# COMMENTS ON THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S PROPOSED RULE AND NOTICE OF HEARING ON OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerned the exposure of workers to bloodborne pathogens in the course of their employment. Specific issues mentioned included the existence of bloodborne pathogens in addition to the ones discussed previously that present a risk to employees with occupational exposure to blood, identification of these pathogens, identification of studies or case reports on hepatitis-B virus (HBV) and human immunodeficiency virus (HIV) that should be included in the health effects analysis, the possibility that OSHA should consider HBV infection as a material impairment of health, and whether OSHA employed the correct methodology for determining the quantitative and qualitative risks of exposure. Further areas of concern to NIOSH included the defining of a correct and secure method for worker protection from bloodborne pathogens, the scope of the proposed OSHA standard, the identification of occupations in which exposure would be likely to occur, the circumstances under which exposure could occur, the possibility of transmission through human breast milk, the clear understanding of the terms contamination and decontamination, and the requirements noted in the proposed standard for controlling exposures.

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## INTRODUCTION

The National Institute for Occupational Safety and Health (NIOSH), the Center for Infectious Disease (CID), the Office of Biosafety (OBS), and other Centers and Offices in the Centers for Disease Control (CDC) have reviewed the Occupational Safety and Health Administration's (OSHA's) proposed rule and notice of public hearing for occupational exposure to bloodborne pathogens, published May 30, 1989, in the Federal Register [54 FR 23042]. We are pleased to provide comments in response to this proposed rule.

This rulemaking activity by OSHA is extremely important to the health and safety of workers in the healthcare industry. Focusing as it does on the risks of occupational transmission of bloodborne pathogens, primarily hepatitis B virus (HBV) and human immunodeficiency virus (HIV), the rule is both timely and responsive to a significant risk of morbidity and mortality. However, there are many other infectious disease hazards in these workplaces that are not directly addressed by this proposed rule. OSHA and healthcare employers should regard this rule as only a small part of a larger program to control infectious disease hazards to employees and patients.

Furthermore, the healthcare workplace has numerous and diverse safety and health hazards unrelated to infectious agents. Examples are exposure to chemicals (including carcinogenic and mutagenic substances), physical agents (e.g., ionizing and nonionizing radiation, heat, noise), injuries (e.g., falls, lacerations, punctures), fires, electrocutions, explosion hazards, and stress (ergonomic and psychologic). These issues were reviewed in the recent publication, Guidelines for Protecting the Safety and Health of Health Care Workers [NIOSH 1988].

## SPECIFIC ISSUES OF CONCERN TO OSHA

1. **Are there any bloodborne pathogens in addition to the ones discussed in section IV, Health Effects, that present a risk to employees with occupational exposure to blood? If so, what are these pathogens, and what evidence is available that they present a potential or actual risk to employees?**

The standard addresses little attention to hepatitis delta virus (HDV) infection, although it does acknowledge the dependence of HDV on hepatitis B virus (HBV), that HDV augments the severity of acute and chronic HBV infection, and that prevention of HBV and other bloodborne diseases will prevent HDV infection. The transmission of HDV in the health-care setting has been described [Lettau et al. 1986]. The impact of HDV infection has been incorporated into the HBV risk assessment section.

2. **Are there additional studies or case reports on HBV and HIV that should be included in the health effects analysis? If so, what are they? Has OSHA adequately represented the results of available epidemiologic and case studies?**

There are many HBV and HIV studies and case reports in the literature. The proposed standard adequately represents the salient features of these articles. Current national AIDS case surveillance data are provided with these comments [CDC 1989]. Detailed surveillance data pertaining to health-care workers with AIDS will be updated and provided as part of our testimony.

3. **For its significance of risk determination, OSHA considered clinical hepatitis B, HBV carrier status, hospitalization, and death to be material impairment of health. Because of the possibility of infecting others (sexual partners, newborns) and the possibility of becoming an HBV carrier, should OSHA consider HBV infection as a material impairment of health?**

Infection with HBV should be regarded as a material impairment of health, regardless of the ultimate clinical course of that infection. The potential consequences of HBV infection are grave. Furthermore, the risk of secondary infection by sexual [Redeker et al. 1975] or perinatal [Tong et al. 1981] exposure to persons with acute HBV infection is well documented, and is present for both cases with symptoms as well as those without symptoms.

4. **Has OSHA employed the correct methodology for determining the quantitative and qualitative risks of exposure? Are alternative risk assessments available? Are there demographic factors which should be controlled for in estimating the background risk for HBV?**

The methods used to determine risk of occupational exposure to HBV are correct. The estimates made are generally accurate and appropriate. Although some estimates might be adjusted somewhat, the overall calculations would not be substantially changed.

The only demographic factors which clearly influence risk of acute HBV infection are sex (men have 1.5- to 2-fold higher risk than women) and race/ethnicity, with blacks at several-fold higher risk of HBV infection than Caucasians [McQuillan et al., in press]. Adjustment for these factors probably would have only a minor effect on the estimated risk. Because the hospital workforce is predominantly female — 77% compared with 40% for the total workforce [Gun 1983] — this might increase risk attributable to occupational exposure.

5. **OSHA has chosen to protect employees from bloodborne pathogens by requiring that they be protected from exposure to blood and other potentially infectious materials. Is this the correct approach and is it the most protective approach? If not, what other approach should be employed?**

OSHA is correct to adopt the approach of requiring that workers be protected from exposure to blood or other potentially infectious materials, and this should apply to any industry or occupation where such exposure can be reasonably anticipated. Protection of workers against reasonably anticipated exposure to blood and other potentially infectious materials is the only practical approach, and provides the best available protection to workers.

Effective immunization is available only for hepatitis B. However, the antibody response is inadequate to confer immunity in approximately 5% of those vaccinated. As shown by OSHA in the risk assessment, the residual risk of HBV infection in a vaccinated workforce would be sufficient to require enforcement of mandatory universal precautions even if hepatitis B infection were the only concern. Because there are no alternatives for protection against other bloodborne pathogens, most notably HIV, prevention of exposure to blood or other potentially infectious material would be required even if all workers received a 100% efficacious HBV vaccine.

6. **The scope of the proposed standard would be based on occupational exposure to blood and other potentially infectious materials, whether or not the individual is employed in the healthcare industry. Is this approach the most protective? Will another approach provide greater protection? Should the scope of the standard be limited to one (or a few) industries?**

This is the most protective approach. The scope of the regulation should not be based on employment in one or a few specified industries. OSHA is correct in defining the scope in terms of reasonably anticipated occupational exposure to blood or other potentially infectious material. These exposures occur predominantly but not exclusively in the healthcare industry. Healthcare workers may therefore be most commonly at risk, but it is their blood exposure, not the industry in which they are exposed, that places them at risk. Regardless of the industry in which they may be exposed, all workers with reasonably anticipated occupational exposure to blood or other potentially infectious material should be included in the scope of this rule.

