



## Position Paper—NCCLS M29-2A

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RE: NCCLS M29-2A

August 29, 2001

Dear Ms. McGeary,

The American Biological Safety Association (ABSA) is an organization of biological safety practitioners who work in a variety of academic, governmental, health care, and private work environments. We have many members in the United States, Canada, and in other countries. We are recognized as a leading authority in the field of biological safety. We appreciate the invitation to review your most recent revision to your guideline M29-A2, *Protection of Laboratory Workers from Occupationally-Acquired Infections*.

Please consider these general comments: Your practice of keeping these documents active through a 3-year review process is evident with the inclusion of current information on prions and latex allergy issues.

The Occupational Safety and Health Administration (OSHA) issued a number of new requirements regarding needles and sharps safety earlier this year. The Centers for Disease Control and Prevention (CDC) also issued a safety alert on this subject in 1999. These changes are reflected in sections in your document. To provide proper focus on these major changes, it may be helpful to describe them in a section or preamble early in the document, with a note that further details are to follow in the text of the document.

There are a number of references for the need to

post items with the universal biohazard symbol. These references should also reference the need to include the word "Biohazard" in order to provide full communication of the hazard present and to better address the applicable labeling requirements.

Our specific comments follow the sections of your guideline.

### 3. Definitions

You provide definitions of an "aerosol" and "airborne transmission" in this section. You note that an aerosol is "a system of particles dispersed in a gas, smoke, or fog."

*Mycobacterium tuberculosis* (TB) cultures are tested in clinical laboratories, and they pose the risk of airborne infections through the inhalation of *respirable* aerosols. In this context, the aerosol definition should reflect that aerosols are respirable particles that can be retained in the lungs.

You note that airborne transmission involves "infectious agents...carried by or through the air, usually in small droplets." However, later in section 5.2.4, you note that aerosols are invisible particles, which are typically less than 10 microns in diameter. Small droplets are generally not considered to be respirable. The airborne transmission definition should be reflective of infectious agents that can be transmitted through retention in the lungs of a respirable infectious aerosol. May we suggest rewording this definition to define airborne transmission as "*the spread of infection by inhalation of respirable size particles containing infectious agents*." This would provide the consistency and clarity needed for the development of information to follow in the document.

You have good definitions for "needleless system" and "sharps with engineered sharps injury protections."

It shows early on that you have a document with current pertinent information from OSHA and the CDC.

The definition of "medical waste" is inclusive of "infectious waste" (well defined in these definitions) and of "non-medical waste." To better make this distinction, the use of the term "*regulated medical waste*" is suggested. It would be defined as "Materials generated as a result of diagnosis and treatment of patients that require special handling. This may include 'Infectious Wastes.'"

## 5.2 Lab Transmission

There is a statement regarding the types of fluids from which HIV has been isolated. We recommend adding to the next statement, "Only blood, bloody body fluids, or concentrated virus solutions have been implicated in the laboratory transmission of HIV to date."

You also may want to mention that although the OSHA Bloodborne Pathogen Standard identifies only certain fluids that have been epidemiologically linked to HIV transmission, it also includes any body fluid that contains blood. The CDC Standard Precautions recommend precautions with all body fluids except sweat.

Tables 2 and 4: The data are those recorded through June, 2000, not June, 1999.

## 6. Protection Techniques

In the text following this heading, the hierarchy of controls identified in the original OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030) is listed. The listing includes standard precautions. The reference should be to "*universal precautions*." In the text of the OSHA Bloodborne Pathogens Standard, there is no definition for standard precautions. There is no reference to it in the text of the standard itself that follows the definitions section. We appreciate the later definitions of both Universal Precautions and Standard Precautions.

### 6.1 Handwashing

When water is not available, proper guidance is given regarding alternative means of cleaning hands on an interim basis. It needs to be clear that these interim measures do not substitute for washing of hands in soap and water. This must still be done as soon as possible in these situations when soap and water become available.

### 6.2.1 Gloves

Your document indicates that gloves are meant to help prevent exposures to health care providers who procure specimens. Employees who collect blood specimens from patients are to wear gloves that are recognized as medical devices by the Food and Drug Administration (FDA). FDA issues a 510(k) number to glove manufacturers, which enables them to label their product "patient examination gloves." Gloves, which meet this requirement, would be the appropriate standard of care for the gloves used by employees who handle and test specimens from patients. This should be noted in your document.

