community if a large disaster occurs. The reasons may include damage to the communications infrastructure itself, but usually there is massive

saturation of the telephone system by private and emergency responding users. Thus, phone system failure has been a consistent observation in large-scale disasters domestically, and it is best to simply plan for it.

Another common misunderstanding is a presumption that, if the phones don't work, the fax, cell phone, and pager systems will remain operational. If these systems in the facility rely on public phone systems to conduct messages, it should be anticipated that they will fail also. Conversely, phone and fax function may not be affected for internal facility or health system operations. Pagers may be unaffected if the facility operates its own paging system and transmitter.

A caveat: the relative security (confidentiality) of backup communications systems varies greatly, and is influenced by technical choices and options at the disposal of the communicator. Analogue FM voice communications (the most common communications technology used for public service and disaster communications) are least secure, although some frequencies are ordinarily not available in many scanners. Digital voice systems (such as found in trunked radio systems) are secure to the level of authorized users. Digital messaging backup systems, such as packet radio (a type of digital wireless communication), unless of commercial quality and highly encrypted, are relatively secure to all but the technically most sophisticated. It is advisable to limit patient identifiable information to fully secure communications modes, or if absolutely necessary, to route as little such information as possible via the most secure modes available during an emergency.

Simple modes should not be overlooked. For some situations, paper or bulletin board (HIPPA compliant) messages may suffice.

Thus, a communications assessment should be conducted with appropriate and knowledgeable personnel in one's own facility. Table 5 offers an outline of laboratory communications, risks, and options.

Table 5. Laboratory Communications, Risks, and Options

Function	Mode (routine)	Failure risk	Emergency Mode Option	Comments
Personnel management	Phone, cell phone, fax	High	Preplanned report for work response; community announcements (EAS); facility wireless backup	Must comply with facility response plans.
Personnel management	Pager (public phone system-dependent)	High	Preplanned report for work response; community announcements (EAS); overhead page; facility wireless backup	Must comply with facility response plans. May be supported by backup wireless and community media resources.
Result reporting — extra-facility	Fax, phone-based modem	High	Courier, e-mail, encrypted facility digital or voice wireless backup	Nonencrypted wireless backup may compromise HIPAA.
Consultation — extra-facility	Phone, cell phone	High	Courier, e-mail, encrypted facility digital or voice wireless backup	Nonencrypted wireless backup may compromise HIPAA.

Table 5. (Continued)

Function	Mode (routine)	Failure risk	Emergency Mode Option	Comments
Specimen accession—entry at extra-facility site	Phone-based point of service ADT and order entry	High	Courier, e-mail, within-lab acces-sioning	Nonencrypted wireless backup may compromise HIPAA.
Transfusion services—extra-facility provider	Phone, fax	High	Courier, e-mail, encrypted facility digital or voice wireless backup	Nonencrypted wireless backup may compromise HIPAA.
Reference laboratories—consultation, specimen transport, and result receipt	Phone, fax	High	Courier, e-mail	Must comply with facility response plans. May be supported by backup wireless and community resources.
Personnel management	Pager (public phone system-independent)	Low	Preplanned report for work response; community announcements (EAS); overhead page, facility wireless backup	None
Specimen accession—intra-facility	LIS; manual in-lab	Low	Manual; LIS backup procedures	None
Result reporting—intra-facility	Internet; within health system LIS; intrafacility phone or fax	Low	Courier; e-mail, phone; Fax; encrypted digital or voice wireless backup	None
Billing	Manual, LIS, Internet, clinical information system	Varies	Courier; manual requisitions	Complicated by lack of demographic information for emergency care and admission.
Any services	Internet	Low	Courier; wireless backup, encrypted or nonencrypted	Principal Internet service risks are physical connection damage or direct electronic attack.

6.4 Failure of Utilities

The laboratory must assume that during an emergency there is a high risk for the institution's main power to be lost and that the institution will need to depend on emergency power. It is the laboratory's responsibility to assure that key instrumentation is plugged into emergency power outlets or UPS devices — sites that the institution knows will be able to deliver emergency power during a power outage. This must be verified at least on an annual basis. While most emergency power challenges will be predictable

or known already by laboratory staff or facility engineering personnel, routine hospital operations seldom permit a prolonged, or perhaps even full, emergency power test. The laboratory should consider additional sites that should have emergency power available during a disaster.

- Do potential testing sites within the Emergency Services (ES) Department (see Section 6.1.1) have access to emergency power? If the laboratory moves testing into the ES, emergency power must be available at those sites. The designation must be made before a crisis and be part of the emergency power verification program.
- Will electrical failure expose laboratory personnel to unsafe conditions?
    - Will hoods work and not backflush into common spaces? Airflow reversals can occur in hoods connected to exterior exhaust systems.
    - Will instruments require cleaning because of stoppage in sampling or dispensing cycles, thus exposing personnel to unusual cleanup?
- Is the laboratory's water supply dependent on electrical power? Type I water is a necessary consumable for many laboratory instruments, and the laboratory needs to be assured of a constant supply. Are there alternative sources of water available, i.e., bottled/boxed water that would suffice in an emergency?
- Has the laboratory reviewed power-down procedures?
- Are personnel facilities (e.g., a bathroom) available with emergency power?
- Will heavily instrumented testing areas, where refrigerators are also commonly placed, experience elevated room temperatures? Emergency power systems may not support optimal temperature regulation throughout the facility. Room temperature may exceed the acceptable operating limits of modern instruments and compromise some blood banking procedures. The temperature may reach unacceptable levels within minutes. Availability of large cooling fans and portable air conditioners can be critical, especially during the summer season.
- Will there be loss of some (or all) overhead lighting in critical laboratory and patient care areas? Phlebotomy may discover that supplemental portable lighting (flashlights, other) is required in some hospital areas. Laboratory remodeling may, over time, convert space from uncritical to critical operational importance, beyond the boundaries of originally planned emergency lighting support. Newly remodeled areas may be found to lack overhead lighting during a true outage.
- Have all emergency power plugs been tested? In rare instances, emergency power plugs and strips are found to not actually be "hot" under emergency conditions. Extension cords are invaluable.
- Does the morgue have emergency lighting?
- Do morgue body coolers have emergency power?
- Does sufficient fuel exist for facility generators? Secure immediately.
- Will auto-flush systems in bathrooms function?
- Will blood culture instruments, incubators, and hoods function on emergency power?