7. **In addition to law enforcement personnel, firefighters, and corrections personnel, are there any other occupations with potential for exposure that are predominantly or entirely confined to the public (federal, state, or local) sector? If so, do they perform tasks or procedures that are unique and require special protective measures that are not addressed by this standard? If so, what are these protective measures?**

Laboratory specimens may be transported to clinical or diagnostic laboratories both by public (U.S. Postal Service) and private sector carriers (e.g., Federal Express, United Parcel Service). Some of these workers may be exposed to blood or other potentially infectious materials if the contents of packages leak due to improper packaging or damage in transit. It is not apparent that such exposure constitutes significant risk of disease transmission. Standard measures, primarily gloves as provided for in this rule, would provide adequate protection if used with packages whose contents are leaking on the assumption that the materials could be infectious. Those packages can be placed in transparent plastic bags for further handling.

8. **What circumstances unique to law enforcement and correction officers place these employees at risk of exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any additional training should be required? What can be done to ensure that personal protective equipment is available when and where it is needed?**

See response to question #9.

9. **What circumstances unique to firefighters, emergency medical technicians and paramedics place these employees at risk for exposure to blood and other potentially infectious materials? What, if any, additional requirements are needed to minimize or eliminate these exposures? What, if any, additional training should be required? What can be done to ensure that personal protective clothing and equipment is available when and where it is needed?**

NIOSH has previously addressed these issues in two documents developed and forwarded to OSHA in accordance with the Health Omnibus Programs Extension of 1988 [PL 100-607]: Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers and A Curriculum Guide for Public-Safety and Emergency-Response Workers--Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus (Exhibits 15 and 16 in the OSHA docket for this rulemaking). Specific recommendations are made in these Guidelines that are tailored to the needs and working conditions encountered by public safety, emergency response, and corrections personnel.

OSHA requested comment (page 23042) "where these guidelines differ with the proposed requirements of this standard (e.g., which body fluids require the use of precautions in emergency situations.)" OSHA also invited comment (page 23112) "on whether the proposed definition of 'other potentially infectious materials' should be amended to make it consistent with the guidelines." The Guidelines are not inconsistent with previous CDC definitions of other potentially infectious materials. They do, however, recognize that public safety and emergency response personnel often work under conditions that preclude informed judgments regarding the type of body fluid present. The Guidelines therefore recommend that whenever "emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous." This is not a question of definition, but rather one of judgement and flexibility in a particular situation.

10. **There is evidence that HIV may be transmitted through human breast milk. Are employees at risk of infection due to exposure to human breast milk? If so, what tasks or procedures do they perform that place them at risk? What special protective measures, if any, should be required for these employees?**

There probably is a need to include some mention of human breast milk as a "special" situation; i.e., whereas universal precautions ordinarily are not required, gloves may be worn by workers in situations where exposure to breast milk might be frequent or intense, such as in breast milk banks. There is no evidence that health-care workers are at risk of infection because of contact with breast milk. The only reported cases have been in infants who are breast feeding and who, therefore, have mucous membrane exposures to large volumes of breast milk or exposures to maternal blood through fissures in the mother's breast.

11. **Throughout the proposal, OSHA uses the terms "contaminated" and "decontaminated." Are these terms clearly understood? Should OSHA define these terms? If so, what are the appropriate definitions? Should laundry be considered "contaminated" only when blood or other potentially infectious materials are visible on the laundry? If not, what should indicate "contaminated" laundry?**

These terms should be defined as proposed below in the comments on the regulatory text. "Contaminated" should refer to the presence on an item of a bloodborne pathogen or fluid requiring universal precautions, such that handling the item might constitute a risk of disease transmission. "Decontamination" refers to lowering the concentration of bloodborne pathogens by removal or inactivation, rendering the item safe to handle.

The term "contaminated" is not usually appropriate in reference to linen or other laundry, as these items have not been implicated in the transmission of bloodborne disease. "Soiled" is a more appropriate term in reference to laundry, referring to laundry that has been used. Standard practice calls for minimal handling and agitation of laundry in patient care areas because soiled linens and other laundry may present a risk of nosocomial infection, but not with bloodborne pathogens. Gloves or other protective equipment are not required for handling linens or other laundry that is merely soiled.

Laundry should be considered contaminated only if blood or other fluids requiring universal precautions are present. It is these fluids that are a concern, not the linen per se. A person changing an individual sheet can easily see if the sheet is contaminated, and if it is can determine whether gloves or other protective clothing is required, or whether the uncontaminated portion of the sheet provides and adequate barrier. Laundry that is grossly contaminated should be transported in such a way as to prevent leakage, but it is not necessary to require "leakproof" bags for laundry. It is sufficient to require that bags "must be of sufficient quality to functionally contain wet or soiled laundry without outer contamination of the bag." Such bags need not be labeled, and persons transporting these bags do not require personal protective clothing or barrier precautions in addition to the bags. These concepts should be carried over to other parts of this document that discuss labeling laundry and special handling practices.

On the other hand, a person in the laundry room, handling large volumes of laundry, might not see a grossly bloody sheet before contact. Furthermore, improperly discarded sharps may be present, placing laundry workers at risk of puncture wounds and lacerations that might transmit bloodborne disease. Strict enforcement of regulations governing disposal of used sharps is necessary to minimize this risk. However, even with strict enforcement of sharps disposal policies, workers in laundry rooms should use personal protective equipment (e.g., heavy duty utility gloves) when processing soiled laundry.

12. **The proposed standard includes a number of requirements including an infection control plan, engineering and work practice controls, personal protective clothing and equipment, training, signs and labels, provision of HBV vaccination, and medical follow-up for exposure incidents. Are these requirements appropriate? Do they provide adequate protection? Should other provisions be added?**

It is appropriate to require a combination of administrative, engineering, and work practice controls along with personal protective equipment to manage these risks [NIOSH 1983].

It is important to recognize that no single action or control measure is sufficient to remove the risk of infection. Vaccination is the single most effective action possible to prevent HBV infection, but it is not totally effective. Protection against HIV and other bloodborne pathogens requires a spectrum of applicable engineering controls, work practices, and personal protective devices in all activities involving exposure to blood or other potentially infectious material.

The proposed infection control plan, training, and use of signs and labels are essential elements in reinforcing this necessity in the minds of employers as well as employees. Medical follow-up of exposure incidents as proposed is essential to minimize any adverse consequences whenever prevention fails and a worker is exposed to potentially infectious material.

As written, the provisions for the infection control plan [paragraph (c)(2)] are inadequate in that the plan includes no requirement for periodic review, for evaluation of the duties of new employees to identify those whose tasks will entail occupational exposure to blood or other potentially infectious material, for making copies of written institutional policies and procedures available to the employee, or for evaluation of the circumstances of exposure incidents to determine whether changes in policies or practices are needed to prevent recurrences of similar incidents.

These last two omissions are particularly serious. Protocols should be established to formally and systematically evaluate all exposure incidents and other failures of controls so that any contributory deficiencies in institutional policies and procedures can be identified and corrected. It is equally essential that institutional policies and procedures be available to all employees in writing. This should include written job-specific standard operating procedures. These could be collected in a biosafety manual specific to a work site. This manual would contain warnings and protocols for safe procedures as well as other specific safety instructions; it would serve as an on-site adjunct to the overall infection control plan, would reinforce educational programs, and should be used in mandated training programs.

