Compendium of OSHA Questions and Answers from their Archives (Partially edited)

OSHA FAQs

02/27/2009 - Compliance with the OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030.

Question 1: Do "universal precautions" apply to the activities of medical and dental facilities (e. g., the handling of masks, goggles, gloves, lab coats or other personal protective equipment (PPE))?

Reply 1: Yes. According to the Bloodborne Pathogens Standard, "*Universal precautions*" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens." 29 CFR 1910.1030(b). 29 CFR 1910.1030(d)(1) requires that universal precautions be observed to prevent contact with blood or other potentially infectious materials. This would include the handling of PPE that has become contaminated with blood or other potentially infectious materials (OPIM) in medical and/or dental facilities.

Question 2: Would it be a violation of the Bloodborne Pathogens Standard if medical or dental facilities failed to adhere to universal precautions for the handling of blood, OPIM, or items, such as laundry contaminated with blood or OPIM?

Reply 2: Yes. Medical and dental facilities failing to adhere to universal precautions would be in violation of section 29 CFR 1910.1030(d)(1) unless the facility is observing a more stringent set of guidelines. According to the Centers for Disease Control and Prevention's (CDC's) *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings 2007*: "Standard precautions combine the major features of Universal Precautions and Body Substance Isolation and are based on the principle that all blood, body fluids, secretions, excretions except sweat, nonintact skin, and mucous membranes may contain transmissible infectious agents. Standard Precautions include a group of infection prevention practices that apply to all patients, regardless of suspected or confirmed infection status, in any setting in which healthcare is delivered. . ."[1] These include hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; and safe injection practices. Standard precautions are more stringent than universal precautions alone and would be acceptable.

Question 3: Would potential contact of textiles, such as linen or laundry, with *unknown* body fluids in medical or dental settings where universal precautions are practiced trigger coverage under OSHA's Bloodborne Pathogens Standard at that medical or dental facility? Also, would the contaminated textiles require special handling under the Bloodborne Pathogens Standard?

Reply 3: Pursuant to 29 CFR 1910.1030(a), the Bloodborne Pathogens standard is applicable to all occupational exposure to blood or other potentially infectious material (OPIM), as defined in 29 CFR 1910.1030(b). The definition of OPIM includes saliva in dental procedures, among other things. Occupational exposure is defined as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the

performance of an employee's duties." A determination of the duties, tasks, and scope of the employees' work must be done by the employer to assess whether employees have reasonably anticipated exposure to blood or OPIM [29 CFR 1910.1030(c)(2)]. Employers with employees who launder or otherwise handle linen contaminated with blood or OPIM (e.g., housekeeping staff in a healthcare setting; employees in a commercial laundry facility with a contract to launder contaminated linen from medical/dental settings) would be considered to have reasonably anticipated exposure and would be covered by the standard. Blood is often found on linen and laundry in medical facilities, and saliva is often found on such materials in dental offices. With respect to unknown fluids, 29 CFR 1910.1030(d)(1) provides in pertinent part: "Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials." The fact that the contaminated textiles are in a medical or dental facility where universal precautions are practiced would not preclude coverage under the Bloodborne Pathogens Standard.

With regard to the handling of contaminated laundry, 29 CFR 1910.1030(d)(4)(iv) sets forth the requirements for the handling and transport of laundry contaminated with blood or OPIM. For example, 1910.1030(d)(4)(iv)(A) and 1910.1030(d)(4)(iv)(A)(1) - 1910.1030(d)(4)(iv)(A)(3) cover the handling, containerization and transport of contaminated laundry, while sections 1910.1030(d)(4)(iv)(B) and 1910.1030(d)(4)(iv)(C) cover use of PPE while handling contaminated laundry and use of color-coded or labeled bags for transport to off-site facilities that do not use universal precautions in handling all laundry (e.g., transport to an off-site commercial laundry facility). Please refer to these sections of the standard for the specific requirements.

Question 4: Would an off-site facility (e.g., commercial laundry facility) which handles contaminated linen from healthcare settings be required to have a written exposure control plan?

Reply 4: Yes, as stated in the response to question #3, employers with employees who launder or otherwise handle linen contaminated with blood or OPIM (e.g., employees in a commercial laundry facility with a contract to launder contaminated linen from medical or dental settings) would be considered to have reasonably anticipated exposure to blood or OPIM and, thus, would be covered by the Bloodborne Pathogens Standard. Consequently, such employers are required to establish a written exposure control plan designed to eliminate or minimize employee exposure. 29 CFR 1910.1030(c)(1).

Question 5: Does an employer need to also ensure the proper laundering of contaminated linen?

Reply 5: The Bloodborne Pathogens Standard covers the handling and transport of contaminated laundry for the protection of employees; however, OSHA regulations do not have specific requirements for actual laundering procedures for assuring patient-specific infection control. OSHA's authority is limited to the protection of workers. As you noted in your inquiry, there are existing infection control guidelines set by the CDC. In the 2003 *Guidelines for Environmental Infection*

Control in Health-Care Facilities, the CDC provides guidance for the handling, cleaning, and disinfection of contaminated laundry. The document can be found at

http://www.osha.gov/pls/oshaweb/owaredirect.html?p_url=http:/www.cdc.gov/mmwr/preview/mmwrhtm/rr5210a1.htm.

Question 6: Is it permissible for employees to launder personal protective equipment like scrubs or other clothing worn next to the skin at home?

Reply 6: In your inquiry, you correctly note that it is unacceptable for contaminated PPE to be laundered at home by employees. However employees' uniforms or scrubs which are usually worn in a manner similar to street clothes are generally not intended to be PPE and are, therefore, not expected to be contaminated with blood or OPIM. These would not need to be handled in the same manner as contaminated laundry or contaminated PPE unless the uniforms or scrubs have not been properly protected and become contaminated.

Question 7: Is an employer in a dental office responsible for implementing an exposure control plan at the establishment if that employer launders the contaminated linen or PPE onsite?

Reply 7: Yes. Again, please see the response to question #3 above. Also, please be aware that dental offices would have other reasonably anticipated exposure scenarios other than the laundering of contaminated PPE that would make it necessary to develop and implement an exposure control plan. The exposure control plan should cover all job classifications and tasks in which employees have occupational exposure.

Question 8: Is that same employer responsible for following the CDC guidelines for laundering contaminated laundry?

Reply 8: The CDC guidelines are not mandatory. They are recommendations written with the intent of enhancing infection control measures in all healthcare facilities, including dental settings.

Question 9: How would OSHA regard an employer in a dental office who does not adhere to the requirements of the Bloodborne Pathogens Standard (e.g., use of universal precautions and establishment of an exposure control plan) and who does not use proper procedures for laundering contaminated laundry?

Reply 9: Again, please see the response to question #3 above. All employers having employees with occupational exposure must comply with the requirements of the Bloodborne Pathogens Standard and would be considered noncompliant for failing to do so. Please see the response to question #8 above with regard to the use of proper procedures for laundering contaminated linen.

05/05/2008 - Clarification of the use and selection of BBP safety devices.

Question 1: The OSHA Bloodborne Pathogens Standard requires employers to use engineering controls, such as appropriate "safety engineered" sharps. Can an employer select a device that is not expressly labeled by the manufacturer as a safety device and that does not have corresponding safety claims that have been cleared by the Food and Drug Administration (FDA)?

Response 1: As you know, employers are required to use engineering and work practice controls to protect employees [29 CFR 1910.1030(d)(2)(i)]. The standard defines engineering controls as *". . . controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace."* [29 CFR 1910.1030(b)]. With regard to safety-engineered devices used for preventing needlesticks and other sharps injuries, many circumstances would involve the use of safety-engineered devices which are expressly manufactured to replace conventional ones (i.e., sharps with safety engineered sharps injury protections, SESIPs). These devices generally bear a manufacturer's label indicating the type of safety feature along with specific instructions for use. However, the key to preventing needlesticks and other sharps injuries is the isolation or removal of the hazard, and in some circumstances, this may be achieved by completely removing the sharp (needleless technology) or substituting a safer alternative that is not necessarily labeled as such.

As an example, the use of plastic hypodermic syringes has largely replaced the use of glass syringes as an effective safer alternative. Plastic syringes are less prone to accidental breakage and, therefore, offer protection from potential percutaneous injuries from broken contaminated glass. Plastic syringes however, do not necessarily bear a legend of this safety benefit. Another example is the use of alternatives to glass capillary tubes which break easily. In a joint safety advisory on hazards associated with the use of glass capillary tubes, the FDA, NIOSH and OSHA recommended the use of capillary tubes that are not made of glass and glass capillary tubes wrapped in a puncture-resistant film. These alternatives also represent safety-engineered features in that they remove or isolate the sharps hazard.

It is important that employers perform a thorough hazard assessment and fully evaluate the feasibility and appropriateness for use of any engineering control before instituting its use [29 CFR 1910.1030(c)(1)(iv)(B)]. The substitution of a type of device or technology that does not bear a manufacturer's claim of safety must not introduce new hazards nor in itself create a hazard to employees. Additionally, employers should consult device manufacturers prior to making any after-market modifications to medical devices. Unauthorized modifications to medical devices may interfere with their intended use, may violate the FDA's approval of the device, or may create a greater hazard to patients and/or employees. You may wish to contact the FDA directly for additional information on the criteria which manufacturers must meet and the specific labeling requirements for all medical devices, including those with claims of safety-engineering features or capabilities.

Question 2: May an employer make an independent judgment that a device marketed with other claims and for other purposes provides the type of safety-engineered protection anticipated by the standard? If so, what level of documentation or testing is the employer required to have to demonstrate the validity of such judgments?

Response 2: As stated in response #1, the substitution of an alternative device or technology that does not bear a manufacturer's claim of safety must not introduce new hazards nor in itself create a hazard to employees. The requirement for evaluation and selection of a safety device is a performance-oriented provision which depends greatly on the specific medical device and medical procedure(s) in question. Devices must be evaluated for their ability to prevent occupational exposures to blood or other potentially infectious materials (OPIM) in each procedure. The final determination of what safer device is selected for use is a responsibility of the employer; however, when evaluating and selecting safer devices, employers must solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps [29 CFR 1910.1030(c)(1)(v)]. The input from affected employees must be factored into the employer's judgment of the appropriateness for use of a particular safety device.

