

contains only one genus (*Arenavirus*), which in turn harbors many different species with LCMV being one of them.

The book is also poorly edited. Among the harmless typographical or grammatical mistakes are countless examples of wrongly spelled scientific vocabulary: “*Dunacentor*” ticks (*Dermacentor*), “Thottopalyan virus” (Thottopalayam virus), “haemophagic fevers” (hemorrhagic fevers), “Guillaume-Barre syndrome” (Guillain-Barré syndrome), “aenavirus” (arenavirus), or “fucin” protease (furin) are just some examples. The described diseases are most often referred to in a “colloquial” manner—mentioning the latest WHO International Classification of Diseases (ICD-10) designations would have been helpful. Tables in the book are sometimes difficult to read or incomplete, and they are randomly placed; one reference to a table forced me to go back 16 pages to find it.

Viral Haemorrhagic Fevers contains too few references for the specialist or the interested outsider, and the bibli-

ography is heavily biased towards literature written in English and published in Western journals. This is not a trivial point. Omsk hemorrhagic fever, for example, gets cursory treatment with little or no reference to several hundred Soviet/Russian references on the subject.

It is also unclear why the author included hantavirus pulmonary syndrome in the book—a disease that is not characterized by hemorrhages. Likewise, lymphocytic choriomeningitis is described but there is no mention that hemorrhagic manifestations have actually been recorded in rare cases. Furthermore, the text occasionally contradicts itself. While tables list Whitewater Arroyo virus as not being associated with human disease, the accompanying text states that several severe cases of VHF caused by this agent have been recorded.

Viral Haemorrhagic Fevers has the potential to be a wonderful and educational textbook for students and professionals alike. However, a new, carefully edited, and better-referenced version should be prepared before the book could be truly recommended to a wider audience.

Ask the Experts

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Do you have a biosafety question and you’re not sure who to ask? Send your questions to the “Ask the Experts” column and I’ll get them answered for you. Drawing from my own experience or that of other experts in the field, we’ll try to compile a thorough and comprehensive answer to your question. Please e-mail your questions to jkeene@biohaztec.com or to Co-Editor Barbara Johnson at barbara_johnson@verizon.net or Co-Editor Karen B. Byers at karen_byers@dfci.harvard.edu.

Non-Compliant Biocontainment Facilities and Associated Liability

It is a fact that a large number of biocontainment laboratories in universities, corporations, and other institutions are not up to current standards as stated in the 4th edition of the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and that a significant number of new biocontainment laboratories are being built. Because of the public perception with regard to the safety of these facilities, a number of institutions and biosafety professionals are concerned when, for one reason or another, the institution does not follow the guidelines for insuring containment. Several questions have been

raised concerning liability for failure to follow the guidelines.

For an expert answer to these questions, I asked R. Leonard Vance, JD, PhD, PE, CIH, Associate Professor, Department of Epidemiology & Community Health, Medical College of Virginia, Virginia Commonwealth University to respond. Dr. Vance is the former Director of Health Standards for Federal OSHA under the Reagan Administration. His answers follow:

What is the potential liability, in the event of an injury, for an institution that does not follow the BMBL or the NIH Guidelines for the Design and Construction of Laboratories (NIH-DCL)?

Assuming:

1. The BMBL is the “standard of the industry” when it comes to how biocontainment laboratories/facilities should be operated;
2. The BMBL states that biocontainment laboratories should be validated with regard to design construction and procedure prior to initiating work; and

3. The NIH has developed a set of design and construction guidelines that also have been accepted as the “standards of the industry.”

The question raised has several possible responses and encompasses issues of common law negligence, contractual liability, and regulatory compliance. Let us begin by assuming all three of the conditions above are true and the laboratory we are discussing operates outside of either set of guidelines. What are the consequences for the following entities?

- A person not employed by the lab who is injured by an incident occurring in the lab;
- The owner of the lab;
- A consultant who designed the lab;
- An employee working in the lab who is injured.

Negligence and Standards of Care

The elements of common law negligence are duty, breach of duty causation and damages. Duty is established based on the relationship, or absence thereof, between the parties involved in an injury. Breach of duty involves the question of determination of the standard of conduct to which the defendant must conform. It is that standard one speaks of when discussing the standards of care. The standards of care depend on facts surrounding injury to the plaintiff and the relationship of the parties. Ordinarily, the standards of care are those which a prudent person would use under like circumstances. The legal question to be answered by the court is: Was the defendant’s conduct reasonable in light of the apparent risk?

Health and safety standards issued by safety organizations such as the National Safety Council, The American Conference of Governmental Industrial Hygienist (ACGIH, The American National Standards Institute (ANSI) have been routinely used to establish the standards of care in negligence litigation. The BMBL and NIH-DCL and other similar federal guidelines are simply another such set of guidelines counsel for an injured person would introduce in connection with establishment of standards of care. If the guidelines had not been followed, an injury victim would likely introduce them for the purpose of showing noncompliance with the standards of care. If the guidelines had been followed, a defendant, e.g., the owner of the lab or its designer, would likely introduce them as defense evidence. When such guidelines are used as evidence, the evidence must ordinarily be presented by expert witnesses. Thus, either a plaintiff or a defendant might retain a biosafety professional to testify as to the standards of care.

