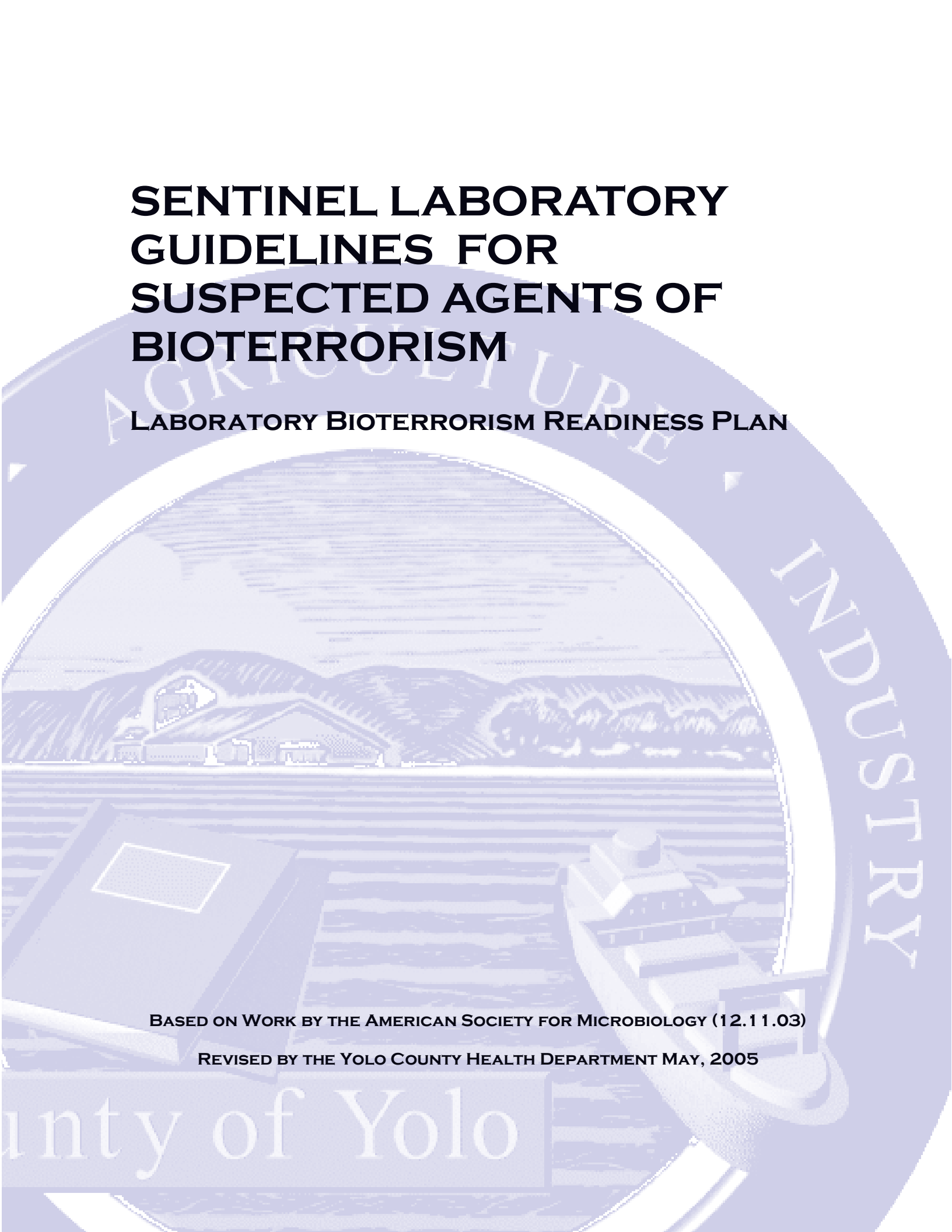
SENTINEL LABORATORY GUIDELINES FOR SUSPECTED AGENTS OF BIOTERRORISM

Laboratory Bioterrorism Readiness Plan



Based on Work by the American Society for Microbiology (12.11.03)