With regard to the documentation needed to justify selection of safety devices, employers are required to have an exposure control plan which includes the initial exposure determination required by 29 CFR 1910.1030(c)(2) as well as the documentation of the methods of compliance, which includes implementation of engineering controls [29 CFR 1910.1030(c)(1)(ii)(A) and 1910.1030(c)(1)(ii)(B)]. The exposure control plan must be reviewed and updated annually to include documentation of the employer's consideration of newer technology [29 CFR 1910.1030(c)(1)(iv)(A) and 1910.1030(c)(1)(iv)(B)]. The standard does not specify the level of detail that must be included in this documentation; however, sufficient information must be provided to substantiate the facility's judgment. As discussed in the preamble of the Final Rule, consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption; the method or methods used to evaluate devices and the results of the evaluations; and justification for selection decisions. [See 66 *Federal Register* 5319, under discussion of paragraph 1910.1030(c)(1)(iv).]

Question 3: OSHA has previously clarified, in the context of Group Purchasing Organizations (GPOs), that price and contractual availability cannot be the sole basis for selecting a safety device. May other contractual requirements provide a basis for selecting a particular device? For example, if a multi-product manufacturer offers a contract that has a cost basis associated with being the employer's exclusive provider of a range of medical devices, and/or offers overall volume discounts that would be impacted by selecting another manufacturer's safety device, is a decision to use the contracting supplier's safety engineering sharps devices on this basis acceptable?

Response 3: 29 CFR 1910.1030 does not address contractual arrangements between employers and device manufacturers. Therefore, the standard does not specifically preclude the use of GPOs as

long as the employer is still able to meet the intent of the standard. As stated in the response to question #2, non-managerial employees involved in patient care must be afforded the opportunity to provide feedback in the evaluation and selection of safer devices. If an employer enters into an exclusive contractual arrangement with a manufacturer, the availability and variety of devices may be restricted. As technology advances, it is difficult to determine whether a safer and more appropriate device might become commercially available from a competitor of the exclusive supplier. Employees may be limited in the variety of available safety devices, particularly with regard to equipment that has few available choices. Additionally, each employer must review and update the exposure control plan annually and the annual review must include documentation of the consideration of newer technology [29 CFR 1910.1030(c)(1)(iv)(A)]. Advances in technology might not be captured if an employer is bound by contract to only evaluate devices from a single manufacturer. Finally, 29 CFR 1910.1030(d)(2)(i) requires that employers eliminate or minimize, i.e., reduce to the lowest extent feasible, occupational exposure. Thus, irrespective of the arrangements used in obtaining safety devices, the determination of an employer's compliance will be based on whether the requirements of the standard are being met.

06/21/2007 - Whether the BD SmartSlip™ is an acceptable safety-engineered device under 1910.1030.

Scenario: Becton Dickinson (BD) has developed the BD SmartSlip™ technology as an engineering control for use with smooth-tipped Luer Slip syringes which do not possess the locking threads of a Luer Lock syringe. Previously manufactured safety devices do not fit securely onto Luer Slip syringes which, in the United States, are used most frequently on 1 ml syringes in neonatal intensive care and pediatric units. BD created the SmartSlip™ technology to provide a secure attachment of BD safety needles to Luer Slip syringes.

Question: Would OSHA consider BD SmartSlip™ technology an engineering control that prevents unintentional needle disengagement which can potentially cause inadvertent sharps injuries?

Reply: OSHA may not and does not endorse or approve products. Compliance with the bloodborne pathogens standard is established on a case-by-case, facility-by-facility basis. As you may know, it is not merely the device itself that determines compliance, but the appropriate selection of engineering controls, accompanied by safe use of the device, safe work practices, and annual employee training. The final determination of whether a safety-engineered device prevents inadvertent sharps injuries must take into account all factors pertaining to the use of the safety device at a particular worksite. This must include an evaluation, including direct observation of employee work practices and all conditions of use in the workplace as well as an assessment of the equipment or device itself.

Although OSHA cannot, of course, approve or endorse particular products, the BD SmartSlip™ technology appears to be an acceptable safety-engineered device for employer consideration and use. The employer is ultimately responsible for ensuring compliance with the Bloodborne Pathogens Standard, including soliciting input from non-managerial employees responsible for direct patient care in the selection of appropriate safety devices and ensuring that employees are trained on the proper use of new devices and work practices necessary to prevent needlestick injuries [29 CFR 1910.1030(g)(2)(vii)(F)].

Frequently Asked Questions:

OSHA's Occupational Exposure to Bloodborne Pathogens Standard (29 CFR 1910.1030) and Smallpox Vaccination Programs

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NOTE: These FAQs were drafted in cooperation with the Centers for Disease Control and Prevention (CDC) and are intended to address questions about how the provisions of OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) apply to healthcare workers who administer smallpox vaccinations during the current vaccination program. For additional information on smallpox vaccinations, visit Centers for Disease Control and Prevention (CDC).

What is the Bloodborne Pathogen Standard?

OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030) as amended pursuant to the 2000 Needlestick Safety and Prevention Act, is a regulation that prescribes safeguards to protect workers against health hazards related to bloodborne pathogens. It has provisions dealing with exposure control plans, engineering and work practice controls, hepatitis B vaccination, hazard communication and training, and recordkeeping. The standard imposes requirements on employers of workers who may be exposed to blood or other potentially infectious materials such as certain tissues and bodily fluids.

Are workers who administer the smallpox vaccine covered by the Bloodborne Pathogens Standard?

Federal OSHA authority extends to all private sector employers, as well as to federal entities employing civilians. State and local government employers are only subject to the Occupational Safety and Health Act if they are in one of the 26 states and territories that have opted to develop and operate their own OSHA-approved State Plans. In the remaining states, these governmental employers are not required to comply with OSHA standards.

The Bloodborne Pathogens Standard is fully consistent with relevant CDC guidelines, and many state and local government healthcare employers comply with those guidelines. CDC recommends that all smallpox vaccination clinics comply with the Standard's provisions.

What are employers involved in smallpox immunization efforts required to do to comply with the standard?

Because these employers should already be complying with the standard, only a few additional precautions will be necessary, including updating their exposure control plans so that they address smallpox vaccination, and providing their employees with vaccination procedure-specific training.

As of January, 2003, CDC has determined that no commercially available safety-engineered bifurcated needle is an appropriate replacement for the bifurcated needle that is included in the pre-packaged kit that is being distributed for administering smallpox vaccine in this national program. If, in the future, improved safety devices become commercially available, the standard requires

employers, as part of any exposure control plan modification, to evaluate whether any of those devices, including sharps with engineered sharps injury protections (SESIPs), may be appropriate for the work practices of their employees.

The exposure control plan

The Bloodborne Pathogens Standard requires employers to review and update their exposure control plans at least annually or whenever necessary to reflect new or modified tasks or procedures affecting employee exposure. Facilities involved in the smallpox immunization plan will need to ensure that their plans include provisions relevant to the administration of smallpox vaccine.

Existing plans should already include the following elements:

1. Exposure determinations defining which job classifications have occupational exposure. In this instance it is individuals who perform vaccination and/or handle sharps disposal containers, as well as individuals who perform follow-up care for people who have been vaccinated.
2. Engineering and work practice controls, e.g., appropriate medical devices, sharps disposal containers, hand hygiene.
3. Personal protective equipment.
4. Housekeeping, including decontamination procedures and removal of regulated waste.
5. Information and training, including training associated with the performance of new tasks or procedures (see below).
6. Hepatitis B vaccination.
7. Post-exposure evaluation and follow-up.
8. Recordkeeping (including sharps injury log).

Aspects of the exposure control plan that may need special attention relevant to the smallpox vaccination program include:

1. Training on the safe use and disposal of bifurcated needles (see below).

2. Procedures for safe performance of vaccination including:
    a. Ensure that vaccination supplies, including sharps containers, are conveniently located at the point of vaccination.
    b. Prior to performing vaccination, explain the procedure to the vaccinee, including the risk of sharps injury to the vaccinator, and the need to avoid inadvertent movement during the procedure.
    c. Maintain visual contact with the bifurcated needle until vaccination is completed and the needle disposed.
    d. Immediately dispose of the bifurcated needle in the point-of-use sharps container. (If bifurcated needles must be reprocessed, safety measure to prevent injury after use and during reprocessing should be followed.)
    e. If a bifurcated needle drops, pick it up carefully in such a way as to minimize the possibility of accidental needlestick, preferably through the use of forceps or other

methods that reduce the chance of accidental needlestick. In no event should an employee touch the sharp end of the needle.

f. Dispose of vaccine vials and blood-contaminated gauze in the appropriate waste containers in accordance with applicable state, county, municipal regulations.

3. Procedures for reporting and follow-up management of blood exposures at vaccination clinics. If the creation of vaccination clinics will alter the employer's existing procedure for exposure reporting and medical evaluation and treatment, then this aspect of the exposure control plan will need to be amended.

If these steps are followed diligently, the opportunity for blood exposure and sharps injury should be minimal.

Safer medical devices

As a primary method of employee protection, the Standard requires employers to eliminate or minimize employee exposure to blood and other potentially infectious materials, to consider using appropriate commercially available and effective safer medical devices such as SESIPs to meet this obligation, and to document that consideration whenever they update their exposure control plans. Only one medical device incorporating the bifurcated needle design is part of the prepackaged kit for the licensed Dryvax smallpox vaccine. As of January 2003, CDC has determined that no other commercially available bifurcated needles are appropriate for administering the smallpox vaccine being distributed in this prepackaged kit. If, in the future, improved safety devices become commercially available, employers will be responsible for evaluating whether any of those devices are appropriate for use at their workplaces.

Training

The Bloodborne Pathogens Standard also requires employers to provide training to each worker in any new tasks or procedures that affect the employee's occupational exposure. Administration of the smallpox vaccine would be such a new task or procedure for most workers. The materials provided by the vaccine manufacturer and the training provided by CDC provides the foundation for meeting this requirement.

Other provisions

Other OSHA requirements are applicable to workers administering the smallpox vaccine, including additional provisions of the Bloodborne Pathogens Standard, the Hazard Communication Standard, and recordkeeping, record retention, and record access rules. For example, workers administering vaccine must be offered hepatitis B vaccination and appropriate follow-up, and an employer's obligations if an employee sustains a needlestick injury during vaccine administration would be the same as they would for any other needlestick injury. However, health care employers are already required to comply with those requirements so no new obligations would be imposed because of the smallpox vaccination program.

03/28/2005 - Containment and disposal requirements for disposable razors used in long-term health care facilities for personal grooming.

Scenario: Some state environmental and public health agencies have provided written opinions declaring or advising that disposable razors used for personal grooming should not be considered infectious or otherwise regulated medical waste and should not be disposed of or labeled as a biohazard, but should instead be disposed of in the regular waste stream.

Question 1: Does the standard allow nursing homes to use an empty laundry detergent bucket that bears the appropriate biohazard label and a notation that it is for razors only for the disposal of used razors? When the container is full and closed, can the facility remove or mark out the biohazard sticker at the point the container is disposed of in the regular waste stream?