Signs and labels are discussed in relation to page 23129 of the Preamble. While it is appropriate to inform workers of potential infectious hazards with signs and labels as required in paragraph (g) of this proposed rule, the biohazard symbol should not be used to designate materials that require universal precautions. This symbol should be reserved to designate known sources of etiologic agents, such as in laboratories. Labels required under paragraph (g)(1)(ii) should bear the legend "UNIVERSAL PRECAUTIONS," with or without a symbol especially designed to denote the same. These labels should not use the biohazard symbol.

13. **The Agency has traditionally preferred engineering and work practice controls over the use of personal protective equipment. Do employees, in nearly every case, need to use a combination of methods that include personal protective equipment, or are there tasks or worksites where exposures can be adequately minimized or eliminated by adherence to engineering or work practice controls alone? How could OSHA best structure the methods of control requirements to reflect actual working conditions?**

OSHA is correct to prefer engineering controls as the first line of defense against occupational hazards, followed by work practices, and finally personal protective equipment. That hierarchy of control [NIOSH 1983] should be observed in this case. Because of the nature of health-care, public-safety, emergency response, and other tasks in which occupational exposure to bloodborne pathogens is expected, it is unlikely that adequate protection could be offered by engineering or work practice controls alone. Furthermore, when the potential consequences of a failure of control are as severe as in the case of HIV infection, it is reasonable to mandate redundancy of controls. OSHA should assume that every case will require a combination of methods that may include personal protective equipment. However, the proposed rule properly reflects the variability of actual working conditions by allowing for a degree of discretion in rare and exceptional circumstances.

14. **The available evidence indicates that an exposure incident that involves a percutaneous exposure, resulting from an injury with a needle or other sharp object, carries the highest risk of HIV or HBV infection. Many of these injuries result from the need to disassemble the device after use, poorly designed equipment or other factors that relate to the basic design of the equipment. How can OSHA encourage the development of safer instruments and equipment to further reduce the likelihood of percutaneous exposure?**

The publication and enforcement of this proposed rule will be a powerful stimulus for the subsequent development of safer equipment and of devices to increase the safety of workers. OSHA will encourage safer instruments and equipment to reduce the likelihood of injury and percutaneous exposure by requiring the preferential use of engineering controls over work practices and personal protective equipment.

15. **The proposed standard does not require the use of respirators. Do aerosols present a risk for transmission of bloodborne pathogens? Are there instances when these bloodborne pathogens may be transmitted in respirable particles generated during medical procedures such as laser surgery or the use of medical or surgical instruments such as a bone saw? Are there other instances where respirable particles containing (or potentially containing) bloodborne pathogens may present a risk to employees?**

Aerosols are not known to present a risk of transmission of bloodborne pathogens in the healthcare environment. There are no known instances in which bloodborne pathogens have been transmitted to workers by way of respirable particles generated during medical procedures, nor are other instances known in which airborne particulates containing bloodborne pathogens have presented a risk to healthcare workers. Therefore, use of respirators for protection against bloodborne pathogens is not recommended.

The possibility that healthcare workers might be infected via inhalation of aerosolized bloodborne pathogens has been investigated, focusing on hepatitis B. Almeida et al. [1971] reported possible airborne spread of hepatitis B in a dialysis unit following a spill of HBsAg-positive blood. However, experimental studies [MRC 1975] using tracer organisms (Bacillus globigii spores and T3 phage) in a simulated dialysis unit suggested that aerosolization was not a probable route of transmission. Neither blood nor HBsAg could be detected in air samples collected in dialysis units [Petersen et al. 1976] or during dental procedures [Petersen et al. 1979]. The Immunization Practices Advisory Committee [ACIP 1985] did not mention inhalation of aerosols in their discussion of the modes of transmission of HBV in healthcare settings. The current opinion of experts is that, while aerosol transmission is a theoretical possibility, it does not contribute measurably to occupational transmission of HBV, which is attributed to direct blood exposure or contamination of environmental surfaces [Petersen 1980; Favero 1987, 1989].

Splattering of blood onto skin or mucous membranes is a recognized mode of transmission of hepatitis B. Protection of the mucous membranes of the face and upper respiratory tract against large droplet spattering is needed. As required by OSHA in this draft rule, glasses, goggles, face shields, and surgical masks, alone or in combination as appropriate to the task being performed, can provide that protection.

Some workers have requested and some employers have attempted to provide respiratory protection against possible inhalation exposure to bloodborne pathogens in healthcare workplaces. Some manufacturers and suppliers of surgical masks have responded to these potential markets with sales programs implying that surgical masks offer respiratory protection. Reported filtering efficiencies of the mask material are sometimes offered as evidence that a product offers respiratory protection.

Surgical masks, designed and approved for use in the healthcare industry, including use in sterile environments, were not designed or approved as respiratory protective devices. The minimal testing specifications for surgical masks do not appear to measure filter efficiency accurately, precisely, or reproducibly, and do not require face fit testing. Whatever the filtering efficiencies of the mask material, most surgical masks do not form an occlusive seal to the face

and therefore are not expected to be efficient respiratory protective devices. However, as previously stated, respirators are not recommended for protection against bloodborne disease because there is no evidence that bloodborne pathogens can be or have been transmitted in the healthcare workplace by the respiratory route.

16. **Commenters have indicated that some procedures with potential for exposure are performed in locations where handwashing facilities are not available or not located near the work area (e.g., crime scenes or mobile blood collection sites). Is there an acceptable substitute for handwashing that can be used under these circumstances? Does it provide protection that is equivalent to handwashing?**

Handwashing with soap and water, alone or in combination with application of decontaminants, is preferred. When normal handwashing facilities (a sink with running water and soap) cannot be made available, the employer should be required to provide for handwashing using an antiseptic hand cleaner that does not require the use of water, or disposable disinfectant towelettes. A variety of products is available, but handwashing with soap and water should follow as soon as possible. Towels, either paper or cloth, should be provided in all cases.

17. **In paragraphs (d)(3)(vii)(B), (D), and (E) OSHA has proposed that fluid-resistant clothing be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials while 'fluid-proof' clothing must be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials. Is the distinction between 'fluid resistant' and 'fluid-proof' clear? Should these terms be defined? Are the requirements for two types of protective clothing based on anticipated exposure appropriate? If not, what other approaches will assure employee protection?**

Fluid-proof implies a high degree of protection against fluid permeation (molecular movement of contaminant through the interstitial spaces of the protective material) and penetration (bulk movement of contaminant through seams, closures, and fissures of the material). Protective clothing is fluid-proof if it allows essentially no permeation or penetration. Fluid-resistance implies a lower degree of protection against penetration and permeation, but does imply that the clothing at least provides adequate time for the wearer to remove protective gear before contamination reaches interior surfaces.

Lab coats, gowns, scrub suits, etc., made of ordinary fabric material are appropriate for most circumstances if sufficiently fluid-resistant to prevent minor splashes or splatter from contaminating street clothing worn under them. Operating room gowns and other garb are

somewhat more fluid-resistant, depending on the type of material and manufacturer, but for the most part they are not fluid-proof. Truly fluid-proof garments might result in excessive heat stress if worn for extended periods, and are only appropriate in extreme situations.