Also consider adding to the list of appropriate glove use (6.2.1.3) the correct protective measures to be taken for ensuring that a health care provider's hands are adequately protected if they have a cut or if their skin is otherwise compromised, such as with dermatitis. The cut or broken skin should be covered with a water-resistant bandage and gloves worn while handling clinical specimens.

The NCCLS draft document states, "It is the opinion of this subcommittee that used gloves should be discarded as biohazardous wastes." Minimally contaminated materials such as gloves, gauze, or band-aids are not always designated as regulated medical wastes by state regulations or by OSHA, and pose almost no risk of bloodborne pathogen transmission. We would ask that a general statement about proper disposal of all disposables in laboratories be referred to the local state medical waste regulations.

#### 6.2.1.1 Latex Hypersensitivity

The American Society of Testing and Materials (ASTM) in ASTM D 3578-00a recommends that latex gloves should contain no more than 200 micrograms/decimeter squared of water extractable protein in order to be considered low protein. This limit should be noted in the recommendation for the selection of low protein gloves.

### 6.2.2 Facial Protection

The first paragraph states, "Facial barrier protection should be used if there is a reasonably anticipated potential for spattering or splashing blood or body substances." We suggest that a biological safety cabinet, splashguard, or other engineering control be the preferred method of facial protection. If these are not

available, then a full "plastic face shield best provides facial protection unless there is the potential for respirable aerosols containing airborne pathogens." Then the statement, "Splashguards may serve as an acceptable alternative to plastic face shields," can be deleted.

Paragraph 3 states, "If face shields are not used, a personal respirator and eye protection should be used." The preceding commentary in this section deals with protection against splashes and spattering of facial mucous membrane surfaces. A personal respirator is meant primarily to provide protection against respirable infectious aerosols. Its reference here could cause some confusion, especially since readers are being referred to Section 10 for further information regarding protection against airborne pathogens such as TB. The sentence should reference the use of a face covering that protects the facial mucous membrane surfaces, such as a fluid-resistant surgeon's mask.

The last statement, "The prevention of transmission of *Mycobacterium tuberculosis* is discussed in detail in Section 10," is an unnecessary statement under the facial protection section.

#### 6.4.1.1 Disinfectants and Sterilants

A useful example under the FDA-approved chemicals for the laboratory would be the antiseptics or antimicrobial handwashing agents.

Table 7: Please complete the right-hand side of the table ("Activity Level") for the Sterilants, or fill in as N/A.

#### 6.4.2 Procedures and Products

In paragraph 5 of this section, there is the statement, "...It is the opinion of the committee that germicides of the intermediate-level category (i.e., have a tuberculocidal claim) be used for surface decontamination in laboratory areas as a safe minimum." We suggest adding a statement regarding attention to the contact time recommended by the manufacturer in order to achieve tuberculocidal activity.

Footnote "g" in Table 7 makes some statements regarding the efficacy of alcohols as intermediate-level germicides. It would be helpful to also note that alcohol solutions are not sporicidal.

#### 7.2.3 Mask, Eye Protection, Face Shield

A short statement indicating that respirators

should only be worn when there is a risk of exposure to a respirable, infectious aerosol or droplet nuclei (such as cleaning a spill of TB cultures or drawing blood from TB patients) should be added.

Again, we would suggest adding a statement that biological safety cabinets or splashguards are the preferred methods for protection when splashes are anticipated.

### 8.1 Facilities and Practices

Facilities for handwashing are described in this section. We recommend that foot-, knee-, or other automatic faucets be used in laboratories for washing hands to avoid contamination of handles.

7th bullet: Should read PPE, not PEP

### 8.2 Blood Collection

When using a hypodermic needle and syringe for transferring blood, consider using a safer blood transfer device to avoid the need for attaching a needle to puncture the vacuum tube stopper.

#### 8.2.1 Blood Collection Equipment and Safety Devices

The second sentence in the first paragraph indicates that Federal Needlestick Safety and Prevention Act authorized OSHA to revise its Bloodborne Pathogens standard. Under this act, OSHA was *required* to amend the standard; it was not an optional action that could be considered by OSHA. The use of the word "mandated" would be more appropriate.

An important point is that the revised OSHA Bloodborne Pathogens standard requirements are applicable to *any* sharps that may be contaminated with blood and other potentially infectious materials. There has been much discussion in many forums about needle safety, but scalpels are also covered under the revised standard if they are used in procedures such as autopsies. A reference should be made here to this extent. Or, this should be noted as part of Section 8.11 that deals with autopsies.