A true, complete emergency power audit is invaluable. These may be rare, occasioned by facility transformer replacement or major community power outage, but are worth careful study when they are planned or occur.

6.5 Laboratory Supplies and Inventory

6.5.1 Maintaining Operations

Laboratory personnel need to develop a "Continuity of Operations Plan" (COOP) in case their laboratory should be forced to close down due to a variety of disasters including fire, tornado/hurricane, flooding, loss of electrical power, or contamination from biological, chemical, or radiological exposure. This plan could range from setting up a temporary laboratory facility in an adjoining building to moving the affected sections of the laboratory to an offsite facility to sending samples to a nearby facility. Many clinical laboratories decide to send out their more unusual or specialized tests to larger laboratories.

These laboratories act as reference laboratories in either their local geographical setting or as a national entity. Smaller clinical laboratories, if unable to develop a COOP that utilizes a temporary laboratory on their premises, may be forced to turn for help to these reference laboratories or other clinical laboratories in their city or nearby cities. Memoranda of understanding (MOUs) need to be drawn up and signed between hospital laboratories in order to facilitate specimen transfer, work-up, and reporting of results while respecting patient and hospital confidentiality. In addition, an MOU that would allow for laboratorians to work in another hospital setting where specimens were being transferred would be beneficial to both institutions.

The community's local emergency operations plan may include memoranda of understanding between cooperating community health facility resources and other community resources and entities, which detail their mutual aid arrangements. The LEOP may also direct staffing of the emergency operations center with health facility representatives and/or a director or coordinator of medical resources. In a disaster, such arrangements are substantial assets. Because they reside within the local emergency management agency, they centralize resource sharing between responding facilities and also provide integration with other responding community assets such as paramedics, law enforcement, transportation, and public services. The institution's, local emergency management office should have information regarding the planning arrangements within the community. Local emergency preparedness plans are public documents. The community's plan may be available via the Internet.

6.5.2 Maintaining Supplies

Besides COOPs and MOUs for specimen testing and reporting, clinical laboratories need to look at their sources of laboratory media, testing reagents, and supplies to make sure that they would be able to quickly replace or receive additional quantities of media or reagents if necessary. The sudden and unexpected influx of specimens for immediate testing could not only quickly overwhelm the laboratory staff, but could deplete the usual inventory of media and reagents routinely kept in-house. The same type of situation could occur if a chemical exposure event took place, due either to terrorism or accident.

Besides MOUs that would allow staff from adjoining facilities to help out where the influx of testing was occurring, MOUs need to be in place with supply companies that would guarantee overnight delivery of specified media, supplies, and reagents necessary to test a large number of specimens quickly. Alternate vendor sources should be sought out in case something were to happen that would restrict the supplier from sending the usual order, let alone expedite increased quantities of supplies for emergencies. MOUs with nearby laboratories that use the reagent but that are not involved with the crisis, may allow the institution to borrow reagent until material from a vendor can be supplied.

6.6 Mass Fatalities Planning

Natural or man-made disasters may result in large numbers of fatalities. Hospital morgue facilities and operations conventionally reside in the laboratory domain. Thus, pathologists and laboratory personnel should understand their potential roles in such an incident.

6.6.1 The Community Hospital Morgue Role

In the United States the local coroner or medical examiner is charged with fatalities management and related investigations. The coroner or medical examiner will determine how and where the fatalities will be stored. In the event of mass fatalities, the number of deaths will quickly overwhelm the resources of most communities including equipment, personnel, facilities, and body storage capacity. Communities should be prepared to establish a morgue that is secure and independent of existing medical facilities that may be overwhelmed with the care of large numbers of casualties. In most cases, it is not prudent to distribute remains throughout the community due to issues of security, chain of evidence, chain of custody, or cause of death, especially involving nuclear, chemical, or biological agents.

6.6.2 The Community Mass Fatalities Plan

The single most important asset a hospital-based pathologist and laboratorian can have is a complete and effective community mass fatalities plan. Lacking this, depending upon the causation and location of deaths, hospital facility and laboratory personnel may be faced with management of unusual numbers of remains, coping with distraught family members and media, and cooperation with coroner's and investigating officer's requests—among other routine duties.

A mass fatalities plan customarily resides or is referenced in the local emergency operations plan. The plan coordinates local public services, coroner, emergency management agencies, funeral directors, hospital morgue and pathologist, mental health, community, and national (general and specific) supporting resources to effectively manage the substantial challenges of this kind of incident. A sound community mass fatalities plan will protect laboratories and individual facilities from many of the aforementioned difficulties. Unfortunately, many communities do not yet have a detailed plan.

- Is the community's mass fatalities plan sufficient to assist the hospital morgue role?

  While good plans vary among communities, a well-developed plan usually:
  - stipulates a specific number of deaths which would trigger the mass fatalities plan;
  - promotes a central mass fatalities site which localizes all operations; and
  - includes prearranged security, transportation, media, mental health, spiritual care, family care services, temporary morgue and fatalities command structure.