18. **Should OSHA specify that all nonintact skin be bandaged or otherwise covered before performing tasks or procedures with a potential for occupational exposure?**

It is appropriate to require that nonintact skin be covered in such a way as to prevent exposure of the nonintact skin to blood or other potentially infectious material if a specific task poses a reasonably anticipated risk of contamination of that skin surface. To be effective, the bandage or other cover must be fluid-proof. This requirement should be restricted to open wounds or other significant lesions, such as skin that is chapped, abraded, or afflicted with dermatitis. Workers with exudative lesions or weeping dermatitis should refrain from all direct patient care and from handling patient-care equipment until the condition resolves.

19. **The proposed standard allows the use of utility gloves for housekeeping and laundry workers. Is the decontamination and reuse of these gloves appropriate? Should OSHA require that these gloves be puncture-resistant?**

Reuse of utility gloves is appropriate. These gloves should not require disinfection or sterilization. With proper training, cleaning of any soiling with soap and water, or a mild hospital disinfectant if compatible with the glove material, should be sufficient.

No gloves are puncture proof, and none are tested or certified for puncture resistance. However, utility gloves are puncture resistant relative to surgical or examining gloves used in the healthcare industry. For tasks that entail a risk of puncture wounds or lacerations, workers should be provided with gloves offering the highest degree of puncture resistance consistent with the dexterity required by the task.

20. **Are the requirements for HIV and HBV research laboratories adequate and appropriate? What additional requirements should be included? Is the definition for "research laboratories" clear? Does the definition clearly differentiate between research laboratories and clinical (diagnostic) laboratories?**

The definitions of and distinctions between research and clinical (diagnostic) laboratories are adequate and appropriate.

The requirements outlined for research laboratories [paragraph (e), "HIV and HBV Research Laboratories and Production Facilities"] are appropriate so far as they go, but omit some important provisions. For

research laboratories and production facilities, this rule should make mandatory all of the recommendations contained in the 1988 CDC Agent Summary Statement for Human Immunodeficiency Virus [OSHA Ex. 6-312]. Specifically, the rule should require use of biosafety level (BSL) 3 practices and equipment in BSL 2 facilities, as defined in Biosafety in Microbiological and Biomedical Laboratories [OSHA Ex. 6-338].

Requirements for clinical laboratories should be detailed in a separate section [a new paragraph (f) "Clinical and Diagnostic Laboratories"] inserted after the existing paragraph (e). The contents of that section should include no less than the complete set of recommendations for biosafety level (BSL) 2 practices, equipment, and facilities as defined in Biosafety in Microbiological and Biomedical Laboratories [OSHA Ex. 6-338].

21. **Are the requirements for HIV and HBV production facilities adequate and appropriate? What additional requirements should be included? Is the definition for "production facilities" clear? Does the definition adequately differentiate between research laboratories and production facilities?**

If modified as suggested in response to question 20, the requirements of paragraph (e) "HIV and HBV Research Laboratories and Production Facilities" will be adequate and appropriate as they pertain to production facilities.

22. **Some research laboratories use blood and blood components but do not propagate bloodborne pathogens. Are the requirements for clinical laboratories adequate for these research laboratories? If not, what additional provisions should be required?**

Requirements for clinical laboratories, if specified as proposed in response to question 21, will be adequate and appropriate for these laboratories. These requirements can be appropriately relaxed if the blood and blood components in use are exclusively materials acceptable for clinical use in humans or have been sterilized or otherwise treated to destroy bloodborne pathogens.

23. **The proposal requires that the HBV vaccine be offered to employees exposed an average of one or more times per month. Should the administration of the HBV vaccine be contingent on the frequency of exposure? Is this frequency appropriate? If this approach is not appropriate, what justification can be provided for an alternative approach.**

HBV immunization should be offered to "all workers whose jobs involve participation in tasks or activities with exposure to blood or other body fluids to which universal precautions apply" [NIOSH 1989a]. The once per month exposure criterion invites disputes over actual frequency of exposure. It would permit high frequency exposure of

unimmunized workers in the event of temporary job rotations arranged by employees themselves or the employer to cover vacations, temporary staff shortages, break time, etc.

Furthermore, it is not clear that HBV immunization is to be required for students and other trainees. These personnel should be offered the HBV vaccine in sufficient time to begin the series before first blood exposures. They should not be required to first establish a work history of exposure according to some frequency of exposure criterion.

24. **The proposed standard requires that the HBV vaccine be made available 90 days after the effective date of the standard. Are there sufficient quantities of the HBV vaccine to vaccinate all eligible employees? Assuming that sufficient quantities of vaccine are available, will there be a problem with the distribution of the vaccine? If so, should there be a phase-in period?**

According to informal comments provided by the major licensed vaccine manufacturer, no difficulties are anticipated concerning either supply or distribution. Licensure of a second vaccine is expected before the expected publication of a final rule, which also suggests there will be no difficulties with vaccine supplies.

25. **In paragraph (f) Hepatitis B vaccine and post-exposure follow-up, the employer is required to administer the vaccine and provide effective post-exposure prophylaxis according to "standard recommendations for medical practice." Does this approach give sufficient guidance to the employer on what must be done? For example, should the Agency be more specific about the meaning of "* * * accepted safe effective * * * prophylaxis * * *?" Should these recommendations be those of the U.S. Public Health Service?**

This approach does provide sufficient guidance to the employer. The details of post-exposure prophylaxis according to "standard recommendations for medical practice" are subject to review and change on a regular basis. It would be appropriate to cite one or more examples of current acceptable recommendations, for example those of the Immunization Practices Advisory Committee (ACIP) of the U.S.P.H.S. [ACIP 1985; CDC 1987]. These change from time to time, and the most current recommendations should be observed.

26. **Employees may be reluctant to report exposure incidents if they fear that coworkers or others may gain access to their test results. OSHA has attempted to reduce barriers to the reporting of exposure incidents by requiring that employee medical records, including test results, be kept confidential except as required by law. Has OSHA adequately addressed the issue of confidentiality? If not, what additional measures should be required?**

All employee medical records, including test results, should be kept confidential. The proposed standard should be strengthened by requiring that facilities or employers responsible for such medical records develop a written plan to protect confidentiality. Elements of this plan should include, but not be limited to, how records will be stored and locked or otherwise secured, who will have access to such records, and conditions for release of information contained in the files. Furthermore, facilities or employers should demonstrate familiarity with and knowledge of federal, state, and local laws and regulations regarding the protection of these records.

27. **The biohazard signs required in paragraph (g)(1)(i) do not require the use of the word "Danger." Is it necessary to require the use of "Danger" or other additional warning words in order to warn individuals who may not understand the meaning of "Biohazard?"**

The word "Danger" or other cautionary words are not necessary. Training required under this regulation should result in employees understanding the significance of the biohazard symbol.

28. **OSHA requires that infectious wastes be labelled or "red bagged." If infectious waste is decontaminated prior to disposal, should OSHA allow the label to be removed from the container?**

Red bags or other red containers used in lieu of labels or tags should be imprinted with the legend "UNIVERSAL PRECAUTIONS." Persons who are red-green color-blind would be unable to distinguish ordinary green garbage bags from red bags of infectious waste.

After decontamination wastes no longer require labeling or special handling to guard against infection. However, safeguards must be provided to prevent inadvertent or inappropriate failure to label or removal of labels. There should be severe penalties for deliberately removing labels inappropriately or failing to label. However, after decontamination wastes no longer require labeling or special handling to guard against infection.

