



Regulations and Standards

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The concept of this column is to provide information on new, revised, or proposed regulations, guidelines, and standards that may be of interest to the biosafety professional and other safety professionals who have responsibilities for biosafety. By its very nature, the timeliness of such information is subject to many factors including when information becomes available, how it comes to the attention of the editors, and the publication schedule of this journal. My primary source of information will be through the ABSA Technical Review Committee, currently chaired by Bill Homovec and by monitoring the biosafety listserv. In most cases, I'll reprint summaries obtained directly from the primary source of information. If such information is not available, I'll write my own summary. Following the detailed summaries, I'll provide basic source material that readers may use to find additional information on the topic or published work. I welcome readers' feedback on whether this format works and how to make it better meet their needs. Please send your comments by e-mail to don_callihan@bd.com or to the Editor, Ira F. Salkin, at irasalkin@aol.com.

Activities of the ABSA Technical Review Committee (TRC)

During the past few months, TRC members have reviewed the third draft revision of "Laboratory Biosafety Guidelines" from Health Canada's Office of Laboratory Security and a draft revision of CDC "Guidelines for Hand Hygiene in Healthcare Facilities." Dates for final publication of these documents have not been announced.

TRC also reviewed two proposed modifications to the NIH "Guidelines on Recombinant DNA." The first proposal dealt with reporting adverse events, and the

second dealt with designation of certain strains of *E. coli* as risk group 1 agents. The guidelines have been updated since the submission of these comments to at least include consideration of the *E. coli* proposal.

Last year, TRC commented on the 1/22/01 proposed rule from the U.S. Department of Transportation Research and Special Programs Administration (RSPA) regarding infectious substances that for the first time would regulate the Department of Transportation's shipment of diagnostic specimens. Members should be on the lookout for the final rule to be issued sometime this year.

If interested in participating in the ABSA Technical Review Committee, contact Committee Chairman Bill Homovec at Bill_Homovec@labcorp.com.

Draft Guideline for Disinfection and Sterilization in Healthcare Facilities

Federal Register: April 30, 2002 (Volume 67, Number 83, p. 21252). From the *Federal Register* Online via GPO Access (wais.access.gpo.gov) DOCID: fr30ap02-75. Agency: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS).

Summary

This notice is a request for review of and comment on the Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003, available on the CDC web site at www.cdc.gov/ncidod/hip/dsguide.htm. The guideline has been developed for practitioners who provide care for patients and who are responsible for monitoring and preventing infections in healthcare settings, especially those involved in sterilizing and disinfecting medical devices and surgical instruments. The

guideline is intended to replace the section in Guideline for Handwashing and Hospital Environmental Control (1985) that dealt with sterilization and disinfection.

Supplementary Information

The Draft Guideline for Disinfection and Sterilization in Healthcare Facilities, 2003 presents a pragmatic approach to the judicious selection and proper use of disinfection and sterilization processes in healthcare settings. The guideline is intended to assist healthcare personnel in preventing infections associated with contaminated medical devices or surgical instruments and is targeted to infection control professionals, infectious disease clinicians, physicians who perform endoscopic procedures (e.g., gastroenterologists, pulmonologists), central processing technicians, sterile processing technicians, operating room nurses and technicians, manufacturers of disinfection and sterilization equipment, and manufacturers of reusable medical devices.

- Part 1 of the two-part document provides information on chemical disinfectants recommended for patient-care equipment. These disinfectants include alcohol, glutaraldehyde, hydrogen peroxide, iodophors, ortho-phthalaldehyde, peracetic acid, phenolics, quaternary ammonium compounds, and sodium hypochlorite. Sterilization methods discussed include steam sterilization, ethylene oxide, hydrogen peroxide gas plasma, and liquid peracetic acid.
- Part 2 of the document provides consensus recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) for the practice of disinfection and sterilization in healthcare settings. Most recommendations are pertinent for the inpatient, outpatient, and home care setting, unless otherwise noted.

Hazardous Materials: Security Requirements for Offerors and Transporters of Hazardous Materials

Notice of proposed rulemaking: 49 CFR Parts 107, 171, 172, and 177 [Docket No. RSPA-02-12064 (HM-232)] RIN 2137-AD66. *Federal Register*: May 2, 2002 (Volume 67, Number 85, p. 22028-22035). From the

Federal Register Online via GPO Access [wais.access.gpo.gov] DOCID:fr02my02-30. Agency: Research and Special Programs Administration (RSPA), DOT.