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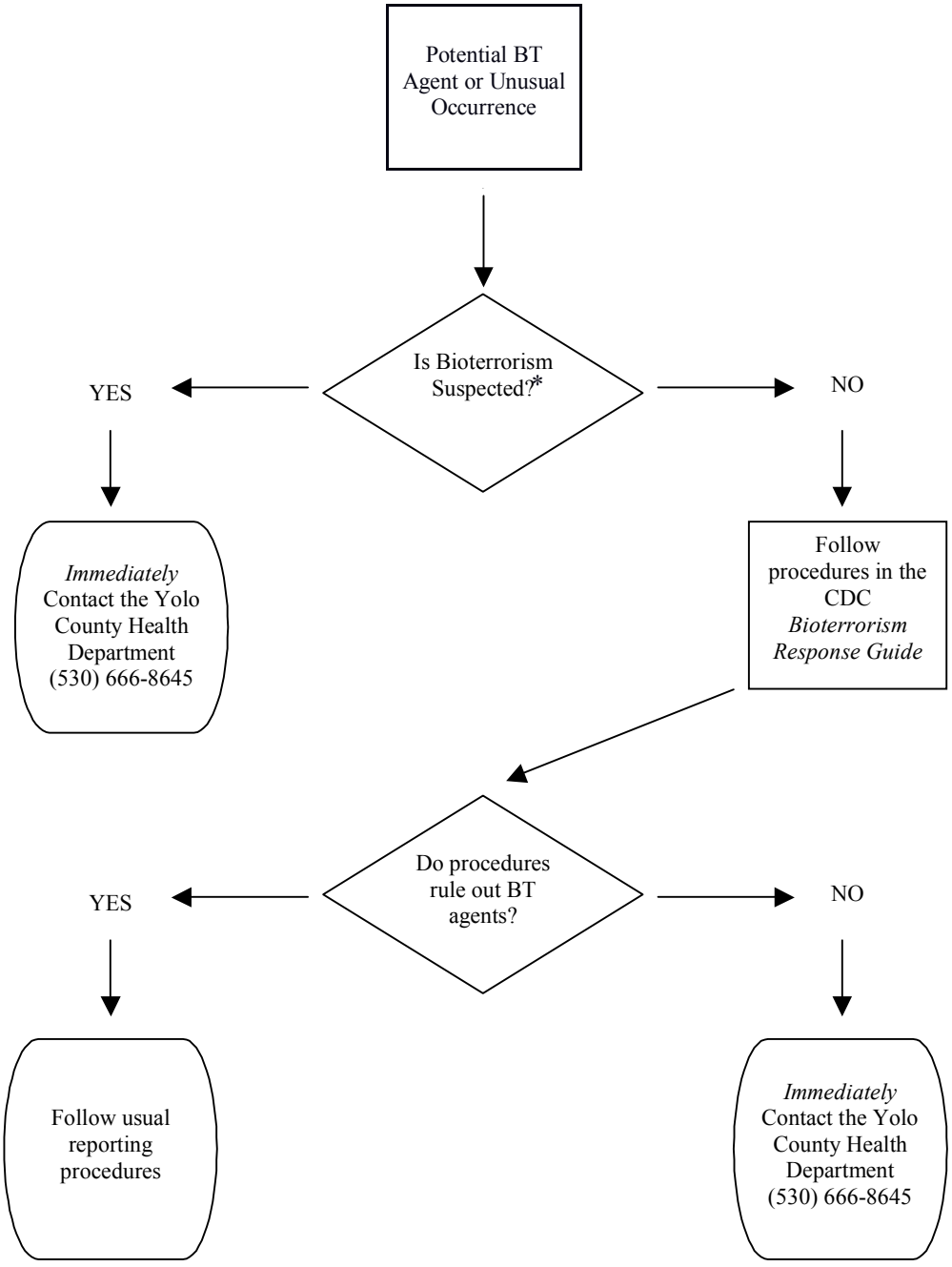
Flow Chart for the Yolo County Laboratory Bioterrorism Response



*Note: Some examples of BT suspect agents are listed in Appendix A; section III of the following guide also describes reasons to suspect bioterrorism.