Suppose a person is injured because of an incident in a laboratory. The injury is caused (arguably) by failure of the lab personnel or owner complying with the guidelines. Who is liable for the damages incurred as a result of the injury? The owner of the lab obviously is exposed to liability in a case like this. If the injured person is an em-

ployee of the lab, the victim’s sole recourse is workers compensation. For anyone else, recovery would be through a suit against the owner of the lab. A design professional who designed the lab would be exposed to liability, as well.

Contractual Liability could also result from non-compliance with the guidelines. Conditions in a grant, e.g., NIH, Department of Defense, Department of Energy, U.S. Department of Agriculture, etc., establish the requirements applicable to the parties to the contract. Failure to perform in conformance with the grant could trigger an order to return all funds expended under the grant. Thus, an institution could find itself obligated to return grant funds already expended if found in non-compliance with the grant requirements.

Regulatory Liability also exists when the guidelines have been incorporated into regulations. Consensus standards are often adopted as regulations by governmental agencies. OSHA has adopted ANSI and ACGIH consensus standards, as well as CDC Guidelines, as Agency standards. In the case of the BMBL, there is a requirement that guidelines be followed as a prerequisite for working with Select Agents under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. This then makes the status of the guidelines in establishing the standards of care much more firm.

Who is ultimately responsible for insuring the containment facility, which belongs to the institution, is in compliance, both from a physical construction standpoint and from an operation/management standpoint?

Each institution is ultimately responsible for insuring that a containment facility belonging to the institution conforms to the standards of care. This is a common law duty recognized throughout the United States. Many institutions may be shielded from liability by the doctrine of sovereign immunity. How sovereign immunity applies varies from jurisdiction to jurisdiction, but sovereign immunity is a defense to a claim of liability. However, sovereign immunity does not lessen the degree of obligation an institution has to operate within the applicable standards of care, both from a physical construction standpoint and from an operational/management standpoint. It simply prevents a claimant from recovering money damages from the institution.

Could the Chief Executive Officer also be found liable if he or she knew about the failure to comply, and/or could the head of engineering or of health and safety

also be implicated if they failed to follow the requirements and did not provide appropriate guidance and/or warning of failure to comply?

Yes, given that the injury is shown to be a result of a specific breach of duty set forth by the applicable standards of care. This is similar to the situation of a malprac-

tice claimant who files suit against both the hospital and the physicians involved with his treatment. Individual officers, or employees of an institution, may be found liable for failure to insure compliance with the applicable standards. Even in the case of a governmental institution, individual officers or employees of the institution may be found liable in their personal capacity, while the institution itself is shielded from liability by the doctrine of sovereign immunity.

Capsule

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What's new, what's hot, what's timely? If you don't have time to search the Internet for the latest developments that might impact your work environment, you just might find some of this information in this "Capsule" column. Please e-mail any comments or suggestions to ekrisiunas@aol.com or to Co-Editor Barbara Johnson at barbara_johnson@verizon.net or Co-Editor Karen B. Byers at karen_byers@dfci.harvard.edu.

Mumps Outbreak Update Information

Changes in recommendations have been made for determining HCW immune status due to the 2006 outbreak published. Determining the immune status of personnel; either by documentation of two MMRs, a positive mumps IgG or history of physician-diagnosed mumps, or birth before 1957, is recommended.

For information regarding clinical disease, infection control measures, and updates on vaccinations see: Mumps-Technical Q&As for healthcare professionals at www.cdc.gov/nip/diseases/mumps/mumps-tech-faqs.htm#exp.

Additional information may also be found at Mumps information for healthcare professionals.

www.cdc.gov/nip/diseases/mumps/default.htm

CDC Health Update: Inhalation Anthrax Case Investigation, Pennsylvania, New York City—Update, 2/24/2006

The recent case of inhalation anthrax presented investigators with some interesting challenges. Was this a case of bioterrorism or something else? The following link provides an update to this somewhat unusual, but not

totally unexpected exposure.

www.bt.cdc.gov/agent/anthrax/han022406.asp

Avian Influenza Virus

Avian influenza virus usually refers to influenza A viruses found chiefly in birds, but infections can occur in humans. The risk is generally low to most people, because the viruses do not usually infect humans. However, confirmed cases of human infection have been reported since 1997.

The CDC updated the following web site on April 24, 2006, with current information regarding the status of this growing concern.

www.cdc.gov/flu/avian/

Emerging Infectious Diseases (EID)

The May 2006 issue of the EID is dedicated to the re-emergence of Tuberculosis. This disease has shown extreme resilience during the past century in spite of the advancements in therapy. For more information, visit www.cdc.gov/ncidod/EID/index.htm

Approaches to Safe Nanotechnology: An Information Exchange with NIOSH

Nanotechnology—do you know what it is? Will your industry be impacted by it? What are the occupational health and safety issues? For an introduction to Nanotechnology, check out the following link. The document is still underdevelopment but provides an entrée to this fascinating field.

www.cdc.gov/niosh/topics/nanotech/nano_exchange.html