Summary

The Research and Special Programs Administration is proposing new requirements to enhance the security of hazardous materials transported in commerce. Proposals include a requirement for motor carriers registered with the agency to maintain a copy of their current registration certificate on each motor vehicle. We further propose to require shipping papers to include the name and address of the consignor and consignee and the shipper's DOT Hazmat Registration number, if applicable. In addition, we propose to require shippers and carriers of certain highly hazardous materials to develop and implement security plans. We also propose to require hazardous materials shippers and carriers to assure that their employee training includes a security component.

Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition. NCCLS document M29-A2

Organization: NCCLS

(Assistant Editor's note: The following information is provided for those readers who may not be aware of this organization and the group that it serves.)

NCCLS is an international, interdisciplinary, non-profit, standards-developing, and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community. It is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related health care issues. NCCLS is based on the principle that consensus is an effective and cost-effective way to improve patient testing and health care services.

In addition to developing and promoting the use of voluntary consensus standards and guidelines, NCCLS provides an open and unbiased forum to address critical issues affecting the quality of patient testing and healthcare.

Summary

This 128-page document contains a single source for information needed by laboratory workers whose primary mission is health care and in research laboratories specializing in medical and biomedical research. It incorporates the recommended safety procedures, practices, and guidelines available at the time of publication (December 2001). The ABSA Technical Review Committee provided comments during the NCCLS approval process.

The guideline contains sections on: epidemiology and laboratory transmission of the agents for which health care workers are potentially at risk for laboratory acquired infection; protection techniques; standard precautions; special precautions for laboratories, including the autopsy suite; management of laboratory accidents; prevention of exposure to *Mycobacterium tuberculosis* in the health care setting; protection from laboratory instrumentation and test equipment; and safety training and monitoring of laboratory personnel. Appendix A includes Criteria for Biosafety Level 2 as well as the Agent Summary Statements for the hepatitis viruses (Hepatitis A, B, C, D, and E); Retroviruses, including Human and Simian Immunodeficiency Viruses; and Transmissible Spongiform Encephalopathies (Creutzfeldt-Jakob, Kuru, and related agents) reprinted from *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 4th edition. These BMBL sections were included because the intended audience is laboratories operating at BSL-2 that may not have access to the CDC-NIH publication. A summary of current information on Biological Safety Cabinets (Appendix B) and Regulation of Antimicrobial Chemicals (Appendix C) is also included. Appendix D, entitled "Prions and CJD: The Special Case of Prions and CJD in Instrument Reprocessing," contains valuable information and reference material on a special topic applicable to instruments for which disposable items are not currently available.

Generally, NCCLS documents are published every 3 years. As part of the consensus process, anyone with an interest in the topic may submit written comments to NCCLS at any time, and such comments will be considered as part of preparations for the next version.

Published Abstract

NCCLS document M29-A2 is intended to be a practical tool for laboratory and health care workers. It promotes the essence of good laboratory practice to protect workers from infectious diseases encountered in the workplace. A few of the many laboratory practices that reduce the risk of infection include standard precautions, safety devices, personal protective equipment, and appropriate decontamination and disposal of biological hazards. New information is included on needles and sharps safety; prions, agents of Creutzfeldt-Jakob Disease; and airborne transmission of potential agents of bioterrorism.

This guideline contains detailed recommendations to protect workers from disease agents transmitted by aerosols, blood, and body substances. It focuses on hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) because they pose a risk that is both common and grave. Other blood-borne viruses of concern to laboratory workers include hepatitis D virus (HDV); hepatitis E (HEV); hepatitis G (HGV); other possible parenterally transmitted non-A, non-B hepatitis viruses (NANB); human T cell lymphotropic virus I and II (HTLV I/II); and other HTLVs. Other viruses that may be found in blood include hepatic A virus (HAV), equine encephalomyelitis viruses, herpes viruses, poliovirus, rabies virus, lymphocytic choriomeningitis virus, influenza virus, poxviruses, vesicular stomatitis virus, and B-virus. It is felt that precautions recommended for HBV are sufficient for these viruses.

Bacteria that are transmitted by airborne droplets or aerosols pose a real risk to laboratory and other health care workers and include *Mycobacterium tuberculosis*, *Bacillus anthracis*, *Brucella* spp., *Francisella tularensis*, *Neisseria meningitidis*, and *Burkholderia pseudomallei*. Other bacterial, fungal, and parasitic agents are not specifically discussed, but the protective measures described are also useful to prevent their transmission.