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I. PURPOSE

As a sentinel laboratory, you may be called upon to assist in the diagnosis and management of patients who have been overtly or covertly exposed to a Bioterrorism (BT) agent. Your laboratory needs to promptly assist clinicians by providing them with accurate information on the selection, collection, and transportation of specimens. In addition, the laboratory must handle these specimens in a manner that will result in the greatest probability of success in establishing a diagnosis, meeting evidentiary requirements (in the event that a crime has been committed), and minimize the exposure of your employees, hospital personnel and patients to infectious agents.

With these responsibilities in mind, the purpose of this document is threefold:

1. To provide a formal description of how your laboratory can coordinate with the Yolo County Health Department to respond to a suspected or confirmed bioterrorism event.

2. To facilitate immediate and effective communication with all appropriate institutional and medical personnel, and public health officials in a response to bioterrorism.

3. To assist the Yolo County Sentinel Laboratories in responding to an act of terrorism in the very real possibility that they are the first to recognize that an isolated organism is a possible terrorist agent.

II. LABORATORY BT CONTACT PROTOCOL: WHEN TO IMPLEMENT

If a possible BT agent is suspected, isolated in the laboratory, or detected by other means, notify the treating physician and have your facility's infection control officer telephone the Yolo County Health Department **IMMEDIATELY .** Yolo County Health Department will make all out-of-county notifications, to include the California Department of Health Services (CDHS) and the Federal Bureau of Investigation (FBI). The FBI, through numerous federal directives and statutes, has criminal and investigative jurisdiction in all threats and incidents involving bioterrorism.

The sentinel laboratory should **also** report its findings to the Yolo County Health Department via the phone number listed below. The Centers for Disease Control and Prevention (CDC) *Bioterrorism Response Guide for Clinical Laboratories,* and the guidance contained within this document can be used to aid in the identification of possible bioterror agents.

Yolo County Health Department
24-hour Bioterrorism and Communicable Disease Reporting
530-666-8645
(after hours follow directions for reporting a "Public Health Emergency")

The Sacramento County reference laboratory may also be contacted for guidance by calling 916-874-9131 (daytime) or 916-875-5881 (24/7 health officer to page the microbiologist on-call).

III. DEFINITION OF BIOTERRORISM

Bioterrorism is defined as the "intentional use of microorganisms, or toxins, derived from living organisms, to produce disease and death in humans, animals, or plants." A bioterrorism event may be either overt or covert.

- An **overt** attack would be accompanied by an announcement that a specific agent was released. These attacks elicit an immediate response by law enforcement and HAZMAT personnel. Public health officials will also be involved to assist in evaluating the risk and control of the disease. Samples (environmental, food, water, animals) for testing would be submitted directly to a public health laboratory.

- A **covert** attack involves the release of an organism or toxin without an announcement. Days or weeks may pass before the release is noticed. The event would probably be signaled by a cluster of disease appearing after the incubation period. Emergency departments may be the first to observe unusual patterns of illness, while clinical laboratories would almost certainly detect the first cases of disease and raise suspicion of a possible event. Public health officials are to be notified of the suspicious event (which may be indicative of a bioterrorism incident), and they will help coordinate the forwarding of samples (or isolated organisms) to the appropriate LRN reference laboratory. Public health officials in concert with law enforcement officials would determine if an attack has occurred, confirm the identity of the agent, and institute protective and preventive measures designed to minimize the spread of disease.

While laboratories may not have clinical symptoms upon which to base their suspicion of bioterrorism, they should be aware of characteristics that may indicate such an event. These characteristics could include: unusual frequency of an organism, rare or non-endemic diseases, or unseasonal presence of an organism or virus. A list of possible bioterrorism agents is included in appendix A.

NOTE: Certain geographic areas are known to have natural human cases of infection due to BT agents (e.g., tularemia in Nantucket and Martha's Vineyard, Massachusetts, as well as Missouri, Oklahoma, and neighboring areas; and plague in much of the southwestern United States, especially New Mexico). While these cases may not be bioterror events, each case must be reported as governed by state law.