After decontamination, sharps continue to pose a risk of injury, but not infection. They should retain identification as a possible safety hazard. Data are very limited on the extent of this risk.

NIOSH has previously commented [NIOSH 1989b] to the Agency for Toxic Substances and Disease Registry (ATSDR) relative to the ATSDR request for information pertaining to health effects of medical waste. As a related point of information, CDC considers it important to use the CDC definition of infectious waste, which has been adopted by OSHA in this proposed rule, in preference to the definition of medical waste adopted by EPA and used in the Medical Waste Tracking Act. The CDC definition is based on the epidemiology of disease transmission, whereas other definitions are much broader and include articles that should not require special handling.

29. **OSHA requires that exposed employees be trained. Should OSHA specify minimum qualifications required for the individual who conducts the training program?**

Qualifications of the trainer should be specified in general terms. The trainer should be a person who has expertise in the subject area, as documented by objective evidence such as satisfactory completion of relevant training courses or degree programs.

The training program outlined covers those concepts with which all workers should be familiar. The rule should also require that each worker receive training specific to those task(s) performed in which exposure to blood or other potentially infectious material can be reasonably anticipated.

30. **The standard would require that all employees participate in the training program when they are hired and annually thereafter. Certain individuals, for example, infection control practitioners or some virologists, would be expected to be thoroughly familiar with some of the material in the training program. Is it appropriate to substitute some measure of competency in lieu of training for these individuals? If so, what criteria would be appropriate?**

Individuals could be excluded from general aspects of training for which they would be a qualified instructor. However, no employee should be exempt from training that pertains to the specific hazards and engineering controls, work practices, and personal protective equipment associated with their job duties.

31. **In all previous OSHA health standards, the Agency has required the employer to bear the cost for all provisions of the standard. This proposed standard would also require the employer to pay for all the provisions of the standard. OSHA seeks comments on this issue.**

OSHA has not made it sufficiently clear in the proposed standard that all costs, e.g., the cost of hepatitis B vaccination, are to be borne by the employer. Explicit language addressing this point should be incorporated into the rule.

The existing OSHA policy of requiring the employer to bear the cost of all provisions of the standard derives directly from the statutory requirements of the Occupational Safety and Health Act. Deviation in this rule from that statutory requirement and policy precedent could be defended only if it were demonstrated that worker safety and health would be improved by excusing the employer from specified costs. No such demonstration has been offered.

32. In order to perform an economic feasibility analysis, it is helpful to have a financial and economic profile of the industries affected by the standard. The following information is requested to aid in that effort. Data should be provided for the last five years. Data already submitted to OSHA or Jack Faucett Associates (JFA) need not be resubmitted.

    a. What were total annual revenues for your facility and/or industry sector?

    No comment on this issue.

    b. What were the total annual investments categorized as replacement, expansion, modernization, and environmental health and safety?

    No comment on this issue.

    c. What were the retained earnings, after tax income, total assets, stockholders' equity, net worth, depreciation charges, and debt-equity ratios?

    No comment on this issue.

    d. What were the total annual employment levels and labor turnover for the affected industries for the last 5 years?

    No comment on this issue.

33. How would an OSHA standard for occupational exposure to bloodborne pathogens affect competition in the healthcare industry?

    No comment on this issue.

34. OSHA and JFA have performed detailed feasibility analyses for all industry sectors. Comments are requested with regard to any other industry segments on additional impacts which should be considered prior to issuing a final standard.

    No comment on this issue.

35. Comments are requested on OSHA's Preliminary Regulatory Impact Analysis (PRIA), the report prepared by Jack Faucett Associates, the feasibility of the proposed standard and alternatives.

    No comment on this issue.

36. **The following information is requested for small businesses in addition to the information OSHA has gathered.**

a. **What kinds of small businesses or organizations would be affected by regulating exposures to blood and other potentially infectious materials? How many such businesses are there?**

No comment on this issue.

b. **Which, if any, federal rules may duplicate, overlap, or conflict with an OSHA regulation concerning exposure to blood and other potentially infectious materials?**

Packaging and labeling of etiologic agents for interstate shipment is governed by 42 CFR 72.

Standards for the tracking and management of medical waste were published by the EPA in March 1989 [54 FR 12328].

c. **Will difficulties be encountered by small entities when attempting to comply with the standard? What requirements, if any, should be deleted or simplified for small entities, while still achieving comparable protection for the health of employees of small entities?**

No comment on this issue.

d. **What timetable would be appropriate to allow small entities sufficient time to comply?**

No comment on this issue.

37. **OSHA's PRIA contains estimates of the current level of compliance for various provisions. Are these estimates accurate? If not, by what means and to what extent are employers currently providing protection to their employees?**

No comment on this issue.

38. **The National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.) requires that each Federal agency consider the environmental impact of major actions significantly affecting the quality of the human environment. Any person having information, data, or comments pertaining to possible environmental impacts is invited to submit them along with supporting documentation to OSHA. Such impacts might include a positive or negative environmental effect that could result should a standard be adopted; as well as any irreversible commitments of natural**

**resources. Also, estimates of the effect on the level of hazardous pathogens in the environment by the proposed OSHA standard and alternatives are requested.**

No comment on this issue.

39. **As discussed in Section IX - Summary and Explanation of the Proposed Standard and Section X - Public Participation, OSHA plans to devote several days of the public hearing to a discussion of Hepatitis B Vaccination. OSHA seeks written comments concerning the elements of a HBV vaccination program that will result in a high degree of compliance of eligible employees.**

The critical elements of a successful hepatitis B vaccination program include provision of vaccine at no cost to the employee, and at a location and time convenient to the employee. This must be accompanied by a strong program of education on the risk and consequences of HBV infection and the efficacy and safety of available vaccines. There should also be active follow-up by the employer to remind workers when it is time for the second and third injections in the series. One additional element of a successful program is the strong endorsement of vaccination by the leading medical authorities at the work location; acceptance has been poor when responsible physicians do not strongly support such programs.

40. **OSHA believes a hepatitis B vaccination program where employers bear the cost of the vaccine, make the vaccine available to employees at a reasonable time and place, and provide information about the benefits of the vaccine is the most appropriate way to assure that a large percentage of eligible employees are vaccinated. The Agency seeks comment on whether this voluntary approach is the correct approach.**

Vaccination is the most appropriate way to protect workers against hepatitis B. Provision of the vaccine at no cost to the worker and at a convenient time and place are indispensable to the success of the immunization effort. Educational programs on the health consequences of hepatitis B infection and the safety and efficacy of the vaccine are also important. Because vaccination requires a series of injections, there should also be active follow-up by the employer to remind workers when it is time for the next injection.

Vaccination should be voluntary for all eligible employees. Vaccination is an invasive procedure and carries a risk, albeit very low, of adverse side effects, possibly including a very low risk of Guillian-Barre Syndrome. It may also be objectionable to some persons on religious grounds. Therefore, it would be inappropriate to make vaccination a condition of employment. Any person, however, who declines vaccination should do so only with full knowledge of the risks of disease, disability, and death that are thereby incurred. Workers

who decline vaccination should also understand that they can reverse that decision at any time and participate in the immunization program at no cost to themselves.

COMMENTS ON PREAMBLE

IV.B. Hepatitis Viruses

Beginning on page 23048, this section says little about the risk of hepatitis delta virus (HDV) infection; it could note that nosocomial HDV infection has been reported [Lettau et al. 1986]. This reference is attached for addition to the docket.