It was good to see that you have referenced the state-specific needle safety requirements. At the time of the preparation of these comments, at least 20 states have passed such laws. You have referenced web sites earlier for information regarding disinfectants and germicides. The University of Virginia Health Care

Worker Safety Center has a web site that tracks these state needle safety laws, and it provides a wealth of information that would be of value to someone performing a risk assessment for their needle safety program. That address is: <http://www.med.Virginia.EDU/medcntr/centers/epinet/>.

### 8.2.3 Skin Puncture

OSHA may allow gauze pads with minimal blood to be discarded with the hospital waste stream as long as it is properly handled. (Although OSHA designates regulated wastes by definition to minimize employee handling or exposure, it does not regulate the disposal of state-regulated medical waste). As with gloves above, the disposal of items minimally contaminated with blood and other potentially infectious materials is an environmental issue that is regulated in many states. Their proper disposition, as per any applicable state environmental agency requirements, also needs to be referenced. Consideration of moving the edited sentence to Section 8.10 should be given.

The last paragraph regarding packaging of specimens belongs under 8.3, Specimen Collection, Handling, and Transportation.

This same paragraph is very confusing. The collection device is...“frequently contaminated on the outside.” Is this a capillary tube? The example of a secondary, leak-proof container (e.g., screw-top test tube) seems to indicate this. OSHA does not require labeling of secondary containers with “biohazard” symbol and verbiage if the specimen is visible and recognizable as a blood or body fluid container, and if the exposure control plan indicates that ALL blood and body fluids are handled with Universal Precautions.

### 8.3.2 Laboratory Requisition Slips

The best practices indicated in the document are good. However, the way contaminated requisitions are managed can vary considerably. This can be due to the testing performed at the site. For example, a facility that is accredited by the Substance Abuse and Mental Health Administration (SAMSHA) must retain original test requisitions as part of its accredited procedures. Contaminated requisitions may need to be placed into biohazard bags, photocopied, and then archived with a requisition photocopy processed with the specimen.

Institutions need to establish internal procedures for the proper management of contaminated requisitions. These need to be communicated to employees and followed by workers.

### 8.7 Shipping Specimens

A laboratory that may have to ship specimens off-site for testing should be referred to the CDC requirements for ground shipment of those specimens or the most current version of the Dangerous Goods Regulations of the International Air Transport Association (IATA) for air shipment of specimens.

### 8.8.2 Microbiology Laboratories

There is a reference to the need to perform some procedures in a biological safety cabinet (BSC) or behind a shield. More specific guidance needs to be provided as to which tasks need to be done in the BSC and which need to be done behind the shield. If specific tasks are not given, then criteria for making this determination need to be provided.

### 8.9.3 One-handed Technique

“A one-handed technique may be used to remove the needle...” needs to be changed to “A one-handed technique may be used to remove the needle, such as with a sharps container that has an integral device that enables one to remove the needle without having to touch it. Alternatively, a holder with a button-release for one-handed needle removal may be used for needle removal.”

### 8.9.4 Manual Removal of Needles

The picture shown properly demonstrates this procedure when a vacutainer needle and standard needle holder are in use. Currently, there is no shortage of needle safety devices that can be used to collect specimens in vacuum tubes using a needle holder. For most employers, the situation demonstrated will not occur with these specific materials. Some specimen collections, such as for arterial blood gases, may need to use the technique demonstrated, since the collected specimen must be injected into a test instrument after collection. If you have a sketch that shows this technique with a standard needle and syringe, consider using it since this may be more representative of an actual situation encountered by the users of your document.

### 8.9.1 Sharps Containers

Sharps containers should not be filled above the fill lines on the sides of the container. The container must not require shaking in order to seal the container.

### 8.10 Medical Waste Management

Throughout this section, attention needs to be given to the distinction between medical waste and *regulated* medical waste (i.e., infectious waste).

The implementation of a medical waste volume reduction program should be a recommended best practice. This program is an environmentally favorable practice, some state environmental agencies mandate this activity, and it reduces the risk of infection to employees and the public. (We have not reviewed GP5, the NCCLS document on the management of medical waste, so it is possible that you may have addressed this in that guide.)

#### 8.10.5 Transport

Regulated medical waste is a hazardous material regulated by the U.S. Department of Transportation (DOT). Containers used to ship medical waste to off-site treatment facilities need to meet the (DOT) performance testing requirements and specific state regulations.