IV. THE LRN: LABORATORY RESPONSE NETWORK FOR BIOTERRORISM

The Laboratory Response Network (LRN) is a consortium and partnership of laboratories that provide immediate and sustained laboratory testing and communication in support of public health emergencies, particularly in response to acts of bioterrorism. The LRN is currently comprised of local, state, and federal public health laboratories in addition to private and commercial clinical laboratories, and selected food, water, agricultural, military, and veterinary testing laboratories; the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) is central to this network. Other key federal partners include the Federal Bureau of Investigation (FBI), the Department of Defense (DOD), the Environmental Protection Agency (EPA), the Department of Agriculture (USDA), the Department of Justice (DOJ), the Department of Energy (DOE), the Food and Drug Administration (FDA), the Association of Public Health

Laboratories (APHL), the National Institutes of Health (NIH), the American Association of Veterinary Laboratory Diagnosticians (AAVLD), and the American Society for Microbiology (ASM). All laboratories are regarded as partners and in some cases, registered members of the LRN. Preliminary testing and screening are performed primarily in a distributed rather than a centralized fashion to ensure a prompt and rapid initial response; a system of triage and referral of specimens ensures transfer of appropriate materials to specialty laboratories where sophisticated equipment, technologies, and expertise are applied to specimen analysis.

The goals of the LRN are to:

(1) Ensure that the nation's public health, clinical, and other select laboratories are prepared to detect and respond to a bioterrorism or chemical terrorism event in an appropriate and integrated manner.
(2) Ensure that all member reference laboratories collectively maintain state-of-the-art biodetection and diagnostic capabilities and surge capacity as well as secure electronic communication of test results for the biological and chemical agents likely to be used in the commission of a biocrime or bioterrorism event.
(3) Work with other departments and agencies to ensure a successful federal response to an act of bioterrorism and to facilitate and optimize the ability of states to competently respond independently to biocrimes or public health emergencies in the state.
(4) Promote the CDC's and HHS' bioterrorism research agenda and CDC's internal response needs.
(5) Enlist an optimal number of registered participating LRN laboratories throughout the United States as determined by the LRN working group.
(6) To comply with established chain-of-custody protocols outlined by the FBI, in accordance with legal standards.

The LRN maintains the following:

(1) A registry and linkage of clinical and private laboratories in the U.S. that would include Sentinel and Reference laboratories.
(2) Complete, accurate, and standardized protocols for all levels of testing for agents deemed critical and likely to be used in the commission of biocrimes or acts of bioterrorism.
(3) Secure but accessible supply of standardized reagents and diagnostic technologies produced and maintained by the CDC.
(4) Secure electronic laboratory reporting that integrates with key epidemiologic, surveillance, and emergency response components
(5) Training and proficiency testing essential to the diagnostic process

Clinical laboratories play a critical role in the LRN. Their heightened awareness to the possibility of recovering the agents of bioterrorism from patient specimens and referral of suspect isolates to the appropriate public health reference laboratory is crucial.

Classification of LRN Laboratories

The classification of bioterrorism laboratories by the LRN was revised in 2003. The original designations of Level A, B, C, and D laboratories is no longer recognized and are now designated as Sentinel, Reference, and National Laboratories (Fig. 1).

Sentinel (formerly Level A). Sentinel laboratories are clinical laboratories that follow Biosafety Level 2 (BSL-2) guidelines. Their primary responsibility is to recognize and rule out or refer suspicious agents by following standardized laboratory guidelines. Even though many Sentinel laboratories are capable of providing a "presumptive identification" of some of the targeted organisms, they must refer isolates to an LRN Reference laboratory.