Page 23051, 3rd column, 2nd paragraph: The statement that "all...AIDS cases who had received hepatitis B vaccine were also members of known AIDS high risk groups" is imprecise. Actually, there is a small number of AIDS patients in the no identified risk category who have received HB vaccine, but AIDS surveillance data reinforce laboratory studies that HB vaccine is not a source of HIV transmission. In practice, this question is or soon will be moot, since the plasma-derived vaccine is passing out of use and is being replaced with the yeast-derived product which cannot be a source of HIV.

Page 23051, last paragraph: The statement that "prevaccination testing...to identify previously infected individuals...is a requirement of the proposed standard" is misleading. The standard requires employers to offer prevaccination testing to all employees (but does not mandate that it must be done).

IV.C. Human Immunodeficiency Virus

Page 23053, 1st column, 3rd paragraph: There needs to be some indication that these published reports of 25 workers represent a minimum number and that there are undoubtedly cases not reported in the literature.

Page 23054, Table 1: Updated data, as of June 1989, are provided with these comments [CDC 1989].

Page 23054, 2nd column, 3rd paragraph: There are at least four published case reports of HIV-2 infection in the United States [CDC 1988a]. Also, there may need to be some acknowledgment that it is likely that additional human retroviruses will be discovered in the future, although this should not change the proposed rule.

Page 23054-55, 3rd column, 6th paragraph: The paragraph which describes Group IV patients implies that HIV wasting syndrome is not part of the AIDS case definition. The September 1987 revision included this as well as HIV encephalopathy as AIDS indicator diseases.

Page 23055, 2nd column: Case data for "Occupational Exposure and HIV Infections" will be provided when testimony is presented.

Page 23060, 1st column, 2nd paragraph: Henderson [Ex. 6-377, Ex. 6-352] has had a seroconversion, which is listed as Case #8 in this document [page 23056, Ex. 6-348].

Page 23060, 2nd column, 3rd paragraph: Updated data for "Healthcare Workers With AIDS" will be provided when testimony is presented.

**V. Preliminary Quantitative Risk Assessment**

**(C) Quantitative Assessment of HBV Risk**

Page 23066, 1st column, 1st paragraph: The estimate of proportion of the at-risk population that is immune (15% to 30%) is probably high if applied at an industry-wide level; a range of 10% to 25% may be a better estimate. In addition, the estimates do not take into account employee turnover in the industry; new persons eligible for vaccination are entering the industry and would increase the number at risk.

Page 23066, 2nd column, 1st paragraph: In the last sentence, OSHA estimates "the annual HBV infection rate...is between 4.89 and 6.63 per 1000 exposed workers." The corresponding estimate in Table C (also on page 23066) is 3.50 to 4.56 per 1000.

**(D) Qualitative Assessment of HIV Risk**

Page 23069, 1st column, 2nd paragraph: The number of health-care workers that were still under investigation as of September 1988 was 97, not 91. Updated data will be provided as part of our testimony.

Page 23070, 1st column, 1st paragraph: The general outline of the formula and its components seem correct.

**VI. Significance of Risk**

Page 23071, 3rd column, 1st paragraph: The incorrect implication is that wasting syndrome is not part of the AIDS case definition.

**VII. Preliminary Regulatory Impact and Regulatory Flexibility Analysis**

Page 23074, Table E.S.-2: Are these rates of compliance accurate, e.g., 100% compliance among funeral services and corrections industries?

b. Industry Profile

Page 23077, Table 23077: At least two of the marginal totals are incorrect, the 'Surgical Tech.' row and the 'Industrial Clinics' column.

c. Benefits—Introduction

We could not successfully duplicate all calculations in the hepatitis portion of this section, and recommend more complete explanation of calculations. We agree that secondary sexual transmission should be included in the nonoccupationally-induced hepatitis B estimates and suggest that attempts be made to estimate cases of perinatal infection prevented by the standard (although these would be relatively few in number).

Page 23082, 1st column, 5th paragraph: The number of needlesticks and other exposures might be significantly underestimated, especially given the paucity of published data.

Page 23083, 3rd column, 1st paragraph: The origin of the estimate that there are "1.7 to 2.1 million workers at risk who will not be protected by vaccination" is unclear.

D. Technological Feasibility

Page 23085, Table VIII-7: Are these rates of compliance accurate, e.g., 100% compliance among funeral services and corrections industries?

Page 23090, 2nd column, 1st paragraph: How were the seropositivity rates for HIV and HBV determined? They are nearly equivalent, which does not seem correct. HIV seroprevalence varies tremendously depending on geographic area, race/ethnicity, sex, risk group, etc. Preliminary data from the sentinel hospital surveillance system indicated a range of seroprevalence rates from 0.12% to 0.80%, with a median of 0.24% [see MMWR, May 12, 1989 Supplement].

Page 23091, Table VII-10: The column totals for estimated needlesticks far outnumber that for mucous membrane and open wound exposures. The accuracy of these data is unknown. There is a misprint in the cell identified by row = police officers and column = needlesticks.

IX. Summary and Explanation of the Proposed Standard

Page 23108, 1st column, last paragraph: There is a possibility that this rule may be misinterpreted, possibly leading to discriminatory actions directed against covered workers if there is a misconception that they represent a population at high risk of HBV or HIV infection. It should be made clear here and in elsewhere in the discussion of the

rationale for this proposed rule that if the recommended precautions are observed, the risk of occupational infection will be low, and that covered workers should not be treated as a new category of persons at high risk of HBV or HIV infection.

Page 23108, 2nd column, 4th paragraph: Substantial comment has been made concerning the desire of some health-care workers to know the HBV and HIV serologic status of individual patients. Some physicians, hospitals, and other interested parties have even advocated denial of services without such testing. While this paragraph indirectly addresses the issue, it could more directly state that these practices have been rejected and are not recommended or accepted practice. The inevitability of undiagnosed infections would render these screening programs ineffective and potentially counterproductive. This was a major factor in the adoption of the concept of universal precautions, according to which all blood and other potentially infectious material is treated as if it were known to be infectious.

Page 23112, 3rd column, 2nd paragraph: Referring to the recently published Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers [NIOSH 1989a], OSHA invited comment (page 23112) "on whether the proposed definition of 'other potentially infectious materials' should be amended to make it consistent with the guidelines." Similarly, OSHA requested comment (page 23042) "where these guidelines differ with the proposed requirements of this standard (e.g., which body fluids require the use of precautions in emergency situations.)" These issues are addressed in response to question #9.

Page 23114, 2nd column, 2nd paragraph: In the discussion of Methods of Compliance, OSHA should emphasize the importance of barriers to skin contact, while at the same time avoiding an implication that gloves are the only acceptable barrier for the hands. Often, gloves clearly are the preferred barrier to hand contact, but there also are situations in which the hands can be adequately protected by other barriers. For example, a drop of blood can be safely wiped from a counter top with an absorbent material moistened with a disinfectant. The material used to wipe the blood can be an effective barrier. When removing a bandaid from a venipuncture site, the bandaid itself is a barrier.