If the community plan lacks one or more of these attributes, the plan may be in need of review and revision. Useful resources include the International Mass Fatalities Center (www.massfatalities.com), the National Association of Medical Examiners (www.thename.org), and the National Mass Fatalities Institute (www.nmfi.org). The International Mass Fatalities Center and the National Mass Fatalities Institute offer a mass fatalities response plan and hands-on and/or web-based training curricula to communities endeavoring to enhance their ability to respond to and recover from a mass fatalities incident. The National Association of Medical Examiners offers a sample mass fatalities plan on its website. It is in the interest of community emergency planners, for humanitarian and financial reasons, as well as potentially averting national disrepute, to prepare for such unpleasant incidents.

If a mass fatality incident accompanies an event sufficient to warrant a presidential disaster declaration, a disaster mortuary team (DMORT) can be dispatched to assist the processing and identification of remains. The services provided by DMORT in coordination with community resources, include remains decontamination, storage, and identification. They do not recover remains and do refer remains to local funeral directors when completed with their work. Days may elapse before a DMORT team can be authorized and respond. DMORT does not alleviate the necessity for a sound community mass fatalities plan.

6.7 Reference Laboratory Relationships

As extensions of the clinical (hospital) laboratory, reference (private or commercial) laboratories play an indispensable role in clinical management of patients and public health in general, and are relied upon by nearly all clinical laboratories. In catastrophic circumstances, including bioterrorism, the normal commerce and information exchange may be disrupted. It would be impossible to anticipate and address every possible disruption in service, but the following should be addressed beforehand:

- How will specimens be sent to the reference laboratory in the event of disrupted air, road, or rail traffic?

- Clinical laboratories should develop local or regional alternate sites for sending their specimens, such as the SPHL or other "laboratory referral systems" in their area. These sites should be within a reasonable amount of time for ground transportation.

- If both ordinary air and ground transportation are impossible or substantially delayed, specimens can be delivered to an alternative site using private courier companies, hospital vans that visit off-site clinics, law enforcement, national guard, or whatever resources are available to the clinic. Military, other general aviation assets, or Civil Air Patrol may provide air transport support.

- Reporting of results to the clinical laboratory in the event of interrupted Internet communications, interrupted phone links, or interrupted mail service will be very taxing. Depending upon the severity and extent of the loss of normal communication systems, back-up methodologies should be looked at for reporting by fax, phones (land-line then cellular), text pager, and wireless communications. As a last resort, private or clinical-based courier services could be employed to transport results via hard copy.

6.7.1 Specimen Transportation

Usual Means	Issues	Response Options	Response Complications
Courier Commercial carrier	Physical barriers. Security barriers. Defection of personnel. Insufficient resources during incident. Communications failure.	Defer testing. Private or official corporate automobile. Transport to physically accessible alternate reference laboratory.	Communications (everyone with everyone). Route planning, circumventing damaged or secure areas. Identification for transporting volunteer or staff acceptable to authorities, if traversing secured areas (or prior communications with EOC, and thus law enforcement). Local or state law enforcement resources may be unavailable for health and welfare assignments.
Air carrier	See "Issues" directly above. Impeded transport to airport. Access to airport or air carrier facilities. Air carrier(s) grounded.	Defer testing. Ground transport to original or accessible reference laboratory. MOUs in advance with alternative transportation modes and providers. General (private) aviation Civil Air Patrol	"Response Complications" directly above. Acquisition of authoritative, up-to-the-minute information regarding air carriers, facilities, and airport operations. Airport operations and security are distinct from community (EOC) control.

During a disaster, the most reliable transportation mode is likely to be the one that is simplest and dependable. It is likely to be a corporate or private vehicle, allowing for the above. If a national reference laboratory services several laboratories in the local community, backup reference laboratory transportation assets could be conserved by cooperatively consolidating such laboratories' specimens into

single shipments. Note that the national reference laboratory may have made all necessary arrangements for transportation in the event of a disaster. Check their contingency plans ahead of time. Consideration should be given to alternative local means of transport of specimens to primary reference laboratories. This activity may require coordination with emergency management and law enforcement during an incident.

Specimen preservation may require packaging considerations for extended transportation periods. Sufficient (and additional) wet ice, dry ice, and/or coolant replenishment may be needed.

Clinical laboratories should be prepared to communicate with their clients regarding the status of reference laboratory testing services during an emergency affecting either site. Requests to limit deferrable testing could be included within such communications.

Result reporting and consultation technologies and their respective vulnerabilities are discussed in Section 7.3.

The state of the art for measurement and interpretation of specific chemical agents within patient specimens, especially for agents deployed in an intentional attack, is evolving at this time. With the exception of cholinesterase or pseudocholinesterase assays (for nerve agents), and cyanide, reference laboratories would not offer specific chemically diagnostic tests. Furthermore, chemical agents act so rapidly that medical diagnosis and therapy need usually be given based upon clinical criteria.

Reference laboratories are also susceptible to disasters. Local laboratories are likely to learn of an emergency potentially affecting their reference laboratory site indirectly, via media reports. The reference laboratory may be inaccessible by telephone, for reasons outlined elsewhere in this report. Reference laboratories should have disaster plans, which include recovery, operations, and client communications plans for incidents affecting them. It is in the local laboratory's mutual interests to know the primary reference laboratory's communications plans, which would be implemented to apprise clients of operational issues during a disaster affecting their communities.

Many of the transportation and communications challenges particular to reference laboratory relationships may also apply to off-site "core" laboratories serving hospitals within large health systems. Commonly, the communications issues would be mitigated by utilization of within-system information and telecommunications technologies, which are insulated from the overload failure risks of community telephone systems. However, transportation issues (such as physical or security barriers) remain and may have even more serious effects, because many hospital laboratories in such relationships operate limited "acute" medical needs test menus.