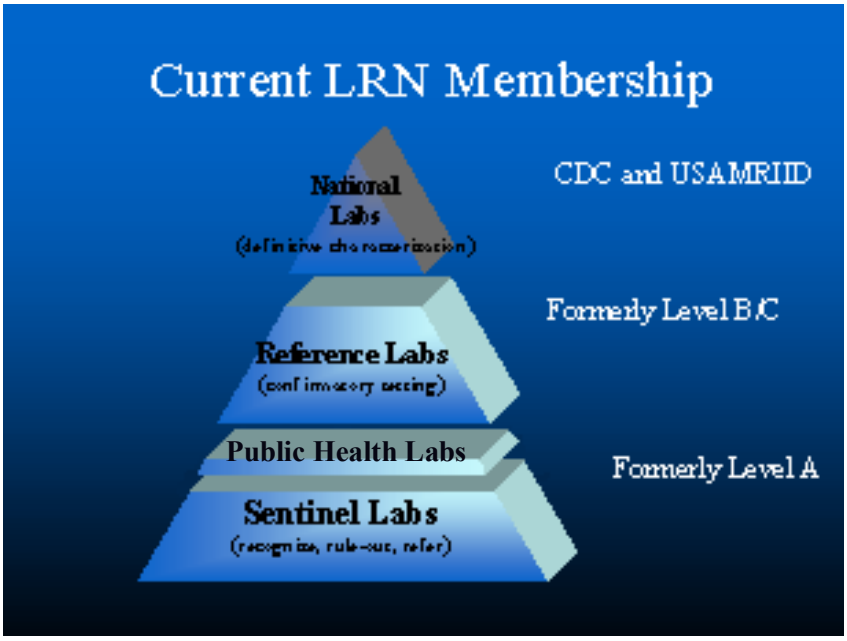

Figure 1: Laboratory Resource Network Membership

Public Health Laboratory. In the State of California, many counties maintain public health laboratories that follow BSL-2 and BSL-3 guidelines. While they do not hold a separate designation under the Laboratory Response Network, their responsibility is to assist in ruling out possible BT specimens, testing of environmental samples, and to coordinate the testing of samples at higher level facilities. Please contact the Yolo County Health Department Laboratory (Direct: 530-666-8644) or the protocols contained within this manual for instructions and guidance regarding the submission of suspicious agents for confirmatory testing.

LRN Reference (formerly Level B and C). LRN reference laboratories are local and state public health laboratories, selected academic- or university-based laboratories, designated specialty laboratories (veterinary, water, food, chemical, military, agricultural) that possess the reagents and technology for definitive confirmation of organisms including toxin testing, referred by BSL-2 laboratories. LRN Reference laboratories follow BSL-3 containment and practice guidelines.

LRN National Laboratories (formerly Level D). LRN National Laboratories are Federal laboratories that have BSL-4 containment facilities and practice guidelines. The primary laboratory at this level is located at the CDC and specializes in the isolation and identification of BSL-4 agents such as Ebola, Marburg, and Smallpox virus. This laboratory also possesses the capability of advanced genetic characterization and archiving of all bioterrorism agents.

V. THE CLINICAL LABORATORY'S RESPONSIBILITY

As members of the LRN, Sentinel laboratories have access to the network and serve as "sentinels" for the early detection of suspicious agents. Sentinel laboratories do not have access to the CDC secure website for Reference Laboratory Testing Protocols or reagents. Instead, Sentinel laboratories must utilize standardized testing protocols (The CDC Bioterrorism Response Guide or ASM Sentinel Laboratory Guidelines) that have been designed to utilize conventional tests to facilitate the "rule-out" or "referral" of a suspicious isolate to an LRN Reference laboratory.

The Sentinel laboratory is NOT responsible for and SHOULD NOT make the decision that a bioterrorism event has occurred; that responsibility rests with local, state, and federal health and law enforcement officials. **A designated individual within your facility (preferably the Infection Control Officer) should be notified of a suspicious agent who, in turn, notifies the local public health officials who will be working with the public health laboratory. In addition, a laboratory report should be made (consistent with California law) by contacting the Yolo County Health Department at (530) 666-8645. The public health laboratory may also be contacted for guidance in the disposition of the suspicious agent prior to referral for confirmatory testing.**

NOTE: In no case should the Sentinel laboratory accept environmental (powders, letters, packages), animal, food, or water specimens for examination, culture, or transport for bioterrorism-associated agents. The transportation and identification of such specimens should be coordinated through the County Public Health Laboratory and the County Hazardous Materials Team.