Page 23119, 1st column, 2nd paragraph: OSHA includes phlebotomy among the "examples of tasks which require the use of gloves." CDC recommends [CDC 1988b] latitude in glove use for phlebotomy:

> "Gloves should always be available to health-care workers who wish to use them for phlebotomy. In addition, the following general guidelines apply:
>
> 1. Use gloves for performing phlebotomy when the health-care worker has cuts, scratches, or other breaks in his/her skin.

2. Use gloves in situations where the health-care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.
3. Use gloves for performing finger and/or heel sticks on infants and children.
4. Use gloves when persons are receiving training in phlebotomy."

Page 23129, 1st column, 3rd paragraph: OSHA is correct to require that workers be informed when handling materials or containers of materials that require observation of universal precautions. It is appropriate to inform workers of the nature of these materials with tags or labels. However, use of the biohazard symbol is inappropriate for this purpose. Use of this symbol should be reserved for instances when an etiologic agent is known to be present, as in laboratories. Paragraph (g)(1)(i) of this proposed rule requires posting of laboratories in accordance with this principle. However, the labels required under paragraph (g)(1)(ii) are for the purpose of advising the worker only that the contents of the labeled container require universal precautions. In comments on paragraph (g)(1)(ii) of the regulatory text, we have suggested that these labels be color-coded and bear the legend "UNIVERSAL PRECAUTIONS." If OSHA judges that some easily recognizable symbol is also required, a unique symbol should be designed for the purpose.

Page 23129, 1st column, last paragraph: OSHA invites comment on designating the HBV or HIV infectious status of a patient or specimen. OSHA asks whether signs and labels should be prohibited, required, or discretionary for this purpose. Signs and labels for this purpose should be prohibited because this use would be contrary to the concept of universal precautions: all blood or other potentially infectious material is to be treated identically, i.e., as if known to be infectious. Handsfield et al. [1987] reported that use of biohazard labels to differentiate infectious from noninfectious laboratory specimens "may actually enhance the risk of infection of health care workers by contributing to a false sense of security and fostering complacency in the handling of unlabeled specimens. We therefore recommend that biohazard labeling not be employed to denote specimens from patients with HBV or HIV infection..."

**COMMENTS ON REGULATORY TEXT**

**(b) Definitions**

Definitions that should be added to paragraph (b) are:

> "Contaminate" means to soil with blood or other potentially infectious material.

"Decontaminate" means lowering the concentration of bloodborne pathogens by removal or inactivation, eliminating infectivity and rendering material safe for further handling.

In definition (2) of "Other potentially infectious materials," both parenthetical qualifications are superfluous. This should read simply:

"Any unfixed human tissue or organ."

The definition of "Sharps" should be broadened by replacing "broken capillary tubes" with "broken glass."

(c) Infection Control

Paragraph (c)(1)(ii) should read:

"Each employer shall identify and document all employees with occupational exposure."

It is not enough to simply identify those "positions" in which occupational exposures occur. It is essential to identify each individual who performs duties in which exposure to blood or other potentially infectious material can be reasonably anticipated. This paragraph can then serve as the trigger ("All persons identified in accordance with paragraph (c)(1)(ii) shall...") by which the employee qualifies for other provisions of this rule, e.g., HBV immunization, training, etc.

Paragraph (c)(2)(ii) should include a new subparagraph (C) that reads:

"(C) The method for evaluating the circumstances surrounding exposure incidents or other significant failures of controls to identify and implement any changes in policies or procedures that may be required to prevent recurrences of similar incidents."

As written, the proposed rule contains no provision for remedial action by the employer following an exposure incident. A requirement for the employer to evaluate exposure incidents and determine ways in which similar exposures can be prevented in the future should be a part of the infection control plan.

Paragraph (c)(2)(iii) should read:

"This infection control plan shall be reviewed and updated at least annually or as necessary to reflect significant changes in tasks, procedures, or personnel."

OSHA should require review of the infection control plan at least once each year, or on some other specified schedule, as well as whenever warranted by changes in the workplace. In addition to changes in tasks or procedures, personnel changes should be a basis for review. At least a determination of exposure under paragraph (c)(1) should be required for all new personnel and for all changes of job assignments.

(d) Methods of Compliance

Paragraph (d)(1) should read:

> "Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials."

The exception provided in this proposal following these words applies not to the general concept of universal precautions, but to the use of personal protective equipment under rare and relatively limited circumstances. These circumstances and the exception to mandatory use of protective devices would be better addressed, as outlined below, in paragraph (d)(3) under a new subparagraph (ii) dealing specifically with the use of personal protective equipment.

Paragraph (d)(2) should include a new subparagraph inserted after the existing subparagraph (i) that reads:

> "Employers shall provide a means for handwashing. When handwashing facilities (sink with running water and soap) are not feasible, the employer shall provide antiseptic hand cleanser that does not require the use of water. Cloth or paper towels shall be provided."

Paragraph (d)(2)(ii) should read:

> "Employees shall wash their hands immediately or as soon as possible after removal of gloves or other personal protective equipment."

Paragraph (d)(2) should include a new subparagraph inserted after the existing subparagraph (ii) (modified as suggested above) that reads:

> "Employees shall immediately wash hands and any other skin or mucous membrane that becomes contaminated with blood or other potentially infectious material. In the event that outer garments are penetrated by blood or other potentially infectious material, the contaminated clothing shall be removed and the skin washed immediately or as quickly as practicable."

Paragraph (d)(2)(iv) should permit the use of devices for the mechanical removal and disposal of needles, permit the resheathing of needles for medical practices for which there are no alternatives

(e.g., blood gas syringes, blood cultures), and permit removal of resheathed needles during those procedures that require it:

"Used needles and other sharps shall not be sheared, bent, broken, recapped, resheathed by hand, or removed from disposable needles by hand unless there is no alternative and the action is required by a specific medical procedure."

Paragraph (d)(3)(i) should read:

"Provision. When there is a potential for occupational exposure, the employer shall provide appropriate personal protective equipment..."

Paragraph (d)(3) should include a new subparagraph (ii) that reads:

"(ii) Use. The employer shall ensure that the employee uses appropriate personal protective equipment.

"(A) The employee may temporarily and briefly decline to use personal protective equipment if, under rare and exceptional circumstances, it is the employee's professional judgement that in the specific instance their use would prevent the proper delivery of health-care or public safety service or pose a greater hazard to the safety of the employee or co-worker.

"(B) Under emergency and other uncontrolled or unpredictable circumstances in which differentiation between fluid types is difficult or impossible, the employee shall treat all body fluids as potentially hazardous."

Paragraph (d)(3)(v) should read:

"Gloves. Gloves shall be worn when the employee can reasonably anticipate direct contact of the hands with blood,..."

Paragraph (d)(3)(vi) should read:

"Masks, Eye Protection, and Face Shields. Masks and...spray, spatter, or droplets of blood or other..."

Paragraph (d)(3)(vii)(A) should read:

"Gowns, lab coats, aprons, or similar outer garments shall be worn if there is..."

Paragraph (d)(4)(ii)(B) should read:

"...These coverings shall be removed at the end of the work shift or at the end of a procedure if overtly contaminated. They shall be removed and replaced between patients if there is a potential need to handle the coverings during treatment."

Paragraph (d)(4)(ii)(D) should read:

> "...and disinfected on a regularly scheduled basis."