7 The Laboratory Response Network

7.1 The Laboratory Response Network for Bioterrorism

The Laboratory Response Network (LRN) for bioterrorism is a program initiated by the Centers for Disease Control and Prevention (CDC) in 1999. The Association of Public Health Laboratories (APHL) serves as the administrative agency of the network. The LRN serves the private and clinical (hospital) laboratory community with a mechanism to provide coordinated, quality laboratory confirmatory testing for agents of bioterrorism according to established CDC consensus protocols under a single operating system using standard reagents and secure reporting systems. The LRN concept utilizes a "multilevel" approach that serves to outline the roles and responsibilities of state and local public health laboratories, clinical hospital laboratories, and privately owned laboratories for all levels of diagnostic testing performed. Generally, members of the LRN are either sentinel laboratories or confirmatory laboratories.

The original LRN model had four levels of membership, designated A through D, based on increasingly more stringent safety levels and increasing testing capability. The current model has two main levels:

Sentinel Laboratories (formerly Level A): These are clinical and private laboratories that perform bacterial diagnostic testing, work-up, and identification; employ at least Biosafety Level (BSL)-2 practices; and perform work utilizing a biological safety cabinet (BSC). These laboratories are the front line in the surveillance for pathogens that could be released by an overt or covert bioterrorism attack, or from naturally occurring diseases. The LRN sentinel laboratory's role is to rule out or refer clinical isolates to a higher-level LRN laboratory. Contact the state public health laboratory to determine if your laboratory is considered a sentinel laboratory: http://www.aphl.org/Public_Health_Labs/index.cfm.

Confirmatory Laboratories (formerly Levels B and C): These laboratories currently consist mainly of local and state public health laboratories (PHLs) and can perform confirmation testing on many of the Category A and B agents. (Please see Appendix A for a complete list of Category A and B agents.) Only laboratories that have been designated at Level B or above have access to the restricted website for viewing protocols and ordering reagents. At the present time there are approximately 120 confirmatory laboratories registered through the CDC, and it is estimated that there might eventually be approximately 250 approved laboratories at this level. Confirmatory laboratories employ either BSL-3 or BSL-2 Enhanced (i.e., BSL-2 conditions with BSL-3 practices consisting of increased personnel protection equipment and heightened security measures). Each CDC-approved confirmatory laboratory has a section of medical technologists and laboratorians that have received advanced training at the CDC for agents of bioterrorism.

Some confirmatory laboratories are capable of working with environmental specimens, including powders. These laboratories will also be called upon to do advanced molecular diagnostic testing on other types of BT agents, as assays are developed and deployed by the CDC.

There are currently two Federal governmental confirmatory BSL-4 laboratories that work with highly pathogenic and potentially fatal agents: the CDC and the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID). These laboratories also do advanced molecular typing and "fingerprinting" and serve as a repository for banking isolates.

Designation of a laboratory for diagnostic capability is agent-specific. Veterinary diagnostic laboratories, USDA, and FDA testing laboratories are being added to the network. Sentinel laboratory (unsecured) consensus protocols are available on both the CDC and American Society for Microbiology (ASM) websites. At the LRN confirmatory level (secured access), CDC consensus protocols are followed.

It is important for clinical (sentinel) laboratories to understand their role in the LRN. At a minimum:

- **Every laboratory should know if it is a sentinel laboratory.** In addition to identifying the clinical laboratories that comprise sentinel laboratories, the state public health laboratory can be consulted for definition of the laboratory's biosafety level (BSL); a site visit can be requested to help determine this. If it is determined that the laboratory has the appropriate equipment and expertise, and is willing to participate in the system, the state public health laboratory can assist with the relevant laboratory protocols for testing and specimen referral, including specimen transportation.

- **It must be recognized that even laboratories that do not want to perform any terrorism- related testing might confront a patient who has been exposed.** To be prepared, such a laboratory must, nevertheless, have a plan in place that has been worked out with the state public health laboratory. An example of such a plan could be as follows: upon consultation with the state public health laboratory (SPHL), the specimen should go to the nearest appropriate sentinel laboratory if there is a low suspicion of bioterrorism. The specimen should be sent directly to the nearest appropriate

confirmatory laboratory if there is a strong suspicion of bioterrorism. This will ensure that time spent in unnecessary testing would not be detrimental to the patient and public health.

- **Every sentinel laboratory must know where the nearest appropriate confirmatory laboratory is; their SPHL can serve as a resource.** In many states there may be more than one confirmatory laboratory, and one of these may be significantly closer than the state public health laboratory. Since LRN confirmatory capability is agent-specific, a laboratory may not have all the equipment necessary to confirm a specific agent of bioterrorism. The state public health laboratory should be contacted initially to determine where, to whom, and how the specimen or isolate in question should be sent.

7.2 The Laboratory Response Network for Chemical Terrorism

Presently, CDC is developing rapid toxic screening capabilities to test for 150 chemical analytes in human blood and urine within a relatively short period of time. Building upon this, the CDC has provided advance training, protocols, and equipment to five public health laboratories located in the U.S. to assist in the screening of clinical samples, and to serve as surge capacity for the CDC in the event of a chemical terrorism incident. Human specimen collection protocols are presently posted on the secured LRN website.

Currently, most hospital laboratories do not have capabilities that allow assessment of chemical events. The CDC is working with the APHL to assess the capacity and capability of state and local public health laboratories in testing for chemical terrorism agents. Plans are being implemented to provide funding in FY 2003, to allow all public health laboratories to begin developing the capability and capacity to perform testing. A nationwide LRN for chemical terrorism would then serve to function in the rapid diagnostic testing of chemical agents (including nerve gases, blistering agents, tearing agents, etc.) for the CDC in the same way that the LRN functions for bioterrorism. Assessment of chemicals in food or the environment (air, water, soil) would be performed by state public health laboratories, as well as FDA, USDA, and EPA. State public health officials should contact these latter agencies.