VI. SENTINEL (LEVEL A) LABORATORY GUIDELINES FOR BT AGENTS

The Yolo County Public Health Laboratory recommends the Centers for Disease Control and Prevention *Bioterrorism Response Guide for Clinical Laboratories* as a first reference for bioterror agents. In addition to this resource, links to the American Society for Microbiology's guidelines, can be found on the Yolo County Health Department website (www.yolohealth.org - select the Public Health Laboratory from the menu on the left-hand column of the page).

VII. SHIPPING AND HANDLING OF INFECTIOUS MATERIALS GUIDELINES

United States, international, and commercial regulations mandate the proper packing, documentation, and safe shipment of dangerous goods in order to protect the public, airline workers, couriers, and other persons who work for commercial shippers and who handle the dangerous goods during the many segments of the shipping process. In addition, proper packing and shipping of dangerous goods will reduce the exposure of the shipper to the risks of criminal and civil liabilities associated with shipping dangerous goods, particularly infectious substances.

The process of properly packing and shipping an infectious substance, a diagnostic specimen, or a biological agent is composed of the following sequential steps:

1. Training of all persons involved in the shipping process
2. Determination of the applicability of the regulations

3. Determination of any applicable shipping limitations
4. Classification of the substance to be shipped
5. Identification of the substance to be shipped
6. Selection of the appropriate packing instructions to use
7. Selection of appropriate packaging
8. Marking and labeling the package
9. Documentation of the shipment

Failure to follow governmental and commercial regulations for the packing and shipping of infectious substances and other dangerous goods can result in criminal prosecution and substantial financial penalties.

A copy of the American Society for Microbiology's (ASM) Laboratory Guidelines on Packing and Shipping Infectious Substances, Diagnostic Specimens, and Biological Agents can be downloaded via the link on laboratory page at the Yolo County Health Department website (www.yolohealth.org). Your laboratory's CDC Bioterrorism Response Guide also contains reference information.

Sentinel laboratories should be aware that, in the case of bioterrorism, law enforcement would most likely coordinate the transportation of laboratory samples. If bioterror is suspected, information on the shipping and handling of specimens will likely be distributed from the Yolo County Health Department in coordination and conjunction with the local FBI office. Sentinel laboratories are urged to call the Public Health Laboratory before sending samples if that guidance has not already been received.

VIII. HANDLING OF A POSSIBLE BT AGENT

The following should be considered when handling possible bioterror agents:

A. A lead BT technologist should be appointed and be notified immediately that a suspected BT specimen or agent is in the laboratory. Laboratory workers are to be informed promptly of the name and medical record number of the person(s) with the suspected infection and, if appropriate, to treat other specimens from the patient(s) appropriately. This must be done in a manner that is in compliance with the Health Insurance Portability and Accountability Act (HIPAA). In addition, chain-of-custody documentation should be initiated, a sample of which can be found in appendix "C." [Laboratories should note that after the involvement of law enforcement in a bioterror investigation, chain of custody documentation will most likely be completed with the investigating agency's forms]

B. All suspected BT specimens are to be processed in the biological safety cabinet **(whenever possible, this should be in a biological safety cabinet in a room that is under negative pressure)** while wearing appropriate personal protective equipment, such as gown, gloves, and mask.

C. In addition to unique sample numbers on each of the plates, tubes, and blood culture bottles for which this applies, they must also be labeled prominently: **"Possible highly infectious agent: [fill in name of agent]"**

D. All plates that have been streaked for culture or subculture must be sealed with shrink seal or the equivalent and labeled as in step C above.

E. Any growth from specimens is to be manipulated in a biological safety cabinet while wearing appropriate personal protective equipment, such as gown, gloves, and mask.

F. As the culture is being worked up, the technologist(s) working on the culture(s) must work closely with the microbiology supervisor and medical director.

G. An identification of the organism is **NOT** the role of the Sentinel microbiology laboratory. An organism that is consistent with, for example, *Yersinia pestis*, will be forwarded to a reference laboratory for definitive identification. **Do not perform any more manipulation of the cultures than is absolutely essential.**

NOTE: Under no circumstances are viral cultures to be set up if smallpox, Ebola virus, or another of the viral agents of bioterrorism is suspected. In the event that these agents are acquired, please contact the Yolo County Health Department for assistance.