The information in this guideline should alleviate much of the confusion and uneasiness currently felt by the laboratory community about the infectious risk of laboratory practices and the protective measures appropriate to that risk.

While this document will serve as a useful resource for a wider audience, it is based on U.S. regulations and is intended for use primarily in the United States.

Reproduced with permission, from *NCCLS publication M29-A2—Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—2nd Edition*. NCCLS document M29-A2 (ISBN 1-56238-453-8). Copies of the current edition may be obtained from NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, USA.

NSF/ANSI 49—Class II (laminar flow) biosafety cabinetry: revised March 2002

Organization: NSF International/American National Standards Institute (ANSI)

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The purpose of this Standard is to establish minimum requirements for materials, design, construction, and performance of Class II (Laminar Flow) Biosafety Cabinetry that are designed to protect personnel, product, and the environment. This standard details requirements for performance testing as well as for field certification testing.

An extensive revision of this Standard was completed. This edition of the Standard contains the following revisions:

- A Normative References section was added (Section 2).
- The Definitions section has been updated and some definitions added, including the renaming of Type B3 cabinets to Type A2.
- New language has been added to Section 5, Design and Construction. This includes a decrease in the total allowable face area of HEPA filter patches, a new Alarms section (5.23) that replaces the previous Fans section, as well as new Work area components placement section (5.29) and Data plate requirements (5.31).
- The Performance testing section (6) and the corresponding Annex A as well as Annex F (Field

Tests) have undergone significant revisions.

- The Halogen test was altered to become a tracer gas leak test, and a pressure decay test was added. Both tests determine whether the cabinet is free of leaks.
- The Temperature rise test has been removed.
- The Lighting intensities—background levels, average intensity, and individual readings—have all been altered to reflect more realistic conditions.
- The requirements for Uniform downflow velocity and Nonuniform downflow velocity were made more specific.
 - ◆ Inflow velocity requirements were clarified for the various cabinet types.
 - ◆ The Airflow smoke patterns test was revised for clarity.
- The Electrical leakage, ground circuit resistance, and polarity test were removed for new cabinets as they must comply with UL-3101-1.
- Annexes B, C, and D were rewritten for clarification purposes.
- Annex E was rewritten to include more specific recommendations for installation of all types of cabinets.

Additionally, installation requirements for roof exhaust systems were included:

- Annex F has been incorporated into the standard as a normative annex.
- Annex G has been clarified and now allows for alternate procedures for the removal of formaldehyde gas.

*The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. As such, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

Table 1

Title	Status	Organization	Additional Information
Draft Guideline for Disinfection and Sterilization in Healthcare Facilities	Draft	Centers for Disease Control and Prevention (CDC) U.S. Department of Health and Human Services	www.cdc.gov/ncidod/hip/dsguide.htm Comment in writing on or before June 14, 2002.
NCCLS M29-A2 Protection of Laboratory Workers for Occupationally Acquired Infections; Approved Guideline—2nd Edition	Approved	NCCLS 940 West Valley Road Suite 1400 Wayne, PA 19087-1898 610-688-0100	www.nccls.org
NSF/ANSI 49—Class II (Laminar Flow) Biosafety Cabinetry: Revised March 2002	Final	NSF International 789 North Dixboro Road P O Box 130140 Ann Arbor, MI 48113-0140	www.nsf.org
The Laboratory Biosafety Guidelines, 3rd Edition—Draft: September 20, 2001	Draft	Health Canada Population and Public Health Branch Office of Laboratory Security Tunney's Pasture, A.L. 0602C2 Ottawa, Ontario, Canada K1A 0L2	www.hc-sc.gc.ca/pphb-dgsp/ols-bsl/lbg-ldmbl/index.html
U.S. DOT Research and Special Programs Administration (RSPA), Security Plan Proposed Rule: Hazardous Materials: Security Requirements for Offerors and Transporters of Hazardous Materials	Draft	Dockets Management System U.S. Department of Transportation Room PL 401 400 Seventh Street, SW Washington, DC 20590-0001	Submit written comments by June 3, 2002 identified as Docket Number RSPA-02-12064 (HM-232). May also submit comments by e-mail by accessing the Dockets Management System web site at http://dms.dot.gov/ and following instructions for submitting a document electronically.