Reply 1: OSHA's bloodborne pathogens standard states: *"Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories"* [CFR 29 1910.1030(d)(4)(iii)(C)]. Thus, long-term care and nursing home facilities must comply with any of these state regulations that describe specific policies regarding the final disposition of used razors, including the requirement that a notation that the containers only contain razors be placed on the container.

OSHA also has requirements to protect workers during the containment, storage, and transport of contaminated sharps, which includes razors used to shave patients in long-term care facilities. Although OSHA does not require specific brands, styles, or size of disposal containers, containers that are used to collect contaminated sharps must meet the requirements set forth in 1910.1030(d)(4)(iii)(A)(1). Among other things, they must be *"(i) Closable; (ii) Puncture resistant; (iii) Leakproof on sides and bottom; and, (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i)."* It is also required that designated sharps containers be *"Replaced routinely and not be allowed to overfill"* [1910.1030(d)(4)(iii)(A)(2)(iii)]. It should be noted that reusable containers are not to be opened, emptied, or cleaned manually or in any other manner which would expose employees to risk [1910.1030(d)(4)(iii)(A)(4)].

Any facility that generates regulated waste, including contaminated sharps such as used disposable razors, must provide employees with training on proper work practices regarding transport and containment [1910.1030(g)(2)(vii)(F)].

Question 2: Does the bloodborne pathogens standard allow a nursing home to maintain one sharps disposal container at a central location, e.g., a nurses' station near the areas where nursing home staff assist residents with shaving and simply have employees drop used razors into an emesis basin, plastic cup, or plastic bags to carry them to the disposal container?

Reply 2: The bloodborne pathogens standard requires that, during use, sharps containers must be *"[e]asily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries)"* [1910.1030(d)(4)(iii)(A)(2)(i)]. The standard also provides: *"Contaminated sharps shall be discarded immediately or as soon as feasible"* [1910.1030(d)(4)(iii)(A)(1)]. As with sharps containers used for collecting other types of contaminated sharps, designating a central collection site for the location of containers may not meet these requirements. Depending on the size of the facility and location of areas where shaving is performed, you may find that employees are required to walk considerable distances before disposing of used razors. In these cases, locating the containers closer to the point of generation may be feasible and would, therefore, be required by the provision of the standard cited above. One way to ensure the containers are located as close as is feasible would be to train staff members to take note of the availability of a medication cart, treatment cart that has a sharps container on it, or soiled utility room that has a sharps container prior to shaving a resident, if there is no sharps container located inside the room in which the shaving will take place. Staff members should pre-plan and determine the closest area for the razors to be disposed of after shaving a resident.

In addition, employers must ensure that care be taken when moving containers used for the collection of used sharps. Under 1910.1030(d)(4)(iii)(A)(3)(i), the containers must be *"[c]losed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping."* In those work situations where nursing home staff assist residents with shaving and must then dispose of the razor in a sharps container which is located, for example, outside the room on a treatment cart, specific details regarding safe work practices to address this procedure must be developed and included in each worksite's Exposure Control Plan [1910.1030(c)(1)(ii)(B)]. Safe work practices may include covering the transport container (which contains the used razor) during travel to the treatment cart or other final disposal container, in order to protect the worker from exposure to the blade or the accidental spilling of the container's contents.

Engineering and work practice controls must be instituted as the primary means of eliminating or minimizing employee exposure [1910.1030(d)(2)(i)]. One way in which employers can eliminate the razor blade from the worksite is to utilize electric razors to shave residents. This alternative constitutes an effective engineering control for the protection of employees. It ultimately reduces the amount of regulated waste for the facility, simplifies the staff training time, and is generally well received by the residents.

05/22/2007 - Application of OSHA's Bloodborne Pathogens standard to contractors who clean up blood following accidents.

Scenario: I have a cleaning company that will be involved in cleaning up blood and body fluids after homicides, suicides, and unattended deaths. The cleaning crew will contact blood and body fluids that have been exposed to air, in most cases, for at least 24 hours and will be using hospital-grade disinfection solutions that will kill HIV, hepatitis B virus, and hepatitis C virus.

Question 1: Does this type of cleaning fall under the Bloodborne Pathogens standard (BBP)?

Reply 1: Yes, the Bloodborne Pathogens standard would be applicable to the cleanup work done by your employees. 29 CFR 1910.1030(b) defines "occupational exposure" as "*reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials [OPIM] that may result from the performance of an employee's duties."* The standard is concerned about exposure to blood regardless of how long it has been exposed to air, and, therefore, the exposure determination for your cleaning crew must be made without regard to the potential 24-hour delay between the time of the blood spill and the time of the cleanup activity. There are studies stating that many bloodborne pathogens are infectious for some time on environmental surfaces. For example, the hepatitis B virus (HBV) is likely to survive longer than two weeks, and hepatitis C virus can survive for up to two weeks.

Question 2: Regarding the waste generated from the cleanup operation, the Illinois EPA does not classify this waste to be potentially infectious medical waste (PIMW) under its statutes. I have been told that since my operation does not involve treatment or diagnosis of patients, I may dispose of the byproduct of the cleanup in a local landfill. Local landfills in my state will not accept containers or bags with biohazard labels. If my work falls under the BBP standard, must the waste generated from the cleanup be placed in containers which are marked or labeled as biohazard or can we simply place the waste in color-coded (red) garbage bags?

Reply 2: With regard to the waste generated from the cleanup of blood as described in your letter, OSHA regards this as "regulated waste" under the Bloodborne Pathogens standard. [See the definition of "regulated waste" in 29 CFR 1910.1030(b).] Because the standard is based on the concept of "universal precautions," an approach to infection control under which "all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV [hepatitis B virus], and other bloodborne pathogens," [29 CFR 1910.1030(b)], the blood or OPIM to which any particular employee is exposed must be presumed to be infectious. The standard requires that regulated waste other than contaminated sharps be placed in containers which are: (1) closable; (2) constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; (3) labeled **or** color-coded in accordance with paragraph (g)(1)(i); and (4) closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or

shipping [29 CFR 1910.1030(d)(4)(iii)(B)].

There are three exemptions to the labeling requirement of paragraph (g)(1)(i). The first exemption, paragraph (g)(1)(i)(E), allows the substitution of red bags for labels on bags or containers of regulated waste. OSHA believes that employees will be protected where red bags are used because employers will have to comply with paragraph (g)(2)(vii)(M) of the standard which requires that employees be trained to understand the meaning of all color coding used to comply with paragraph (g)(1). This would include information on the meaning of red bags, thus assuring that OSHA's intent, to inform employees of hazards present at their worksite, would be achieved by red bagging.

Please be aware that according to 1910.1030(d)(4)(iii)(C), "*[d]isposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories."* As you stated in your letter, you have inquired and received information from the Illinois EPA that waste generated from your cleanup activities are allowed, in your state, to be disposed of in local landfills provided that they are not labeled "Biohazard." As stated above, OSHA's requirements will be met with the use of red bags in lieu of biohazard labels on containers of regulated waste and with appropriate training of affected employees.

10/26/2007 - Clarification of PPE requirements for phlebotomists performing venipunctures in hospital setting and/or rural outpatient clinics.

Questions 1: Are lab coats required to be used by skilled phlebotomists during the performance of routine venipunctures in a hospital setting or in a rural outpatient clinic?

Answers 1: As you may know, when there is occupational exposure to blood or other potentially infectious materials (OPIM), the employer is required to provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, or other PPE deemed necessary. Occupational exposure is defined by the BBP standard, 29 CFR 1910.1030(b) as ". . . reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties." As a general rule, phlebotomists are considered to have occupational exposure. The performance of routine vascular access procedures by skilled phlebotomists in a hospital or clinic would require, at a minimum, the use of gloves to prevent contact with blood [29 CFR 1910.1030(d)(3)(ix)].

Laboratory coats or work smocks, though commonly worn as part of a phlebotomist's uniform, are not typically needed as personal protective equipment (PPE) during routine venipuncture. Nonetheless, employers must assess the workplace to determine whether certain tasks, workplace situations, or employee skill levels may result in an employee's need for laboratory coats or other PPE to prevent contact with blood.

Please keep in mind that the need for PPE must not be based on geographic location. According to the BBP standard, employers must adhere to the concept of Universal Precautions, the infection and exposure control philosophy which advises that all human blood and certain body fluids are to be treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens [29 CFR 1910.1030(b) and 1910.1030(d)(1)].

Question 2: May an employee who performs venipunctures in a rural outpatient clinic setting wear a personal work smock, and may these smocks be laundered at home by the employee, if there is no visible contamination?

Answer 2: Please see the answer for the first question. This question is also specifically addressed in OSHA Instruction 02-02-069, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, paragraph X.III.D.16, which states: ". . . While many employees have traditionally provided and laundered their own uniforms or laboratory coats or the like, if the item's intended function is to act as PPE, then it is the employer's responsibility to provide, clean, repair, replace, and/or dispose of it." The practice of employees laundering their own PPE at home is prohibited by the standard.

If an employee wishes to choose, wear, and maintain his or her uniform or work smock, then he or she would need to don additional employer-handled and employer-controlled PPE when performing tasks where it is reasonable to anticipate exposure which may contact the skin or clothing.

Question 3: May the potential exposure to blood be assessed by the employee (a phlebotomist) on a case-by-case basis, and based on the situational disposition of the patient?

Answer 3: No. It is the employer, and not the employee, who is required to make the occupational exposure determination. As required by 29 CFR 1910.1030(c)(2)(i), the employer must assess each job classification and task. Also, as per 29 CFR 1910.1030(g)(2)(vii)(E) through 1910.1030(g)(2)(vii)(G), the employer is also required to train employees on the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM. Training must also include an explanation of the use and limitations of personal protective equipment.

Question 4: Does OSHA have a comprehensive list of situations where there exists a reasonable chance of exposure to blood during venipuncture operations?

Answer 4: No. Please see the answers for questions #1 and #3.

09/17/2004 - Bloodborne Pathogens Standard as it relates to contaminated laundry, sharps containers, and the Hepatitis B vaccine in fitness centers.

Question 1: Currently, our fitness centers discard laundry soiled with blood or other potentially infectious materials (OPIM) into biohazard waste containers. Should we be discarding these items, and is it appropriate for us to launder them?

Reply: Initially, you must determine whether your fitness centers are covered by the bloodborne pathogens standard, which applies to "all occupational exposure to blood or other potentially infectious materials," see 29 CFR 1910.1030(a). "Occupational exposure" is defined as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties," see 1910.1030(b). The requirements for exposure determinations are set forth in 1910.1030(c)(2).