IX. THERAPY OF BT AGENTS

Specific treatment or prophylaxis for known or suspected exposure to bioterrorism agents will, in the setting of a bioterrorist event, likely be forthcoming from Public Health Authorities. In the absence of this information on the specific therapy for a given outbreak, a good source for information on treatment and prophylaxis is:

> Gilbert DN, Moellering RC, Sande MA. The Sanford Guide to Antimicrobial Therapy. 33rd ed. Table 1B: Prophylaxis and treatment of organisms of potential use as biological weapons, page 46. Antimicrobial Therapy, Inc., Hyde Park, Vermont.
>
> (http://www.sanfordguide.com/)

Please note that the table is "pathogen-based" and does not give information based upon a clinical syndrome in the absence of knowledge of the pathogen.

X. ACKNOWLEDGMENT

ASM acknowledged the Oregon State Public Health Laboratory (http://www.ohd.hr.state.or.us/phl/index.cfm) for information from its web site that was included in their document.

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XI. REFERENCES

1. **Department of Health and Human Services.** 2003. Bioterrorism Response Guide for Clinical Laboratories. Centers for Disease Control and Prevention, Public Health Practice Program Office, Division of Laboratory Systems.
2. **Department of Health and Human Services.** 1999. Biosafety in microbiological and biomedical laboratories, 4th ed. U.S. Government Printing Office, Washington, D.C.
3. **Department of Health and Human Services.** 1999. Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health.
4. **Department of Health, Education, and Welfare.** 1974. Biohazards safety guide. Department of Health, Education, and Welfare, Bethesda, Md.
5. **Pike, R. M.** 1976. Laboratory-associated infections. Summary and analysis of 3921 cases. Health Lab. Sci. **13:**105-114.

APPENDIX

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EXAMPLE BIOTERROR AGENTS AND THEIR ALTERNATIVE NAMES

Agent Category	Name(s)	Other information that may appear on requisition
A	*Bacillus anthracis*	Anthrax, cutaneous anthrax, gastrointestinal anthrax, inhalation anthrax, anthrax meningitis, patient with hemorrhagic mediastinitis
	Viral hemorrhagic fever	Hemorrhagic fever, VHF
	Yersinia pestis	Plague, bubonic plague, pneumonic plague, septicemic plague, bubo, *Pasteurella pestis*, plague meningitis
	Clostridium botulinum toxin	Botulism, botulinum toxin, botulism toxin, infant botulism, wound botulism, food from patient with botulism
	Crimean-Congo hemorrhagic fever virus	CCHF, viral hemorrhagic fever, VHF, hemorrhagic fever
	Ebola virus	Ebola, viral hemorrhagic fever, VHF, hemorrhagic fever
	Francisella tularensis	Tularemia, *Pasteurella tularensis*, rabbit fever, deerfly fever, history of skinning animals, history of rabbit contact, tularemic pneumonia, typhoidal tularemia, oculoglandular tularemia, ulceroglandular tularemia, glandular tularemia, pharyngeal tularemia
	Guanarito virus	Venezuelan hemorrhagic fever virus, viral hemorrhagic fever, VHF, hemorrhagic fever
	Junin virus (a VHF)	Argentinian hemorrhagic fever virus, viral hemorrhagic fever, VHF, hemorrhagic fever
	Lassa fever virus	Viral hemorrhagic fever, VHF, hemorrhagic fever
	Machupo virus	Bolivian hemorrhagic fever virus, viral hemorrhagic fever, VHF, hemorrhagic fever
	Marburg virus	Marburg, viral hemorrhagic fever, VHF, hemorrhagic fever
	Smallpox virus	Variola, smallpox
B	*Brucella melitensis*, *B. suis*, *B. abortus*, *B. canis*	Brucellosis; history of ingestion of goat's milk; history of consumption of Mexican cheese; slaughterhouse worker; history of consumption of unpasteurized milk or cheese; contact with goats, sheep, cattle, or camels; laboratory worker with accident
	Epsilon toxin	Toxin of *Clostridium perfringens*
	Food safety threats	(e.g.: *Salmonella* species, *Escherichia coli* 0157:H7, *Shigella*)
	Psittacosis	*Chlamydia psittaci*
	Ricin toxin	(from *Ricinus communis*—castor beans)
	Typhus fever	*Rickettsia prowazekii*
	Water safety threats	(e.g.: *Vibrio cholerae, Cryptosporidium parvum*)
	Burkholderia mallei	*Pseudomonas mallei*, glanders, laboratory worker with accident
	Burkholderia pseudomallei	*Pseudomonas pseudomallei*, melioidosis
	Staphylococcal enterotoxin B	*Staphylococcus aureus* enterotoxin B, *Staphylococcus aureus* enterotoxin, staphylococcal enterotoxin, food from patient with food poisoning
	Coxiella burnetii	Q fever, pneumonia and sheep exposure, pneumonia and goat exposure, culture-negative endocarditis
C	Nipah virus	Hendra-like virus, pig contact with encephalitis
	Hantaviruses (one causes a VHF)	Korean hemorrhagic fever, Sin Nombre virus, hantavirus pulmonary syndrome, viral hemorrhagic fever, VHF, hemorrhagic fever