7.3 Reporting of Results

Laboratorians at the sentinel level function at the "Rule-out" or "Refer" level for CDC's "A" and "B" classification list of bioterrorism agents. For all agents of bioterrorism, sentinel laboratories will not be able or expected to report a positive result or even a "preliminary positive" result. Presumed positives must undergo further testing by the state public health laboratory that have LRN confirmatory testing capabilities for the presumed organism in question. Therefore, the clinical laboratory needs to be circumspect about any communication of preliminary results. This is especially true when dealing with the media, and in nearly all cases it will be best to have any communications with the media channel through risk management experts at the user's institution. As part of planning for a disaster, including an act of biological, chemical, or nuclear terrorism, the clinical laboratory should identify the institution's communication officer and establish lines of communication and responsibilities.

7.3.1 Smallpox Diagnosis and Reporting

The diagnostic evaluation of possible smallpox is based on clinical presentation. The CDC is working on protocols, reagents, and diagnostic test algorithms to be distributed to LRN confirmatory laboratories. The algorithm, "Evaluating Patients for Smallpox," includes three levels of risk based upon patient signs and symptoms. In the case of a suspected instance of a "pre-event" presentation of smallpox, clinical laboratories should work through their state public health laboratories to determine how to proceed. Ultimately, confirmation must occur at the Centers for Disease Control and Prevention. In the "peri-event" scenario, the clinical laboratory must work very closely with the state public health laboratory and other public health officials to determine how to proceed with work-up of evolving cases.

The “febrile rash illness” algorithm for testing and evaluating patients for smallpox can be ordered as posters (Order No. 99-7157, 11" x 17") at the website:
https://www2.cdc.gov/nchstp_od/PIWeb/NIPOrderForm.asp.

8 Special Attributes of Incidents of Terrorism

8.1 Cooperation with Law Enforcement Officials

It is the intent of this section to outline a reasonable and helpful level of clinical laboratory cooperation with law enforcement. Terrorism involves a criminal activity. Therefore, all patient specimens and property associated with a bioterrorism incident constitute potential evidence. There should be facility chain of custody (COC) forms and related procedures. Patient care comes first. It is impractical to use COC for every clinical specimen received by the laboratory, and COC should not be permitted to significantly interfere with patient care during a crisis situation.

Law enforcement will advise or can be consulted to help select those specimens for which COC is deemed most critical to future criminal investigations. In the event of a terroristic scenario, the FBI assumes the role of lead federal agency for investigation. In general, specimens submitted for toxicologic or microbiologic assay would be expected to be of greatest forensic value, thus needing COC. COC ideally complements controlled (locked) and restricted access to all designated specimens. In a hospital-based clinical laboratory, once clinical specimens have been obtained, further contact with law enforcement should be limited to or controlled by those persons designated by facility executive leadership to brief or release information to outside parties. This position is commonly, but not always, designated as the Information Officer. During an incident, any interaction of this individual(s) and law enforcement with laboratory staff and results should be managed in consultation with the laboratory director and laboratory management. Physical evidence may require special cooperation with examining pathologists, in consideration of medical staff and hospital policies and procedures. Local facility procedures should supersede the above outline, if conflicts with such procedures and this section are found to exist.

8.2 Cooperation with Public Health Officials

Public health officials, elected officials, and law enforcement officials all have different agendas specific to their roles in the incident. Reporting algorithms need to be agreed upon at the start of the testing process. Officials from each of these disciplines will have pressure to report results to their immediate superiors. When reporting results, careful consideration and detailed attention has to be given to the confidentiality of test reporting relative to the governing laws of the local and state public health community and to law enforcement officials. In the event of a terroristic or criminal incident, federal statute has determined that the FBI has authority. Hence, the reporting of all bioterrorism-related testing results should be done first through their agency for subsequent release to the media.

8.3 Chain of Custody (See Appendix B)

Because confirmed or suspected acts of bioterrorism are criminal acts whose perpetrators are punishable by local, state, and federal laws, laboratorians will need to initiate COC forms and follow COC procedures for all specimens involved in a legal investigation. At the point that an act of bioterrorism is recognized or suspected, a COC form must be initiated and used whenever the specimen is handled. These COC forms can be obtained from forensic or criminal investigation laboratories, or from the state public health laboratory (see the table in Section 4.4 for the state public health listing website) or local LRN registered laboratory. Attention will need to be given for documentation of custody, as well as to possession of the evidence before, during, and after the testing has been completed and the evidence is released or discarded. A location that can be locked and secured, with limited access, will need to be

used. Laboratorians will need to complete the COC form every time they remove the specimen from its secured location, or handle the specimen to perform a diagnostic test. Depending upon the outcome of testing and the nature of the criminal act, the FBI or other law enforcement agencies may want the evidence back or may ask the laboratory to discard it. Whatever the outcome, complete documentation needs to be done by the laboratorians.

9 The Responding Laboratory: Developing an Emergency Response Plan

In order to be adequately prepared to respond to an emergency and to ensure that the clinical laboratory operations continue uninterrupted or contingency plans are immediately put into effect, careful planning is required.

The following checklist is designed to help determine the laboratory's preparedness to continue operations during a disaster and to identify what areas require additional preparedness planning. It should be noted that these items collectively portray ideal preparedness. They are intended as guidelines for preparedness enhancement, not as mandatory accomplishments. Clinical laboratories, and the hospital or facility in which they exist, should consider these checklist items mutually, and interpret or implement them within the context of facility and community plans as they currently exist and/or are being revised.

- ❑ Laboratory and facility representatives are familiar with healthcare-related community's response plans, having knowledge about contents of relevant documents, such as the LEOP and relevant annexes, and memoranda of understanding that exist between health care and relief agencies in the community.