Normally laundry in a non-healthcare setting would not be covered by the bloodborne pathogens standard. However, if there is "occupational exposure" as defined above and if the laundry is soiled or contaminated with blood or OPIM, it would be necessary for an employer to comply with provisions of the standard. The standard requires that soiled linen should be handled as little as possible and with minimum agitation to prevent exposure to the handler, see 1910.1030(d)(4)(iv)(A). Linen soiled with blood or OPIM which is sent to a facility to be laundered must be placed and transported in specially marked bags that also prevent leakage, see 1910.1030(d)(4)(iv)(A)(1). The standard does not prohibit the employer from laundering on site as long as the laundering is performed by trained individuals utilizing universal precautions. Other provisions on laundry are set forth in 1910.1030(d)(4)(iv).

OSHA does not require that soiled **non-disposable** linens be discarded. If the soiled linens can be laundered, then there is no reason for the soiled linens to be discarded.

Question 2: How much blood is necessary in order for an item to be considered soiled? Is a drop from shaving, a paper cut, or a pimple enough?

Reply: The determination of whether an item is soiled is not based on actual volume of blood or OPIM, but rather on the potential to release blood or OPIM. The question is whether, when compacted, the item would release blood or OPIM or whether it is possible for dried blood or OPIM to flake off during handling. It is the employer's responsibility to determine whether these criteria are met.

Question 3: Some of our facilities provide razor blades for customers. Are we required to provide sharps containers? If so, how many are required per square foot of bathroom area?

Reply: No. The employer is not required to provide sharps containers because customers, not employees, are exposed to the razor blades.

Question 4: I don't see the relevance of having to provide Hepatitis B shots for employees of a fitness center.

Reply: Fitness center employees normally are not considered to have "occupational exposure," and they are not covered by the standard unless they are trained in first aid and designated as responsible for rendering first aid. See OSHA CPL 02-02-069 [CPL 2-2.69] Section XIII.A.3.C (this OSHA directive is available at the OSHA website noted in the last paragraph of this letter). If the fitness center employee's only exposure is due to being designated as a first-aider and first aid is only a collateral duty, the preventive vaccination series does not have to be offered if the requirements in OSHA CPL 02-02-069 Section XIII.F.8 are met. The vaccine must be offered **following** the employee's involvement in an incident in which the employee was exposed to blood. The employer must have an exposure control plan in place that details how the Hepatitis B vaccine will be administered to the exposed employee within 24 hours of the incident. Other requirements are set forth in the provisions of the directive mentioned previously.

06/03/2005 - Definition of contaminated sharps; engineering controls and good work practice controls must be implemented; ECP must be reviewed annually.

Question 1: Does OSHA's definition for "contaminated sharp" include non-needle sharps such as blades and scalpels? If a facility used conventional blades and scalpels, and if safety-engineered options were commercially available, would healthcare facilities be required to use them?

Reply 1: As you know, the bloodborne pathogens standard defines "contaminated sharps" as *"any contaminated object that can penetrate the skin, including but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires,"* 1910.1030(b). Scalpels and blades are included in this definition.

In response to the second part of this question, if safety-engineered blades and scalpels were commercially available, a healthcare facility would be required to evaluate them for appropriateness and effectiveness. Since no one device is appropriate for use in all circumstances, the decision to select a safety device is always based upon evaluation and a determination that the device is appropriate and effective for the particular procedure, 1910.1030(c)(1)(iv). Since safety-engineered blades and scalpels are types of engineering controls within the meaning of 1910.1030(b), their use is required by the employer if they are engineering controls which will eliminate or minimize employee exposure, 1910.1030(d)(2)(i).

Question 2: The standard does not require engineering controls if their use would compromise worker or patient safety or if they are not commercially available. Does the standard excuse an employer from using engineering controls because of practitioner preference?

Reply 2: In many cases, a practitioner's "preference" is a result of a familiarity with a device and a reluctance to break routine. It is true that clinicians might initially consider the use of a newly selected safety device to be cumbersome or awkward and in most cases they may simply need additional practice or training until they feel comfortable using a new and different device. Thus, practitioner preference is generally not an excuse for failure to use engineering controls. In some surgical procedures, however, the "feel" of a device in the hands of the surgeon may be crucial to properly executing the surgical technique. The importance of the "feel" of a device could be a critical factor which may affect the outcome of the procedure and, ultimately, the safety of the patient. The intent of the OSHA standard was never to usurp the practitioner's authority in deciding the best method of achieving a positive health outcome for a patient during a procedure. The standard requires that employers use engineering **and** work practice controls to eliminate occupational exposure to the lowest feasible extent, 1910.1030(d)(2)(i). OSHA recognizes there might be unique circumstances where the safety of the patient or the integrity of a procedure might be best served with the use of a device that is not a safety device. In those situations, it is important that good work practice controls, such as eliminating hand-to-hand instrument passing in the operating room, be

implemented to provide protection to employees who are at risk of getting injured by an unprotected device.

Question 3: Practitioners may feel that in some specific procedures in certain clinical scenarios a situation may arise where implementation of an engineering control, such as SESIPs, might result in a potential negative clinical outcome. How must this be documented and demonstrated in order to fulfill compliance with the standard?

Reply 3: Engineering and work practice controls that the employer determines to be appropriate must be documented in the employer's Exposure Control Plan (ECP), 1910.1030(c)(1)(ii)(B). If a safer medical device compromises patient safety, worker safety or the medical integrity, its use would not be required. Whether or not an engineering control is chosen for a specific procedure, an annual review of safer medical devices is required and that review must be documented in the ECP, 1910.1030(c)(1)(iv)(B).

11/21/2002 - Safer medical devices must be selected based on employee feedback and device effectiveness, not Group Purchasing Organizations.

This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence. Your letter is paraphrased below followed by OSHA's response.

We (Terumo) understand that the evaluation of new sharps safety devices should be conducted by frontline healthcare workers. Many healthcare facilities operate under a Group Purchasing Organization (GPO) contact, intended to organize purchasing and availability of medical supplies. The GPOs typically offer little, if any, variation with regard to needlestick safety products. In light of the OSHA requirements to use safer medical devices dependent on an evaluation performed by healthcare workers, GPOs should not restrict the selection and evaluation of such products. What is OSHA's viewpoint on this?

Your interpretation is correct. Devices must be selected based on employee feedback (29 CFR 1910.1030(c)(1)(v)). They must be evaluated for appropriateness for each procedure and effectiveness in preventing occupational exposures to blood and other potentially infectious materials (OPIM). If the availability and variety of devices is restricted, the employer may be in violation of the requirements: (1) to review and update the exposure control plan to reflect changes in technology that eliminate or reduce exposure to blood and OPIM (29 CFR 1910.1030(c)(1)(iv)(A)); (2) to review and update the plan annually, documenting the consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure (29 CFR 1910.1030(c)(i)(iv)(B); and (3) to use engineering controls to eliminate or minimize employee exposure (29 CFR 1910.1030(d)(2)(i)).

Remember, selecting a safer device based solely on the lowest cost is not appropriate. Selection must be based on employee feedback and device effectiveness. OSHA compliance officers have issued citations to employers at facilities that were not using effective engineering controls because of the product availability limits of their purchasing contracts. Again, if during an OSHA inspection, it is determined that an employer did not evaluate and select appropriate and effective devices, the employer may be cited. In an effort to best serve the safety and regulatory needs of their clients, GPOs should offer a variety of different safer devices.

03/19/2003 - Engineering control requirements for allergy and immunization injections.

Scenario: Allergists give millions of injections, including subcutaneous and intradermal injections, every year using small bore (26- or 27-gauge) needles.

Question: Must allergists comply with the requirement to use engineering controls [e.g., sharps with engineered sharps injury protection (SESIPs)]?

All employers with employees who have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with all applicable provisions of the bloodborne pathogens standard (the standard). Potential exposure must be determined by assessing the processes and procedures being performed in each individual workplace.

Employees giving injections, regardless of the needle type or size being used, have occupational exposure to blood; the employer must use engineering controls to eliminate or minimize those exposures [29 CFR 1910.1030(d)(2)(i)]. Engineering controls [e.g., sharps with engineered sharps injury protection (SESIPs) and needleless systems - see definitions in 29 CFR 1910.1030(b)] must be evaluated, selected, and put into use based on feedback from employees responsible for direct patient care [29 CFR 1910.1030(c)(1)(v)].

Engineering controls must be selected based on their appropriateness for the specific procedures being performed and their effectiveness in reducing worker exposures to blood and contaminated sharps. If engineering controls (e.g., SESIPs) are commercially available and feasible (e.g., use does not compromise patient safety, worker safety, or the medical procedure) for a specific procedure, they must be evaluated and implemented.

There are dozens of commercially available syringes with engineered safety features for intramuscular and subcutaneous injections. When giving these types of injections, SESIPs must be selected and used as a means to control exposures.

We understand that currently appropriate controls for intradermal injections may be more limited. Therefore, it is important to identify safer options that may exist, evaluate them for effective safety and appropriateness for the procedures being conducted, and select one based on employee feedback. This must be done on an annual basis as a part of the employer's evaluation of his or her exposure control plan [29 CFR 1910.1030(c)(1)(iv)]. If, based on thorough evaluation, a SESIP is not appropriate to use for intradermal injections, based on the criteria listed above, that fact must be documented in the facility's exposure control plan (ECP). It is then the individual employer's responsibility to evaluate new commercially available devices the following year.

Please be aware that compliance is assessed on a facility-by-facility, instance-by-instance basis, therefore each employer at each facility must determine the appropriateness and effectiveness of the use of SESIPs for the specific procedure being conducted. Selection and implementation should not be done on a broad, national basis, unless that employer can ensure that the selection of devices is

unique to the procedures being done in each of the facilities and that employees have the opportunity to provide feedback on the selection of the engineering controls.

01/20/2004 - Bloodborne Pathogens Standard application to small healthcare facilities and the annual review of the Exposure Control Plan.

Question #1: *Are physician offices and clinics required to provide safety-engineered sharp devices and needleless systems to employees? Is there a minimum number of employees that must be employed to be governed by this Act [Needlestick Safety and Prevention Act]?*

Reply #1: The Needlestick Safety and Prevention Act directed OSHA to revise its bloodborne pathogens standard [29 CFR 1910.1030]. On January 18, 2001, OSHA published the revised standard, which took effect on April 18, 2001. OSHA's bloodborne pathogens standard, including its 2001 revisions, applies to all employers who have employees with reasonably anticipated occupational exposure to blood or other potentially infectious materials (OPIM).

However, workplaces classified in certain Standard Industrial Classification (SIC) codes are not required to keep OSHA injury and illness records, including sharps injury logs. Health care facilities with SIC codes 801, 802, 803, 804, 807, and 809 are included in this partial exemption for recordkeeping. These employers are still, as stated above, required to be in compliance with the provisions of the bloodborne pathogens standard. They are also required to report any workplace incident that results in a fatality or the hospitalization of three or more employees [29 CFR 1904.39].