Trash containers have not been implicated in the transmission of bloodborne pathogens; routine cleaning is adequate. There is no need to clean and disinfect immediately after visible contamination.

Paragraph (d)(4)(ii)(F) should be placed under (d)(2) Engineering and Work Practice Controls.

Paragraphs (d)(4)(iii)(B) and (d)(4)(iii)(B)(2) should be revised so they do not preclude the possibility of employing reusable containers if procedures are devised that do not increase the risk of puncture wounds.

> "(B) Immediately after use, sharps shall be disposed of in closable, puncture resistant containers that are...
>
> (2) These containers shall be replaced or emptied routinely and not allowed to overfill."

Paragraph (d)(4)(iv)(A) should be revised to read:

> "...or may contain contaminated sharps shall be handled as little as possible and with a minimum of agitation."

**(e) HIV and HBV Research Laboratories and Production Facilities**

Paragraph (e)(2)(i) should read:

> "Standard microbiological practices. All infectious liquid or solid waste shall be decontaminated, autoclaved, incinerated, or treated with appropriate chemical agents."

Paragraph (e)(2)(ii)(F) should read:

> "...No work with these potentially concentrated materials shall be conducted on the open bench."

Paragraph (e)(2)(ii)(F) should read:

> "Laboratory coats...shall not be worn outside of the work area."

Decontamination of laundry prior to washing is unnecessary.

Paragraph (e)(2)(ii)(H) should read:

> "All waste from work areas including animal rooms shall be incinerated, autoclaved, or decontaminated before disposal."

Paragraph (e)(2)(ii)(J) should read:

> "Hypodermic needles...in a puncture-resistant container and incinerated, autoclaved, or decontaminated before being discarded or reused."

Paragraph (e)(3)(i) should read:

> "Each laboratory shall contain a sink for hand washing and an eye wash fountain."

**(f) Hepatitis B Vaccination and Post-Exposure Follow-up**

Paragraph (f)(1)(i) should read:

> "The employer shall make hepatitis B vaccination available to all employees identified in accordance with paragraph (c)(1)(ii), and post-exposure follow-up to all employees with an occupational exposure incident."

Paragraph (f)(1)(iii) should read:

> "The employer shall provide all evaluations, procedures, vaccinations, and post-exposure management at no cost to the employee, at a reasonable time and place, and according to standard recommendations for medical practice."

Paragraph (f)(2)(i) should read:

> "HBV vaccination shall be offered to all employees identified in accordance with paragraph (c)(1)(ii), unless the employee has previously received the complete primary vaccination series or unless antibody testing ..."

Paragraph (f)(2)(ii) should read:

> "...If the employee is found to be immune to HBV by virtue of adequate antibody titer, as defined according to current standards of medical practice, then the employer..."

Paragraph (f)(3) is unclear as written. This seems to require that all employees must be provided with the report described in subsequent subparagraphs. This paragraph should read:

> "Following a report of an exposure incident, the employer shall make available to the exposed employee a confidential medical evaluation and follow-up..."

Paragraph (f)(3)(i) should read:

> "Documentation of the route(s) of exposure and the circumstances under which the exposure occurred."

This part of the post-exposure follow-up report should be made available to the infection control committee or other responsible body for study and evaluation of workplace practices and procedures to determine whether similar occurrences can be avoided in the future. The HBV and HIV status of the source patient, as well as the identities of the source patient and affected health-care worker are irrelevant to this evaluation, and should not be provided to the infection control committee. Determination of HBV and HIV status is covered in (f)(3)(ii).

Paragraph (f)(3)(ii) should read:

> "HBV and HIV antibody status of the source patient(s), if known. If the source patient can be determined and permission...presence of HIV or HBV infection in accordance with current standards of medical practice."

Paragraph (f)(3)(iv) should be revised to read:

> "Follow-up...and effective post-exposure medical management, according to current standards of medical practice. This should include administration of hepatitis B vaccine to any person who has not previously completed the primary vaccination series."

Currently, there is no known "safe and effective post-exposure prophylaxis" in the case of HIV exposure. Administration of the HB vaccine following an exposure incident is also strongly recommended if the exposed person has not been previously immunized.

Paragraphs (f)(5)(i) and (iii) are repetitive. These should be combined in a new subparagraph (i) reading:

> "Specific findings or diagnoses that relate to the advisability of or need for HBV immunization, and the physician's recommendation for or against hepatitis B vaccination for that employee. All other findings and diagnoses shall remain confidential."

Paragraph (f)(5)(ii) should be revised to read:

> "A statement that...the employee has been counseled about any medical condition...and on any need for further evaluation or treatment."

**(g) Communication of Hazards to Employees**

Paragraph (g)(1)(ii)(A) is unclear as to whether OSHA intends to require labeling of primary containers of blood or other potentially infectious material. This should read:

> "Warning labels shall be affixed to containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and secondary and tertiary containers used to store or transport..."

Paragraph (g)(1)(ii)(B) should read:

> "Labels required by this section shall include the following legend:
>
> UNIVERSAL PRECAUTIONS"

As discussed in response to Question 12 and relative to page 23129 of the Preamble, the biohazard symbol, as specified in paragraph (g)(1)(i), should be reserved for use when an etiologic agent is known to be present, such as in a laboratory. Use of the biohazard symbol is not recommended to designate materials that require workers to observe universal precautions.

Paragraph (g)(1)(ii)(E) should read:

> "Red bags or red containers imprinted with the 'UNIVERSAL PRECAUTIONS' legend may be substituted for labels on containers of infectious waste."

Paragraph (g)(1)(ii)(F) is unclear. Presumably, the intent is to exempt blood and blood products that have been screened for HBV and HIV antibodies and are released for clinical use. To make that clear, this should read:

> "Containers of blood...and have been released for transfusion or other clinical use are exempted from the..."

**(h) Recordkeeping**

Renumber existing subparagraph (1)(iv) as (1)(v) and insert a new (1)(iv):

> "The employer shall develop a written plan to protect the confidentiality of medical records. This plan shall include, but not be limited to, how records will be stored and locked or otherwise secured, who will have access to such records, conditions for release of information contained in the files, and a summary of federal, state, and local laws and regulations pertaining to the protection of these records."

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony concerned the exposure of workers to bloodborne pathogens in the course of their employment. Specific issues mentioned included the existence of bloodborne pathogens in addition to the ones discussed previously that present a risk to employees with occupational exposure to blood, identification of these pathogens, identification of studies or case reports on hepatitis-B virus (HBV) and human immunodeficiency virus (HIV) that should be included in the health effects analysis, the possibility that OSHA should consider HBV infection as a material impairment of health, and whether OSHA employed the correct methodology for determining the quantitative and qualitative risks of exposure. Further areas of concern to NIOSH included the defining of a correct and secure method for worker protection from bloodborne pathogens, the scope of the proposed OSHA standard, the identification of occupations in which exposure would be likely to occur, the circumstances under which exposure could occur, the possibility of transmission through human breast milk, the clear understanding of the terms contamination and decontamination, and the requirements noted in the proposed standard for controlling exposures.

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the Occupational Safety and Health Administration

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, Health-care-personnel, Infectious-diseases, Disease-transmission, Disease-vectors, Accident-prevention, AIDS-virus, Viral-diseases

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