- ❑ Laboratory and facility representatives are knowledgeable about the existence (if any) and content of centralized emergency plans or representation that may be activated to govern medical resource sharing (supplies and staff) during an emergency.

- ❑ Laboratory and facility representatives are aware of credentialing barriers and the status of pertinent, related facility and state provisions permitting cross-jurisdictional and cross-facility emergency staffing assistance.

- ❑ The community has facilities and plans to receive, process, identify, and assign healthcare professionals from other communities and states to assist.

- ❑ Laboratory and facility representatives have installed and, if appropriate, arranged staffing of wireless backup communications, assuring contact with other healthcare facilities and emergency operations personnel in the event of failure of routine telephone systems.

- ❑ Laboratory and facility personnel have participated in incident command system (HEICS or equivalent) training.

- ❑ Laboratory and facility personnel know whether their community's mass fatalities plan incorporates key markers of a complete plan. See Section 6.6.2.

- ❑ Laboratory and facility personnel understand and agree with the roles of their laboratory, morgue, and security personnel, to assure cooperation with the community's mass fatality plan, if such is activated.

- ❑ An area has been designated as a secondary (expanded) morgue site.

- ❑ Laboratory employees have been educated in key issues surrounding their on-the-job safety and activities in the event of a WMD incident of chemical, nuclear, or biologic type.

- ❑ Laboratory employees know the processes by which the laboratory and facility is to be accessed during facility lockdown.
- ❑ A process is in place to permit preplanned reporting of employees to the worksite in the event of routine telephone systems failure.
- ❑ There are plans to maintain (i.e., lodging, personal care, and feeding) healthcare workers during emergency periods of expanded care.
- ❑ Mental health support for employees, such as CISM, is part of the facility response plan.
- ❑ Laboratory and facility leadership are aware of state statutes and penalties for failure to comply with government directives that ensure the safety and care of the public.
- ❑ A full emergency power audit (including all facility lighting, power plugs, environmental temperature regulation) has been conducted during full facility emergency power support (of reasonable duration) during one or more seasonal temperature extremes.
- ❑ Cooling devices, extension cords, and supplementary lighting are available based upon an emergency power audit.
- ❑ Analytic (testing) vulnerabilities occasioned by loss of public water sources have been considered.
- ❑ Laboratory management staff have access to alternate communications systems to assess routing around secure and damaged areas to permit specimen transportation to reference or core laboratories.
- ❑ Volunteer or corporate ground transportation resources (ideally equipped with communications capabilities other than cell phones) are accessible for specimen transportation.
- ❑ MOUs have been developed with the resources cited immediately above, as well as with other support resources germane to emergency operations.
- ❑ A plan to implement or recognize community identification and security challenges, and permit private, corporate, or volunteer transportation of medical specimens and equipment, has been undertaken by the community and facility.
- ❑ Laboratory management has considered the communications technologies used for reference laboratory test ordering, resulting, and consultation, as well as the need for and types of alternative communications.
- ❑ The laboratory has information regarding reference laboratory contact person(s) and their communications plan for communication in the event of a disaster at their locale.
- ❑ The reference laboratory has a disaster plan for alternate site operations or for specimen referral, disaster recovery, and real-time client communications regarding their own operational capabilities during an incident affecting their community.
- ❑ Decontamination (of persons and belongings) can be performed by and at the local facility prior to entry into patient care areas.
- ❑ A secure site to hold evidence has been identified.

- ❑ Laboratory personnel has established a contact at their state or local public health laboratory that will be able to provide information related to the safe shipping and transportation of specimens being tested for bioterrorism agents.
- ❑ The laboratory and facility has a chain of custody form. (See Appendix B for a sample form.)
- ❑ Facility procedures exist for security and storage of contaminated clothing and belongings; these procedures include chain of custody maintenance of such items.
- ❑ Laboratory personnel/leadership are involved in facility disaster planning.
- ❑ There are provisions for childcare for healthcare workers, in the event of an incident.

Appendix A. Category A and B Biological Agents*

A1. Category A Agents

The U.S. public health system and primary healthcare providers must be prepared to address various biological agents, including pathogens that are rarely seen in the United States. High-priority agents include organisms that pose a risk to national security because they can be easily disseminated or transmitted from person to person; result in high mortality rates and have the potential for major public health impact; might cause public panic and social disruption; and require special action for public health preparedness.

-Anthrax (*Bacillus anthracis*)
-Botulism (*Clostridium botulinum* toxin)
-Plague (*Yersinia pestis*)
-Smallpox (*Variola* major)
-Tularemia (*Francisella tularensis*)
-Viral hemorrhagic fevers (Filoviruses [e.g., Ebola, Marburg] and Arenaviruses [e.g., Lassa, Machupol])

A2. Category B Agents

Second highest priority agents include those that are moderately easy to disseminate; result in moderate morbidity rates and low mortality rates; and require specific enhancements of CDC's diagnostic capacity and enhanced disease surveillance.

-Brucellosis (*Brucella* species)
-Epsilon toxin of *Clostridium perfringens*
-Glanders (*Burholderia mallei*)
-Melioidosis (*Burkholderia pseudomallei*)
-Psittacosis (*Chlamydia psittaci*)
-Q fever (*Coxiella burnetti*)
-Staphylococcal enterotoxin B
-Typhus fever (*Rickettsia prowazekii*)
-Ricin toxin from *Ricinus communis* (castor bean)
-Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis])
-Water safety threats (e.g., *Vibro cholerae, Cryptosporidium parvum*)
-Food safety threats (e.g., *Salmonella* species, *Escherichia coli* O157:H7, *Shigella*)

* From the CDC website: http://www.bt.cdc.gov/agent/agentlist-category.asp

Appendix B. Chain of Custody Log Sample Form

CHAIN OF CUSTODY LOG

1. SAMPLE	2. DATE COLLECTED	3. STATE CASE NO.	4. COUNTY CASE NO.

5. I.R. NO.	6. COUNTY	7. COLLECTED BY	8. LAB NO

9. SAMPLE DESCRIPTION (Quote pertinent labeling, firm name and address, pkg., etc.)

I, the undersigned, hereby certify that the sample submitted in this case and listed above, while in my custody, remained and was delivered in essentially the same condition as when I received it, except that material or portion thereof consumed in the analytical process at the laboratory, and that I received and delivered it to the person indicated on the date and time stated.