Question #2*: Are health care facilities, even those that currently use appropriate safety devices, required to review any new technological developments with regards to safety devices if these may reduce the risk of exposure? Do they have to have this review at least annually and document these reviews?*

Reply #2: OSHA's bloodborne pathogens standard requires employers to review and update the Exposure Control Plan (ECP) at least annually [29 CFR 1910.1030(c)(1)(iv)], even those who currently use appropriate safety devices. It is also a requirement that the annual review and update of ECPs reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens and that employers document annually their consideration and implementation of appropriate commercially available and effective safer medical devices [29 CFR 1910.1030(c)(1)(iv)(A-B)]. Solicitation of input from non-managerial employees who are potentially exposed to sharps injuries is an important component of the selection and implementation of safety devices [29 CFR 1910.1030(c)(1)(iv)-(v)].

If, after employee input, an employer determines that an engineering control is effective, the employer must simply keep abreast of new and emerging technologies and document this in the ECP. It is not necessary to evaluate all newly emerging engineering controls each year, but an employer must make a concerted effort to evaluate new technologies in order to determine which device is effective in reducing injuries.

Question #3*: Can an individual manager choose not to review a new safety device without the input from non-managerial workers?*

Reply #3: It is the employer's responsibility to determine which engineering controls are appropriate for specific hazards, based on what is appropriate to the specific medical procedures being conducted, what is feasible, and what is commercially available. However, it is necessary that employers include solicitation of input on the identification and selection of available engineering controls from non-managerial employees who are potentially exposed to sharps injuries [29 CFR 1910.1030(c)(1)(iv)-(v)]. This should be documented in the ECP.

02/08/2007 - Safety considerations for handwashing of medical instruments.

Question: A surgeon in an operating room wants to have employees hand wash all instruments after use. Are there any OSHA standards which address safety considerations for washing medical instruments by hand?

Reply: As you may know, the Centers for Disease Control and Prevention (CDC) has developed *Guidelines for Handwashing and Hospital Environmental Control, 1985,* which include guidance for cleaning reusable medical instruments. The guidelines state: *"[a]ll objects to be disinfected or sterilized should first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue."*[1] OSHA does not specifically prohibit the handwashing of instruments that, according to these guidelines, should be pre-cleaned before being disinfected or sterilized. Furthermore, OSHA's bloodborne pathogens standard (BBP), 29 CFR 1910.1030, which provides protection for employees from exposure to blood or other infectious materials (OPIM), in general, requires employers to establish appropriate cleaning and decontaminating procedures for all contaminated equipment. The standard, at paragraph (d)(4)(ii), requires that *"All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.*"

However, according to paragraph (d)(2)(i) of OSHA's BBP standard, where engineering and work practice controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. This would include the use of existing, feasible, commercially available engineering controls, such as the use of ultrasonic cleaners. In circumstances where ultrasonic cleaners or other engineering control measures are deemed infeasible, the implementation of work practices, such as the use of long-handled brushes for physically removing organic material on reusable sharps is expected in order to reduce the potential for employee exposure to blood or OPIM on contaminated sharp instruments.

Additionally, employers must provide personal protective equipment when the use of engineering controls and work practices does not eliminate the hazard. As an example, employers who assign employees the task of cleaning medical instruments by hand must evaluate the task and provide impervious gloves for additional protection against cuts or lacerations from sharp objects [29 CFR 1910.1030(d)(3)(i)].

Regarding the storage and reprocessing of contaminated reusable **sharp** instruments, 29 CFR 1910.1030(d)(2)(viii) requires: "*Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed*". Additionally, 1910.1030(d)(4)(ii)(E) provides: "**Reusable sharps** *that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.*"

06/14/2007 - The applicability of OSHA's bloodborne pathogens standards to the use of sharps containers on hospital crash carts.

Scenario: Crash carts with specialized life-saving equipment are used in emergency response situations in healthcare facilities and are moved throughout the medical facility as needed. In general, each crash cart is equipped with either a disposable or reusable sharps container which is attached in an upright position to the cart to allow for prompt disposal of contaminated sharps in emergency situations. The sharps container is essentially integral to the crash cart in that it remains in position on the crash cart until the container is ready to be replaced.

Question 1: What is considered the "area of use" for a movable crash cart?

Reply 1: With regard to sharps containers, OSHA interprets the area of use to be the location where used sharps are deposited into the containers. In the case of movable crash carts whose contents are only removed or used at the time and location where they are needed, "area of use" is the location where the medical procedure requiring the cart is being performed.

Question 2: Does 29 CFR 1910.1030(d)(4)(iii)(A)*(3)(i)* mean that a sharps container on a crash cart needs to be closed during transport from one location of use to another within the same hospital?

Reply 2: Yes. The intent of this requirement is to ensure that employees are protected from contaminated sharps that may fall out while sharps containers are being transported from one area of use to another. In order to assure employees' safety, employers must select from the variety of commercially-available sharps containers which are suitable for the intended use, in this case moving safely from one location to another [29 CFR 1910.1030(c)(1)(iv)(B)]. Among available products are portable sharps containers designed with counter-balanced doors and sharps containers equipped with closable flaps for mobile phlebotomy functions. The design features of these containers allow for immediate disposal of sharps and provide an acceptable temporary barrier from spillage of sharp objects during transport. In addition, these types of containers allow users to lock the closures in place once containers are filled and ready to be removed for final disposal.

According to recommendations from the National Institute for Occupational Safety and Health (NIOSH) document, *Selecting, Evaluating, and Using Sharps Disposal Containers*, the selection of a [sharps] container should be based on a site-specific hazard analysis. One important criterion in the selection of sharps containers is the assessment of containers that accommodate transport or mobility needs.[1] This essentially means that whether containers are being transported on a cart or by hand, employees will be afforded the best protection when employers select sharps containers which are appropriately constructed and will allow for safe transport. Containers located on movable carts should be secured with brackets or other positioning mechanism (s) to minimize the likelihood of the container tipping or becoming overturned and should have a protective barrier over the opening to prevent protrusion of displaced sharps.

Question 3: Allowing the use of sharps containers on crash carts would promote compliance with 29 CFR 1910.1030(d)(4)(iii)(A)*(2)(i)*, *"[d]uring use, containers for contaminated sharps shall be: [e]asily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found. . . "* Healthcare facilities, today, do not close these containers. If the containers were closed and reopened after the cart has been moved, would this be a violation of another part of the regulations 1910.1030(d)(4)(iii)(A)*(4)* regarding opening of sharps containers?

Reply 3: OSHA agrees with your statement that the placement of sharps containers on crash carts is an effective means of meeting the requirement that employees dispose of contaminated sharps as soon as possible after use. With regard to the appropriateness of employers permitting employees to manually reopen reusable sharps containers that have been closed, it is, indeed, a violation to do so. In addition to meeting the requirement for immediate disposal of contaminated sharps, employers have the additional obligation to forbid the opening, emptying, or cleaning of reusable containers manually or in any other manner which would expose employees to the risk of sharps injury [29 CFR 1910.1030(d)(4)(iii)(A)*(4)*].

However, the use of commercially-available sharps containers which are designed to provide temporary barriers to protect employees during the transport of containers from one area of use to another are often necessary and are permitted. As mentioned above, there are a variety of portable containers produced by more than one manufacturer which are equipped with counter-balanced doors or closable flaps for temporary closure. These containers can provide interim protection from the sharps contained within the container and are suitable for use on mobile carts.

04/20/2004 - Clarification from OSHA regarding the use of the NeedleguardTM in a hospital environment.

Issue: [PDMP, Inc.] has developed a product, Needleguard™, which uses a method of disabling the needle of a luer-type syringe after use. The Needleguard™ is a portable encapsulation device designed to permanently adhere the luer lock and bottom hub of the syringe into a sheath after the healthcare provider has used the syringe on a patient. [PDMP, Inc.] has been asked by the Food and Drug Administration's Center for Devices and Radiological Health (FDA/CDRH) to get an opinion from OSHA regarding the use of the Needleguard™ in a hospital environment.

Response: The information you provided us described the Needleguard™ as "a self-contained sharps disposal device that permanently and fully encloses, by encapsulation, the needle of a luer-type syringe." The bloodborne pathogens standard establishes several requirements for containers used for discarding contaminated sharps. The standard requires that such containers be (1) closable, (2) puncture-resistant, (3) leak proof on sides and bottom, and (4) labeled or color-coded [29 CFR 1910.1030(d)(4)(iii)]. If the Needleguard™ meets this definition, then, like other sharps disposal containers, this device is proper sharps container. Because the Needleguard™ is intended to eliminate the needle after use, it may be beneficial in reducing or eliminating exposure to downstream workers. However, it provides no protection to an employee after contamination with blood or other potentially infectious materials (OPIM) and prior to placing the needle in the device. This is where employee exposure occurs.

In hospitals and other healthcare facilities where medications are administered using syringes, devices are currently available that will reduce exposures prior to the point of disposal. OSHA has previously responded to a substantially similar question regarding another product (Letter to George Salem, September, 2002). In that response, OSHA stated: "*Where feasible, the most effective way of removing the hazard of a contaminated needle is to eliminate the needle altogether by converting to needleless systems. In other situations, the hazard can be reduced through using a sharp with engineered sharps injury protection (SESIP), which isolates the sharp from the healthcare worker as it is withdrawn from the patient." Additionally, OSHA has previously stated that, "the most effective way of removing the hazard of a contaminated needle is to eliminate the needle completely by converting to needleless systems. If this is not possible, removal of the hazard as soon as possible after contamination is required. This is best accomplished by using a sharp with engineered sharps injury protection (SESIP)*" (Letter of Interpretation to Congressman LaTourette, June 27, 2001).

To comply with 29 CFR 1910.1030, an employer must evaluate, select and ensure use of engineering and work practice controls that will "eliminate or minimize employee exposure" [29 CFR 1910.1030(d)(2)(i)] and employers must solicit input from non-managerial employees in the selection process [29 CFR 1910.1030(c)(1)(iv)-(v)]. In previous interpretation letters OSHA stated the use of SESIPs provided a first line of defense against needlesticks. As such, Needleguard™ may be most appropriate for clinical procedures where SESIPs are either not feasible or not commercially

available (for example, certain procedures in pediatrics, dermatology, or the administration of certain allergy medications).

09/01/2004 - Limiting factors for implementing the use of engineering controls, i.e., safety scalpels, under the Bloodborne Pathogens standard.

Question 1: Do healthcare facilities need to use reengineered safety scalpels to be in compliance with the bloodborne pathogens regulations, or can they simply evaluate?