#### 8.10.6 Treatment and Disposal

Generators of regulated medical waste are responsible for its proper treatment. On-site treatment by the generator affords the best opportunity for addressing this concern. In many cases, treatment by an offsite medical waste contractor is needed. In these situations, it is strongly suggested that the medical waste treatment site be audited to ensure that treatment is done effectively and in accordance with the terms of the site's operating permit(s).

#### 8.10.7 Radioactive Biohazards

We recommend changing the term "sterilization" to "decontamination" when discussing treatment of wastes.

### 8.11 Autopsy and 8.11.1 General

There are conflicting statements in this section: "The guidelines that follow should be used for all cases and are considered suitable for autopsies on individuals

infected with HIV, HCV, or HBV." vs. "In established or suspected cases of serious bloodborne infections such as HIV, HCV, or HBV, the prosector may wish to apply more stringent precautions than those recommended herein." Using Standard Precautions, as listed in the following sections, is appropriate, and no more stringent precautions are necessary, unless you mean to address CJD instead of HIV, HCV, or HBV.

In the recommendation of "airflow of 12 air changes per hour," should read "at least 12 air changes per hour."

#### 8.11.5 Personal Protective Equipment

In the NCCLS draft document, wearing a N95 respirator or a HEPA-filtered respirator under the face shields of persons participating in an autopsy is recommended. Some pathologists will balk at wearing a respirator because they claim it interferes with their ability to accurately record their descriptions on the autopsy audio recording. The document, as written, could be interpreted as requiring the use of a respirator during any autopsy. The October 28, 1994 CDC Recommendations, "*Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health Care Facilities*," indicate that these respirators are to be worn by personnel while performing autopsies on deceased persons who *may have TB at the time of death*. This qualification should be placed with the respirator recommendation in the document. Providing this focus will increase the likelihood that employees will wear face shields during any autopsy and respirators when a determination has been made that their use is warranted. See also 10.5 Autopsy Rooms.

#### 8.11.6 Autopsy Procedures

The discussion of scalpel and/or needle and syringe use should include the requirement to evaluate and implement safer devices such as sheathing scalpel blades or safety needles.

A respirator use issue also exists in the section dealing with bone cutting. The N95 respirator is needed only with suspected *M. tb* cases.

#### 8.11.7 Decontamination

Again, emphasize the use of safety scalpels and discourage the removal of scalpel blades from the holders for disposal.

### 8.12.1 Personal Protective Equipment

Emphasize the use of biological safety cabinets (BSCs) or splashshields when processing unfixed, large specimens where splatter would be expected.

#### 9.1.1 Exposure Report

The investigation of bloodborne pathogen exposures has been an OSHA mandate for years. The 2001 OSHA Bloodborne Pathogen Standard revision now requires that a sharps injury log be prepared to record the circumstances of exposures that involve a sharp. The second bullet implies that a medical device is involved in any bloodborne pathogen exposure. It should note that prompt identification of any sharps involved in the injury is needed and that the name, type, and brand of any sharp involved needs to be recorded.

#### 9.1.4 Postexposure Prophylaxis (PEP)

On June 29, 2001, the CDC released its consolidated PEP recommendations for exposure to HIV, HBV, and HCV. This document should be specifically referenced.

#### 9.2 Postexposure to HBV

It was good to see that specific sites for the HBV vaccination and specific needle lengths are recommended. Both of these items are factors that may affect the immune response to the inoculation.

It is good to see that prompt administration of the HBV immunoglobulin within 24 hours is noted. This gives added incentive to provide a prompt medical evaluation for the exposed worker so he or she may benefit from this treatment.

#### 9.4 Potential Postexposure to HIV

The second paragraph is timely, good guidance. Laboratories need to make arrangements with a medical provider that has access to HIV PEP drugs *before* an exposure occurs. Many physicians do not routinely administer these drugs and therefore are unfamiliar with their appropriate dosages, indications, and contraindications, as well as the side effects associated with these medicines. These steps are important to provide an effective, beneficial medical evaluation to the exposed worker. These considerations are echoed in Section 9.4.2.

### 10 *Mycobacterium tuberculosis* in the Health Care Setting

The tasks that need to be performed at Biosafety Level (BSL) 3 should be identified. The tasks that are to be performed at BSL-2 need to be identified. If these tasks are not detailed here, then readers should be referred to the most current version of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) or the *CDC Guidelines for Working with TB in Laboratories* for guidance.