10. SAMPLE ACKNOWLEDGEMENT

Sample received from	Date/Time	Sample received by	Date/Time	Remarks

11. SAMPLE RELEASED TO:

Name:_____ Date:_____ Time:_____

Address:_____

Received by:_____ Date:_____

Witnessed by_____ Date:_____

12. SAMPLE STORAGE CONDITIONS

Websites

ACP-ASIM American College of Physicians-American Society of Internal Medicine
http://www.acponline.org/index.html?ft

Agency for Health Care Research and Quality
http://www.ahrq.gov/

Agency for Toxic Substances and Disease Registry
http://www.atsdr.cdc.gov/

American Red Cross
http://www.redcross.org/
Disaster Services
http://www.redcross.org/services/disaster/

American Society for Microbiology
http://www.asm.org/

Association for Professionals in Infection Control and Epidemiology, Inc.
http://www.apic.org/bioterror/

Centers for Disease Control and Prevention
http://www.cdc.gov/

The Disaster Preparedness and Emergency Response Association
http://www.disasters.org/dera/

Emergency Preparedness and Response Branch
http://www.cdc.gov/nceh/emergency/default.htm

Epidemic Intelligence Service
http://www.cdc.gov/eis/

Federal Response Plan Partners
http://www.fema.gov/about/frp.shtm

Hazardous Materials Information Resource System (HMIRS)
http://www.dlis.dla.mil/hmirs/default.asp

Hazardous Technical Information Services
http://www.dscr.dla.mil/htis/htis.htm

Health Resources and Services Administration
http://www.hrsa.gov/
Bioterrorism Hospital Preparedness Program
http://www.hrsa.gov/bioterrorism.htm

Institute of Medicine
http://www4.nas.edu/IOM/IOMHome.nsf

Joint Commission on Accreditation of Healthcare Organizations (Ernest A. Codman Award)
http://www.jcaho.org/

Metropolitan Medical Response System
http://www.mmrs.hhs.gov

The National Academy of Science
http://www.nationalacademies.org/nas/hashome.nsf

National Center for Infectious Diseases
http://www.cdc.gov/ncidod/diseases/index.htm
Surveillance
http://www.cdc.gov/ncidod/osr/data_reports.htm

National Emergency Management Association
http://www.nemaweb.org/index.cfm

National Information Center on Health Services Research and Health Care Technology (NICHSR)
http://www.nlm.nih.gov/nichsr/nichsr.html

National Institute for Occupational Safety and Health
http://www.cdc.gov/niosh/homepage.html

National Institute of Standards and Technology
http://www.nist.gov/

National Library of Medicine
http://www.nlm.nih.gov/nlmhome.html

National Mass Fatalities Institute
http://www.nmfi.org

National Pharmaceutical Stockpile Program
http://www.bt.cdc.gov/stockpile/

Office of Emergency Preparedness
http://www.ndms.dhhs.gov/

Office of Public Health Preparedness
http://www.hhs.gov/ophp/

Public Health Emergency Preparedness & Response
http://www.bt.cdc.gov/

Research and Special Programs Administration, Office of Hazardous Materials Safety
http://hazmat.dot.gov/

State Health Department Websites
http://www.phppo.cdc.gov/phtn/sites.asp#state

Website Resources

American Association of Blood Banks
Interorganizational Task Force on Domestic Disasters and Acts of Terrorism - Report and Recommendations, January 31, 2002
http://www.aabb.org/Pressroom/In_the_News/idfddat013002.htm

Biologic Agent Information Papers
http://www.nbc-med.org/SiteContent/MedRef/OnlineRef/GovDocs/BioAgents.html

Biological Diseases/Agents Listing
http://www.bt.cdc.gov/Agent/Agentlist.asp

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 4th Edition
http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

Bioterrorism Agent Sheets
http://www.apic.org/bioterror/agentsheets.cfm

Bioterrorism Readiness Plan: A Template for Healthcare Facilities
http://www.apic.org/educ/readinow.cfm

Building Protection: Collective Protection Against Airborne Hazards Including Chemical and Biological Agents
http://buildingprotection.sbccom.army.mil/

Chemical and Bioterrorism Preparedness Checklist (AHA) (October 3, 2001)
http://www.hospitalconnect.com/aha/key_issues/disaster_readiness/content/MaAtChecklistB1003.doc

Critical Incident Protocol
www.cj.msu.edu/~outreach/cip/cip.html

Disaster Operations Handbook
http://aabb.org/About_the_AABB/Disaster_Response/disastercontact.htm#1

Field Manual for Mental Health and Human Service Workers in Major Disasters (2000)
http://www.mentalhealth.org/publications/allpubs/ADM90-537/field.pdf

Guidelines for Mass Fatality Management During Terrorist Incidents Involving Chemical Agents, USASBCCOM, November 2001
http://www2.sbccom.army.mil/hld/downloads/cwirp/guidelines_mass_fatality_mgmt.pdf

Hospital Emergency Incident Command System
http://www.emsa.ca.gov/dms2/download.htm

Hospital Preparedness for Mass Casualties Final Report August 2000
http://www.hospitalconnect.com/ahapolicyforum/resources/disaster.html