Reply 1: OSHA's bloodborne pathogens standard at 29 CFR 1910.1030(c)(1)(iv) requires employers to evaluate safer medical devices to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Employers must solicit input from non-managerial employees in the selection process [29 CFR 1910.1030(c)(1)(v)]. Engineering controls, including safety scalpels, must be implemented where their use is feasible [29 CFR 1910.1030(d)(2)(i)].

Question 2: If not, under what circumstances may they choose not to employ safety scalpels?

Reply 2: OSHA recognizes that no one medical device is appropriate for use in all circumstances and that it is important to safeguard both patients and employees during medical and surgical procedures. If the use of a particular engineering control, in this case a safety scalpel, compromises patient safety, its use would not be considered feasible. The employer, therefore, must determine what engineering and work practice controls effectively minimize hazards without unduly interfering with medical procedures. The standard also recognizes that market availability is another limiting factor in implementing the use of engineering controls and must be considered in both your choice of an engineering control and our enforcement of their use [29 CFR 1910.1030(c)(1)(iv)(B)]. However, please be aware, where exposures have been determined and where engineering controls are commercially available and feasible, they must be used.

Additionally, the bloodborne pathogens standard requires that employers "*document annually [their] consideration and implementation of appropriate commercially available and effective safer medical devices...*" [29 CFR 1910.1030(c)(1)(iv)(B)]. OSHA compliance officers have issued citations to employers at facilities where the Exposure Control Plan (ECP) did not contain such documentation. It is required, therefore, that a site choosing not to employ safety scalpels, specifically address the non-use of a safety scalpel in its ECP.

Question 3: If surgeons don't "like the new safety scalpels as well as the traditional designs," but the surgeons don't demonstrate that the newer designs would result in a negative patient outcome, is it then permissible not to use the reengineered safety scalpel devices?

Reply 3: Please see Reply #2.

Question 4: Are there definitive guidelines regarding safety scalpels listed within any of the OSHA websites?

Reply 4: While OSHA's website does not have specific guidelines regarding safety scalpels, OSHA maintains a safety and health topics page dedicated to bloodborne pathogens and needlestick prevention located at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

Question 5: What is the cost of non-compliance? Is there a schedule?

Reply 5: Section 17 of the Occupational Safety and Health Act, 29 USC §666, outlines the prescribed civil penalties and factors for consideration in the assessment of each violation cited by the agency. A willful or repeated violation may result in a penalty of up to $70,000; there is a minimum penalty of $5,000 for willful violations. Serious violations (where there is a substantial probability of death or serious physical harm) require a penalty of up to $7,000. Other-than-serious violations may result in a penalty of up to $7,000. If an employer fails to abate a violation set forth in a citation which has become a final order, the employer may be assessed a penalty of up to $7,000 for each day during which the violation continues.

01/12/2006 - Employer's obligation to assure the accuracy of the sharps injury log.

Question 1: Is there an obligation for employers to assure the accuracy and meaningfulness of the information that is reported on a facility's sharps injury log?

Response 1: The purpose of the log, which is required by paragraph (h)(5) of the standard, is to aid in the evaluation of devices being used in the workplace and to quickly identify problem areas in the facility. The standard implicitly requires that the information be accurate. Furthermore, any person who makes any false statement in any document required to be maintained under the Occupational Safety and Health Act of 1970 may be punished by fine or imprisonment [29 U.S.C. §666(g)].

Employers must include the type and brand of device involved in the incident, the department or work area where the exposure incident occurred and an explanation of how the incident occurred so that the intended evaluation of risk and device effectiveness can be accomplished. Complete information regarding the type and brand of the device is crucial; this is especially true for the proper documentation of device evaluations required by paragraph (c)(1)(iv) of the standard. Entries on the sharps log need to be complete enough for evaluators to determine accurately which particular product was actually being used when the incidents occurred. Because manufacturers frequently have several product lines, the log entries for "brand" must include, in addition to the manufacturer's name, the specific product in order to accurately describe which particular device was being used. In fact, in many cases, if only the manufacturer's name were entered on the log, it would be difficult to know exactly which device was being used. As stated in OSHA's compliance directive, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*, CPL 02-02-069, XIII.H.3, employers are encouraged to write as much information as is necessary to aid in the evaluation of problem areas; however, the confidentiality of the injured employee must be maintained throughout the process. Employers may include information in addition to that which is required by the standard, but may not include information that would identify the employee involved in the incident. However, for incidents, such as a housekeeper being stuck through a trash bag, where determining the type and brand of the device would increase the potential for additional exposure, the type/brand may be recorded as "Unknown" [CPL 02-02-069, XIII.H.3].

Question 2: Is the employer required to include an analysis of the data contained on the "sharps injury log" as part of the annual review of the facility's Exposure Control Plan? Should this information be presented so as to indicate whether one or more specific area(s) or issue(s) require action in order to reduce the incidence of sharps injury?

Response 2: Although an analysis of the log required by (h)(5) is not mandated, a review of the sharps log can be very instrumental in identifying the causes of exposure incidents and serve as a valuable tool for reducing future sharps injuries. It may also indicate where further training is needed and identify ineffective devices which may need replacement. As stated in the response to Question #1, the purpose of the sharps injury log is to aid in the evaluation of devices and in the identification of problem areas in the facility. Therefore, OSHA recommends that the log be reviewed periodically

and as part of the annual review and update of the exposure control plan. As you know, employers are required to review and update the exposure control plan at least annually **and** whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure [29 CFR 1910.1030(c)(1)(iv)]. Employers are additionally required to annually document their consideration and implementation of appropriate commercially available and effective safer medical devices [29 CFR 1910.1030(c)(1)(iv)(B)]. They are also required to document exposure incidents [29 CFR 1910.1030(f)(3)(i) and (ii)].

Question 3: Employers are required in their annual review of the exposure control plan to reflect changes in technology and document annual consideration and implementation of commercially available and effective safer medical devices. Should this review include reconsideration of technologies not currently selected even if they are not new, especially if there are indications from the analysis of the sharps injury log that currently used products may not be sufficiently effective?

Response 3: There is no requirement under (c)(1)(iv) to reconsider already considered medical devices. Please keep in mind that it is common for facilities to observe a slight initial increase in injuries after the selection and implementation of a new device. Additional training is often needed when staff attempts to become familiar with a newly selected device. Any analysis of the sharps injury log should take these factors into consideration in arriving at a conclusion about the effectiveness of a newer device. However, if an analysis of the sharps injury log identifies a particular selected engineering device as the root cause of injuries (i.e., as opposed to work practices, employee training, or other issues), then the employer may choose to include one or more of the previously evaluated devices in the annual re-evaluation to determine if a better selection can be made.

Question 4: Employers are required to solicit input from non-managerial employees responsible for direct patient care. Is a simple open request for input adequate, even if none is received or does this require a serious study of user observations, opinions and testing of currently used and alternative devices?

Response 4: A simple open request for input is adequate. The employer must solicit employee input in a manner appropriate to the circumstances in the workplace. Methods for soliciting employee input may include joint labor-management safety committees; involvement in informal problem-solving groups; participation in safety meetings and audits, employee surveys, worksite inspections, or exposure incident investigations; using a suggestion box or other effective methods for obtaining written employee comments; and participation in the evaluation of devices through pilot testing. The opportunities for employee input shall be effectively communicated to employees [CPL 02-02-069, XIII.C.6]. The failure of employees to provide input is not in itself a violation of the standard. No studies are required under this provision.

Question 5: Does the maintenance of the sharps injury log relieve a hospital of the requirement to report sharps injuries under the FDA's Medical Device Reporting requirements, and in accordance

with the Food and Drug Administration's (FDA's) *Needlesticks: Medical Device Reporting Guidance for User Facilities, Manufacturers, and Importers*?

Response 5: No, the requirement under OSHA's bloodborne pathogens standard, 29 CFR 1910.1030(h)(5)(i), does not exempt healthcare employers from having to report deaths and serious injuries related to medical devices to the FDA. The FDA's Medical Device Reporting (MDR) regulation, 21 CFR Part 803, is a separate and independent set of requirements under which facilities using medical devices must report such information to the FDA and/or the device manufacturers. The FDA has specific forms that must be completed and submitted for incidental and annual reporting. You may wish to contact the FDA directly for specific guidance on the information that must be included on the MDR forms.

02/07/2007 - Documentation of employees' hepatitis B vaccin-ation status.

Scenario: It is very common for employees new to our company to have already received the HBV vaccination series while working with a previous employer. Some employees who have been previously vaccinated do not have copies of the vaccination records indicating the exact dates of vaccination.

Question 1: What type of record is sufficient to document an employee's hepatitis B immunization status under the bloodborne pathogens standard?

Reply 1: As you may know, employers are required to maintain an accurate copy of each employee's hepatitis B vaccination status, including the dates of all the hepatitis B vaccinations [29 CFR 1910.1030(h)(1)(ii)(B)]. The documentation of vaccination status serves as a useful tool in assisting healthcare professionals who must administer post-exposure counseling and treatment to employees following an exposure incident. Documentation showing administration of the complete 3-dose series is necessary to prevent unnecessary repeated vaccination. The Centers for Disease Control and Prevention (CDC) considers a reliable vaccination history to be a written, dated record of each dose of a complete series. 1 Employers must make every effort to obtain a reliable record of employees' vaccination status. These efforts may include contacting the previous employer or facility where the vaccination was administered to obtain these records. As it is a requirement that all employers maintain these records for the duration of employment plus 30 years, a previous employer who administered hepatitis B vaccinations would have copies of those records [29 CFR 1910.1030(h)(1)(iv)]. If a copy of the vaccination record cannot be obtained, then OSHA recommends that documentation verifying the employer's attempt to obtain the record be maintained. When these records cannot be obtained from the previous employer, the current employer must obtain from the employee a written statement about vaccination status, including the dates or, where this is not possible, the approximate dates of the vaccinations.

Question 2: If an employer is unable to obtain copies of the actual records verifying an employee's HBV vaccination, is it required that employers provide a blood test to document hepatitis B immune status?

Reply 2: No, it is not required that an employer administer serologic testing in order to document previous hepatitis B vaccination from another place of employment for employees who claim to have received the vaccination prior to beginning a new job. In fact, the standard prohibits making participation in a prescreening program a prerequisite for receiving hepatitis B vaccination [29 CFR 1910.1030(f)(2)(ii)]. When the employer cannot obtain records or employees are uncertain about whether they were vaccinated, the hepatitis B vaccine must be made available, unless previous antibody testing has revealed that the employee is immune or the vaccine is contraindicated for medical reasons [29 CFR 1910.1030(f)(2)(i)]. Vaccination of persons who have previously been vaccinated does not increase the risk for adverse events

03/02/2007 - Requirements for safety-engineered sharps for stock-piled pandemic influenza vaccines and pre-filled syringes.