#### 10.1.2 and 10.2 Transmission and Pathogenesis, Risk of Transmission in Health Care Facilities

You are correct in characterizing droplet nuclei as potential sources of airborne TB from TB patients. The risk of infections from respirable aerosols generated during the testing of specimens and cultures from TB patients is less clear and needs to be more distinct. Although TB can be present in many body fluids from TB patients, it should be noted that TB is found primarily in sputums and other respiratory specimens so that special care is taken when testing these types of specimens.

There is a statement in the first paragraph (10.1.2) which states, "Infection occurs when a susceptible person inhales droplet nuclei..." Please delete the word "susceptible" since all people are susceptible. This same type of situation is found in 10.3, Fundamentals of Infection Control in the first bullet, "...intended to reduce the risk of exposing susceptible individuals." Please delete the word "susceptible."

#### 10.3 Fundamentals of Infection Control

When engineering controls are described, it should be noted that a written preventive maintenance program needs to be prepared and implemented to verify these controls are providing their intended protection (i.e., work within a routinely certified biological safety cabinet). In addition, a written plan needs to be prepared, posted, and implemented for dealing with spills of TB specimens and TB cultures. UV light is recognized as an engineering control, but should be used only as a secondary engineering control to augment other engineering controls. This should be noted in this section.

#### 10.4 Respiratory Protection

The scope of your document includes workers who procure specimens, and respirators are required for the collection of specimens from TB patients in respiratory isolation. Respirators are also needed for TB spill responders and laboratory workers in TB labs at the BSL-3 level. Also note that a Respiratory Protection Program is required per the OSHA Respiratory Protection Standard, and lab workers need to be medically cleared and fit-tested to wear the N95 respirators.

#### 11.5 Storage and Retention of Specimens and Microorganisms

The sentence that indicates that food should not be stored with specimens in refrigeration units should also indicate that beverages should not be stored in this manner.

#### 11.8.3 Flow Cytometry

There is a reference to the generation of aerosols from cell sorters in this section. Please revise to read, "if the fluid being sorted potentially contains organisms that are transmitted by the airborne route, and the cell sorter produces respirable size aerosols, a personal respirator should be worn."

#### 11.10 Policies

"Dirty" work surfaces and items where the use of gloves is mandatory must also be posted with the universal biohazard symbol and the word, "Biohazard." Labeling alone and noting this practice in a policy manual are not sufficient. Employees must be trained to recognize and understand this posting in their work areas.

#### 12.1 Initial Training

Please include in the list of references the January, 18, 2001 issue of the *Federal Register* (Volume 66, Number 12) that announced the revisions to the OSHA Bloodborne Pathogen Standard Revision.

On page 73, there is a statement, "Employees must be trained to report and carefully log each sharps injury with a minimum of information including 1) the identification of the device...." Please include not only the identification of the type of device, but also the brand of the device as well (required by the OSHA Bloodborne Pathogen Standard for the sharps injury log).

To the statement, "The training program should be developed in cooperation with the infection control

department of the institution," please add "...safety office, or other professional group knowledgeable in bloodborne pathogens and other biological safety issues."

#### Appendix B: Biological Safety Cabinets (BSCs)

There should be a statement noting that horizontal laminar flow cabinets are not recommended for use with infectious agents. This containment device was designed for work protection, not employee protection.

BSCs should also be placed away from high traffic areas in order to minimize airflow disruption inside the BSC. The need for at least annual certification of the BSC as per the most recent version of National Sanitation Foundation (NSF) Standard No. 49 or manufacturer's specifications needs to be noted.

#### B.2.2 Preparation of Work Space

It was good to see the recommendation of a post-disinfection wipe of the BSC work surfaces with sterile water after decontamination with diluted bleach. It should be noted that 70% ethanol solutions are not sporicidal and may or may not be effective against fungal or bacterial spores. The reference to the "reduction in mold spores and thereby minimizing contamination of cultures" should be dropped.

#### B.2.3 Material Placement

Work materials should be manipulated at least 4 inches away from the air intake grille in order to take optimal advantage of the laminar sterile airflow within the BSC. It was good to see that the role of the BSC in room air balancing was noted.

#### B.4.3 Gas Decontamination

The NSF currently recognizes only gaseous formaldehyde as a decontamination agent. NSF is still reviewing efficacy data regarding the use of gaseous hydrogen peroxide.

Thank you for the opportunity to review this document. We look forward to similar opportunities in the future.

Sincerely,

Debra L. Hunt, MT (ASCP), DrPH, RBP, CBSP  
President, American Biological Safety Association