Level A Laboratory Protocols
- Introduction (11/7/01) http://www.asmusa.org/pasrc/intro.htm
- Anthrax Protocol (03/21/02) http://www.asmusa.org/pasrc/bacillusanthracisprotocol.pdf
- Botulinum Toxin (12/6/01) http://www.asmusa.org/pasrc/bottoxprotocol.pdf

Brucella Protocol (5/29/02) http://www.asmusa.org/pasrc/Brucella.pdf
Plague Protocol (04/22/02) http://www.asmusa.org/pasrc/plagueprotocol.pdf

Mass Casualty Disaster Plan Checklist: A Template for Healthcare Facilities
http://www.apic.org/bioterror/checklist.doc

Mobile Operations Capability Guide for Emergency Managers and Planners
http://www.fema.gov/rrr/mers01.shtm

OSHA 3114: Hazardous Waste Operations and Emergency Response (HAZWOPER)
http://www.osha.gov/Publications/OSHA3114/osha3114.html

OSHA 3152: Hospitals and Community Emergency Response — What You Need to Know
http://www.osha.gov/Publications/OSHA3152/osha3152.html

Office of Workforce Policy and planning
http://www.phppo.cdc.gov/owpp/

Public Health Response to Biological and Chemical Terrorism: Interim Planning Guidance for State Public Health Officials (July 2001)
http://www.bt.cdc.gov/documents/planning/planningguidance.pdf

Recognition of Illness Associated with the Intentional Release of a Biologic Agent
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5041a2.htm

State Public Health Laboratory Contacts
http://www.asmusa.org/pasrc/StateLabcontacts.pdf

Terrorism and Domestic Preparedness
http://www.ojp.usdoj.gov/terrorism/whats_new.htm

United States Response to CBW and Domestic Preparedness
http://cns.miis.edu/research/cbw/domestic.htm#wmdchart

U.S. Food and Drug Administration
http://www.fda.gov/default.htm
Bioterrorism
http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html

The Quality System Approach

NCCLS subscribes to a quality system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents through a gap analysis. The approach is based on the model presented in the most current edition of NCCLS HS1—*A Quality System Model for Health Care.* The quality system approach applies a core set of "quality system essentials (QSEs)," basic to any organization, to all operations in any healthcare service's path of workflow. The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The quality system essentials (QSEs) are:

Documents & Records	Equipment	Information Management	Process Improvement
Organization	Purchasing & Inventory	Occurrence Management	Service & Satisfaction
Personnel	Process Control	Assessment	Facilities & Safety

X4-R addresses the quality system essentials (QSEs) indicated by an "X." For a description of the other NCCLS documents listed in the grid, please refer to the Related NCCLS Publications section on the following page.

Documents & Records	Organization	Personnel	Equipment	Purchasing & Inventory	Process Control	Information Management	Occurrence Management	Assessment	Process Improvement	Service & Satisfaction	Facilities & Safety
											X

Adapted from NCCLS document HS1— *A Quality System Model for Health Care.*

Related NCCLS Publications*

AST2-A **Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline (1999).** This document contains guidelines to provide users of *in vitro* diagnostic (IVD) devices outside the clinical laboratory with the guidance necessary to produce reliable results comparable to those obtained within the clinical laboratory.

AST4-A **Blood Glucose Testing in Settings Without Laboratory Support; Approved Guideline (1999).** This document provides recommendations for personnel performing blood glucose testing at sites outside the traditional clinical laboratory, addressing test performance, quality control, personnel training, and administrative responsibility.

C30-A2 **Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline—Second Edition (2002).** This document contains guidelines for performance of point-of-care (POC) blood glucose testing that stress quality control, training, and administrative responsibility.

EP18-P **Quality Management for Unit-Use Testing; Approved Guideline (2002).** This guideline recommends a quality management system for unit-use devices that will aid in the identification, understanding, and management of sources of error (potential failure modes) and help to ensure correct results. It is targeted for those involved in supervision of laboratory-testing quality management, and it addresses issues related to specimen collection through reporting of results.

GP2-A4 **Clinical Laboratory Technical Procedure Manuals; Approved Guideline — Fourth Edition (2002).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the laboratory testing community.

GP6-A **Inventory Control Systems for Laboratory Supplies; Approved Guideline (1994).** This document contains recommendations for inventory control systems to ensure availability of reagents and supplies in the laboratory.

GP9-A **Selecting and Evaluating a Referral Laboratory; Approved Guideline (1998).** This guideline provides an outline of reasons and criteria for choosing a referral laboratory. A checklist for evaluating potential referral laboratories is included to assist in the decision process.

GP17-A **Clinical Laboratory Safety; Approved Guideline (1996).** This document contains general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.

H3-A4 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard — Fourth Edition (1998).** This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children.

H4-A4 **Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition (1999).** This document provides a technique for the collection of diagnostic blood specimens by skin puncture, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic blood specimens obtained by skin puncture are also included.

H18-A2 **Procedures for the Handling and Processing of Blood Specimens; Approved Guideline —- Second Edition (1999).** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

H21-A3 **Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline – Third Edition (1998).** This document provides procedures for collecting, transporting, and storing blood; processing blood specimens; storage of plasma for coagulation testing; and general recommendations for performing the tests.

M29-A2 **Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report(2001).** Based on U.S. regulations, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

Related NCCLS Publications (Continued)

M40-P **Quality Control of Microbiological Transport Systems; Proposed Standard (2002).** This standard provides criteria to manufacturers and end users of transport devices to assist with provision of dependable products for the transport of microbiological clinical specimens. Quality control considerations are presented, as well as techniques, control organisms, and acceptability criteria. This document provides a consistent protocol for initial testing or microbiological transport devices by manufacturers and a method by which laboratories can validate manufacturer claims and compare devices.

NOTES

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