Question 1: Many state and local public health officials, as well as hospital administrators and purchasers, are beginning to mobilize to procure supplies and relevant resources, such as medical devices, that will be needed to immunize the public in the event of an influenza pandemic. When stockpiling syringes for pandemic influenza vaccination and treatment, are healthcare facilities and public health practitioners required to procure safety-engineered sharps in adherence with the OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030)?

Reply 1: As you may know, state and municipal public health officials do not fall under the jurisdiction of federal OSHA. States and municipal employers in states with OSHA state plans must comply with state bloodborne pathogens standards (generally the same as the federal standard.) Hospitals and others over whom federal OSHA does maintain regulatory authority must comply with 29 CFR 1910.1030, the federal bloodborne pathogens standard. Also, outside of OSHA state plan states, state and local public hospitals receiving Medicare payments must comply with the federal bloodborne pathogens standard as a condition of their agreements with Medicare [42 USC §1395 cc(a)(1)(V)]. The standard at 29 CFR 1910.1030 applies whenever there are employees with occupational exposure to blood or other potentially infectious materials (OPIM). Using needles and syringes for vaccination is one way that employees may become exposed to blood, specifically through a needlestick from a used needle.

As you may know, the Department of Health and Human Services (DHHS) has been assigned the responsibility for developing a national stockpile of vaccine for influenza strains with pandemic potential and to expedite the rapid development, licensure, and production of new influenza vaccines.[1] DHHS recommends that each state develop a plan for receiving and managing the storage and distribution of supplies from the Strategic National Stockpile (SNS). Additionally, DHHS recommends that during the pre-pandemic phase, healthcare facilities work with state and local health departments on plans for distributing pandemic influenza vaccine.[2] It is recommended that health care administrators with the responsibility of preparing for pandemic influenza keep abreast of updates to the recommendations from the DHHS. Healthcare facilities may need to stockpile a wide range of medical supplies, including syringes, when preparing for possible disruptions in delivery service. It is a requirement of OSHA's bloodborne pathogens standard that employers, who have employees exposed to blood and/or OPIM, evaluate, select, and use engineering controls (e.g., sharps with engineered sharp injury protections, SESIPs) to eliminate or minimize exposure [29 CFR 1910.1030(c)(1)(v) and 1910.1030(d)(2)(i)]. It is advisable for healthcare facilities to anticipate their needs for specific consumable and durable medical supplies, including safety syringes and to develop a plan for stockpiling.

Question 2: A possibility exists that some portion of the pandemic influenza vaccine will be

packaged in pre-filled syringes. Historically, vaccines and other curatives and therapeutics packaged in pre-filled syringes have not been accompanied (or prepackaged) with safety-engineered needles. If pandemic influenza vaccine is packaged in a pre-filled syringe, will those employers administering the vaccine be required to purchase safety needles to attach to those pre-filled syringes per paragraph [1910.130(d)(2)(i)] of the OSHA Bloodborne Pathogen Standard?

Reply 2: As you stated, it has been the practice for a variety of vaccines to be made available in pre-filled syringes, many of which are not equipped with safety devices. 29 CFR 1910.1030(d)(2)(i) requires employers to make available safety devices for use by employees who are exposed to blood or OPIM. It is uncertain exactly how the occurrence of a pandemic influenza situation will impact the healthcare community and the market availability of safety syringes. However, where safety-engineered equipment, such as add-on safety devices, is commercially available, employers are expected to implement their use to prevent needlestick incidents. Furthermore, we are unaware of any technical reasons that would prevent the use of safety-engineered needles for pre-filled syringes at this time.

01/02/2008 - Applicability of OSHA's bloodborne pathogens standard to the containment and disposal of electric razors in correctional facilities and health care settings.

OSHA's bloodborne pathogens standard has provisions for the protection of employees during the containment, storage and transport of contaminated sharps and other regulated waste [29 CFR 1910.1030(d)(4)(iii)(A)-1910.1030(d)(4)(iii)(B)]. In general, sharps containers used for discarding disposable razors used for shaving in nursing homes, healthcare or correctional facilities must be: *(i) Closable; (ii) Puncture resistant; (iii) Leakproof on sides and bottom; and, (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i).* It is also required that designated sharps containers be: *Replaced routinely and not be allowed to overfill* [1910.1030(d)(4)(iii)(A)(2)(iii)]. OSHA's bloodborne pathogens standard states: *Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories* [CFR 29 1910.1030(d)(4)(iii)(C)]. Thus, healthcare settings, nursing care, and correctional facilities must comply with any of these state regulations that describe specific policies regarding the final disposition of used razors. This issue has been previously addressed by OSHA in a letter of interpretation (Mr. Frank A. White, March 28, 2005). A copy of the letter is enclosed for your information.

However, electric shavers are generally not considered disposable and usually are less likely to create a potential for cuts/lacerations that lead to them becoming contaminated. The containment requirements of the bloodborne pathogens standard applies to "contaminated" sharps and would be applicable to electric shavers only if they become contaminated with blood or other potentially infectious materials (OPIM).

06/02/2009 - Disposal of blood and other potentially infectious materials (OPIM).

Question 1: What are the policies for disposal of blood/body fluids and infectious waste? Is blood treated differently than other body fluids?

Reply 1: The final disposal of all regulated waste must be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories [29 CFR 1910.1030(d)(4)(iii)(C)].

OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030, has provisions for the protection of employees during the containment, storage, and transport of regulated waste other than contaminated sharps [29 CFR 1910.1030(d)(4)(iii)(B)]. The bloodborne pathogens standard defines regulated waste as liquid or semi-liquid blood or other potentially infectious material (OPIM); contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIM [29 CFR 1910.1030(b)].

In general, regulated wastes, other than contaminated sharps, must be placed in containers which are: *(i) Closable; (ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping; (iii) Labeled or color-coded in accordance with paragraphs (g)(1)(i); (iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping* [29 CFR 1910.1030(d)(4)(iii)(B)(1)(i)-(iv)].

Question 2: Is it acceptable to dispose of items that have blood or body fluids present in either septic systems or normal garbage? If so, how much blood and body fluids can be present?

Reply 2: Please see our reply to question #1 for OSHA's definition and requirements for containerization of regulated waste as well as information on the requirements for final disposal of regulated waste. It is the employer's responsibility to determine the existence of regulated waste. This determination is not based on actual volume of blood, but rather on the potential to release blood, (e.g., when compacted in the waste container).

Question 3: What are the repercussions when addressing facilities where violations have been found on improper disposal, and what are the common disposal-related violations found during OSHA inspections?

Reply 3: When OSHA conducts an inspection addressing regulated waste concerns, compliance with the Bloodborne Pathogens Standard is evaluated on a case-by-case basis. If OSHA determines that sufficient evidence exists that the standard has been violated, a citation carrying monetary penalties may be issued to the employer. Over the past 5 years, OSHA has issued numerous

violations for improper containerization of regulated waste [i.e., violations of section 1910.1030(d)(4)(iii)(B)(1) of the Bloodborne Pathogens Standard].

Question 4: Are there different guidelines for body fluid disposals with clinics versus hospitals?

Reply 4: Employers in clinics and hospitals must comply with the Bloodborne Pathogens Standard. Employers must evaluate their individual workplaces and institute measures to eliminate or minimize employee exposure to blood or OPIM based on the unique set of scenarios or tasks in the facility. An exposure control plan is the employer's written program which is required to outline the protective measures taken.

11/24/2008 - OSHA's position on the use of Novartis' Fluvirin® device.

The Occupational Safety and Health Administration (OSHA) has been made aware of a recent issue regarding nationwide dissemination of Novartis' Fluvirin® Suspension for Intramuscular Injection 2008-2009 Formula (NDC #66521-111-01) in pre-filled injection syringes with permanently affixed, unprotected needles. We understand that Novartis has been made aware of the occupational health hazard that these devices present and that the company has been working with Cal/OSHA and public health officials in the state of California to address the issue. We would like to inform Novartis that this issue is also of great concern to Federal OSHA and request your cooperation in addressing the matter in other affected states.

OSHA estimates that 5.6 million workers in the health care industry and related occupations are at risk of occupational exposure to bloodborne pathogens, including human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), and others. Needlestick injuries pose one of the greatest risks of bloodborne pathogens exposure in healthcare. OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030 requires that employers who have employees with reasonably anticipated exposure to blood and/or other potentially infectious materials (OPIM) evaluate, select, and use engineering controls (e.g., sharps with engineered sharp injury protections (SESIPs)) to eliminate or minimize exposure [29 CFR 1910.1030(b), 29 CFR 1910.1030(c)(1)(v), and 1910.1030(d)(2)(i)]. This applies to the pre-filled injection devices for influenza vaccine or other vaccines.

Federal OSHA has been notified that Cal/OSHA has made a notification to the public health community in California by placing a notice of this issue on their website. Federal OSHA is preparing to place a similar notification on the OSHA website. The use of the Fluvirin® device with an affixed, unprotected needle violates the requirement of 29 CFR 1910.1030(d)(2)(i) to use engineering controls. OSHA is aware that Novartis markets the vaccine in pre-filler syringes with a "luer" lock connection which allows employers to make the selection of a SESIP to use for injections and that the company has agreed to replace the unprotected devices disseminated in the state of California. As in California, we are requesting that Novartis does the same in other states where the pre-filled devices with affixed needles have been shipped.

10/04/2000 - Responsibility for cleaning/preventing exposure to contaminated emergency medical equipment.

According to the scenario illustrated in your letter, a fire or rescue service ("first responder") responds to emergency situations using their equipment to transport and treat patients while en route to a healthcare facility. The hospital or other healthcare facility then removes the patient from the used, contaminated equipment provided by the first responders and proceeds to use its own equipment and medical devices. The facility leaves the equipment used and contaminated for the first responders to pick up and clean.

Your question is: "who is responsible for cleaning this equipment?"

Simply, it is *every* employer's responsibility to ensure a safe and healthful workplace for its employees. More specifically, according to the Bloodborne Pathogens Standard, each employer with employees who may have an occupational exposure to blood or other potentially infectious materials (OPIM) is responsible for eliminating or reducing the potential hazard. In this case, where equipment is shared between first responders and emergency department or general hospital staff, each employer has responsibilities for protecting employees from exposure to blood or body fluids.

The equipment to which you are referring belongs to the first responders or emergency medical service (EMS) personnel and is to be returned to them for reuse. If a hospital places such equipment, contaminated, in the hallways or in closets awaiting pickup, it is exposing its employees and anyone in the area to potential bloodborne pathogens.