Note: While this list provides a variety of the common bioterror agent names, this list should not be considered complete.

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INFORMATION CHECKLIST

(This Checklist may help in the gathering of information in a suspected bioterror event. The Checklist is to be filled out by the shift operations manager, shift supervisor, or other designated personnel.)

Step	Task/Data		Date/Time Completed	Signature
1.	Name of patient(s), medical record number(s), patient location(s) and other pertinent information. A. B. C. D. E.			
2.	Who contacted the lab about the possibility of bioterrorism? Name and phone number:			
3.	Suspected bioterrorism agent(s) (e.g.: anthrax, plague, etc., or unknown)	1. 2. 3. 4. 5.		
4.	Contacted Infection Control Officer	☐Yes ☐No Who?		

Step	Task/Data		Date/Time Completed	Signature
5.	Contacted Yolo County Health Department	☐Yes ☐No Who?		
6.	Contacted the treating physician	☐Yes ☐No Who?		
7.	If instructed to contact others *within* facility, write who and whether the person was available.	Who?		
		Contacted: ☐Yes ☐No		
		Who?		
		Contacted: ☐Yes ☐No		
8.	If instructed to contact others *outside* facility, write who and whether the person was available.	Who?		
		Contacted: ☐Yes ☐No		
		Who?		
		Contacted: ☐Yes ☐No		
9.	Law Enforcement Officer Contacted?	Who?		
		Contacted: ☐Yes ☐No		
10.	Specimens for suspected bioterrorism agents placed in the biological safety cabinet in the _____ part of the laboratory.	☐Yes ☐No		
11.	Chain-of-custody documentation initiated.	☐Yes ☐No		

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County of Yolo

HEALTH DEPARTMENT

Laboratory
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PHONE - (530) 666-8644 FAX - (530) 666-8674

CLINICAL LABORATORY CHAIN-OF-CUSTODY RECORD

Patient Number:			Patient Name:	Laboratory Facility Name and Address: Page: __ *o f*	
Sample ID#:	**Date:**	**Time:**	**Condition/ Location Sample Found (at time of Chain-of-custody Start):**	**Description of Item/ Remarks:**	**Name of person who collected sample:**

Custody Initiated By: (Signature)	Date/ Time		Custody Initiated By: (Print Name & Department)	Address and telephone of Custody Initiated By:
Relinquished By: (Signature)	Date/ Time	Received by: (Signature)	Received by: (Print Name & Department)	Address and telephone of Receiving:
Relinquished By: (Signature)	Date/ Time	Received by: (Signature)	Received by: (Print Name & Department)	Address and telephone of Receiving:
Relinquished By: (Signature)	Date/ Time	Received by: (Signature)	Received by: (Print Name & Department)	Address and telephone of Receiving:

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