According to paragraph (d)(4)(i) of the standard, "*(e)mployers shall ensure that (the) worksite is maintained in a clean and sanitary condition."* Paragraph (d)(4)(ii) provides that *"all equipment and environmental and working surfaces shall be cleaned and decontaminated* ***after contact*** *with blood or other potentially infectious materials* [emphasis added]." Additionally, "*(c)ontaminated work surfaces shall be decontaminated with an appropriate disinfectant* ***after completion of procedures; immediately or as soon as feasible*** *when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials;* ***and at the end of the work shift*** *if the surface may have become contaminated since the last cleaning."*

OSHA would regard a hospital as having met its obligations with respect to its own employees either by cleaning and decontaminating the equipment in accordance with (d)(4)(i) of the standard, or, alternatively, by preventing employee contact with such equipment by placing it in durable, leakproof, and labeled or color-coded containers and handling it in a manner similar to that prescribed for contaminated laundry [paragraph 1910.1030(d)(4)(iv)] and contaminated laboratory equipment [paragraph 1910.1030(e)(2)(ii)(B)]. The first responders' employer must then ensure that its employees take proper precautions when retrieving and decontaminating the equipment. The Centers for Disease Control and Prevention (CDC) indicate, in their *Infection Control Practices*, that communication between two parties with regard to handling and decontamination of supplies and materials is of the utmost importance.

09/12/2002 - Needle destruction device use as an engineering control for the Bloodbore Pathogens standard.

Issue #1: ***OSHA inspectors continue to be advised that needle destruction devices (NDDs) are "not compliant" with the Bloodborne Pathogens Standard.***

OSHA Response #1: The standard defines engineering controls as ***"…controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protection and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace."*** A device that reduces the risk to employees by destroying contaminated needles is clearly a type of engineering control, and OSHA's field staff have been so advised.

To comply with the standard, an employer must use engineering and work practice controls that will ***"eliminate or minimize employee exposure"*** (Sec. 1910.1030(d)(2)(i)). OSHA's compliance directive explains that under this requirement ***"the employer must use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent"*** (OSHA CPL 2-2.69 §XIII, D.2.). The employer's exposure control plan is to describe the method the employer will use to meet the regulatory requirement. The plan must be reviewed and updated at least annually to reflect changes in technology that will eliminate or reduce exposure (Sec.1910.1030(c)(1)(iv)).

An NDD may be included as a component of an employer's exposure control plan to the extent it assists the employer in minimizing exposures. Use of an NDD alone will not be sufficient to meet the standard's requirements, however it is appropriate where use of a different or an additional control will reduce exposure to a lower level. In this connection, we note that a Needle Destruction Device, like a sharps disposal container, is an engineering control for the point of disposal. Because an NDD is intended to eliminate the needle after use, it may be beneficial in reducing or eliminating exposure to downstream workers. On the other hand, an NDD provides no protection while an employee is using the needle or prior to placing the needle in the device. This is where much of the employee exposure occurs. For example, according to data from EPINet at the International Health Care Worker Safety Center at the University of Virginia (which you provided in your letter of May 23, 2002), most injuries from contaminated sharps occur during use (32%), between steps (13%), during other activity after use, before disposal (18%), and when putting the item into a disposal container (7%). Approximately 90% of the injuries documented occurred while using a needle without a safety feature.

In many situations, devices are available that will reduce exposures prior to the point of disposal. Where feasible, the most effective way of removing the hazard of a contaminated needle is to eliminate the needle altogether by converting to needleless systems. In other situations, the hazard can be reduced through using a sharp with engineered sharps injury protection (SESIP), which isolates the sharp from the healthcare worker as it is withdrawn from the patient. Congress recognized the value of needleless systems and SESIPs by enacting the Needlestick Safety and Prevention Act (NSPA), P.L. 106-430, 114 Stat. 1901, which amended the bloodborne pathogen standard to include and define these terms. Section 2(7) of NSPA provides that ***"…the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury***

protection, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries."

The distinction between NDDs, on the one hand, and SESIPs and needleless systems, on the other hand has been recognized by Federal OSHA, the State of California Department of Industrial Relations, and the Food and Drug Administration (FDA):
OSHA has stated previously, ***"the most effective way of removing the hazard of a contaminated needle is to eliminate the needle completely by converting to needleless systems. If this is not possible, removal of the hazard as soon as possible after contamination is required. This is best accomplished by using a sharp with engineered sharps injury protection (SESIP)"*** (Letter of Interpretation to Congressman LaTourette, June 27, 2001).

Further, Cal/OSHA, in its response to a petition submitted by BioMedical for its SharpX device ***(Cal/OSHA, Petition File No. 416, September 11, 2000)***, states, ***"other than possibly reducing needlestick injuries during disposal related to their use or failure, alternative disposal technologies [needle destruction devices] no more provide protection from contaminated needlestick injuries at 'the point of use' than do traditional sharps boxes."***

The FDA puts NDDs into the same family of protection as sharps containers. They ***"place sharps needle destruction devices in Class III because the technological characteristics of the sharps needle destruction devices raise new types of safety and effectiveness questions when compared to conventional sharps disposal containers. (Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA, March 2001)."*** The FDA also states that a label on an NDD may claim, ***"the device (NDD) serves as an alternative to or as an effective substitute for conventional sharps containers for disposal of contaminated sharps needles, if data demonstrate that the remaining needle nub is no longer a sharp."***

OSHA recognizes that needleless systems and SESIPs are not available for all situations. Moreover, there is a wide variety of devices available, and the device that most effectively reduces exposure can vary with the procedure. Employers must use their judgment in selecting appropriate engineering controls, and under NSPA, must consult with affected nonmanagerial employees [NSPA Sec. 3(4)(B); 29 CFR 1910.1030(c)(1)(v)]. In selecting controls that will eliminate or minimize exposure to its employees, an employer of course must take into account the full range of exposure, including exposure prior to the point of disposal.

The legislative history of NSPA, to which you have referred, is fully consistent with this position. The Joint Statement of Legislative Intent on Substitute to H.R. 5178 states:

To the extent that specific types of devices, such as catheter securement devices or needle destruction devices can reduce the risk of needlestick injuries, such devices could be appropriate components of an employer's comprehensive exposure control plan. Nevertheless, it is impossible for this legislation to recommend any one type of engineering control (106 Cong. Rec. p. H8676 (2000)).

This language does not say that the use of NDDs is always or generally sufficient to bring employers into full compliance with the standard. It only says that to the extent that they reduce the risk of needlestick injuries, they can be appropriate components of an exposure control plan. In this regard, the selection and use of NDDs may be most appropriate for clinical procedures where SESIPS or needleless systems are either not feasible or not commercially available (for example, certain procedures in geriatrics, pediatrics, and orthopaedics). Where NDDs are used, they should be used in accordance with manufacturer's instructions. For example, the SharpX is not meant to be used in potentially explosive environments, or where flammable gases or liquids are stored or used, such as operating rooms and emergency rooms.

Finally, your letter asserts that some SESIPs are ineffective. You refer to an article describing a citation issued by the State of California. There are many types of SESIPs and needleless systems that are commercially available. The standard requires employers to implement the use of SESIPs that do not compromise worker or patient safety or the outcome of the medical procedure. To meet the definition of a SESIP in the standard, a device must have a ***"built-in safety feature or mechanism that effectively reduces the risk of an exposure incident."*** See 1910.1030(b) (emphasis supplied). If a device that causes needlesticks to occur or blood to be emitted has been chosen, the device may not have been an appropriate selection. As noted, the standard requires the employer to use engineering and work practice controls that will eliminate or minimize exposure, and to review the availability of controls at least annually as part of its exposure control plan review. Thus, the California citation alleged that the employer's device did not meet the definition of a SESIP because it did not provide effective protection, and the article describing the citation states that there are many better, safer products on the market (May 23 letter, Tab 8).

Issue #2: ***NDDs must submit product clearance to the FDA at a "level three" approval, which requires clinical data conclusively demonstrating the product's safety and effectiveness. "Level Three" approvals require the most stringent level of testing, and all instructions, marketing materials and labeling must be approved by the FDA. Assuming that OSHA has been given the authority to institute a "hierarchy" of engineering controls, that "hierarchy" should be based on the classification system established by the FDA, the federal agency tasked with determining a medical device's efficacy.***

OSHA Response #2: The FDA, in a 1994 memorandum to manufacturers and initial distributors of sharps containers and destroyers used by health care professionals, stated that ***"if the type of sharps device submitted in (the) 510(k) submission is found to be not substantially equivalent (NSE) to a predicated device, your device will automatically be classified in Class III, in accordance with the requirements of section 513(f) of the Act, thereby requiring the submission of an application for premarket approval (PMA)."*** In short, FDA "Level Three" approval is required because NDDs are newer devices that are not substantially equivalent to a device manufactured before 1976. Level Three approval does not imply that needle destruction

devices afford greater protection against bloodborne pathogens than other engineering controls, such as needleless systems or SESIPs.

Furthermore, the FDA 510(k) Submission Application allows the label for a medical device with sharps injury prevention features to state that it meets the OSHA bloodborne pathogens standard only if permitted by OSHA.

Issue #3: ***OSHA is only permitting Becton Dickinson to explain the use of its engineering controls; BioMed and other NDD manufacturers formally request the same opportunity.***

OSHA Response #3: As we stated in our May 2002 meeting with you, we welcome BioMed or any other medical device manufacturer to educate our staff on the use of its products. We have never restricted a manufacturer of a safety product from doing so. We welcome the opportunity for our staff to meet with device manufacturers and have had the pleasure of meeting with several companies that offer several different types of medical devices, personal protective equipment, training materials, and the like.

Issue #4: ***OSHA is apparently advising employers that OSHA is in the process of compiling a "report" concerning NDDs.***

OSHA Response #4: OSHA is not compiling a report on NDDs or any other engineering control.

In conclusion, OSHA continues to categorize NDDs, and conventional sharps containers, as engineering controls for the disposal of contaminated needles. NDDs are currently designed to be used only with standard syringes that present the risk of exposure during use and prior to disposal. The use of an NDD alone, therefore, will not be sufficient to meet the standard's requirements where a different or an additional control, such as a needleless system or a SESIP appropriate for the procedure, is commercially available and feasible and will reduce exposure to a lower level.

12/09/2004 - Needle removal procedures for situations where other methods of disposal are infeasible or required by a specific procedure.

Scenario: The FDA has recently approved a new osteoporosis drug, Forteo®, which is being prescribed for use in long term care facilities. The drug is currently only available in a pen-type syringe, which is attached to an unprotected needle prior to administration. This pre-filled pen contains multiple doses and may be administered for up to 28 days after the first injection. As there is currently no other way a patient may be injected with Forteo®, the practice in long term care facilities is to remove the used needle after administration of this drug, either by recapping and removing the needle manually, or by using a sharps container equipped with a mechanical unwinding device. The pre-filled pen is then recapped and refrigerated for future use.

Question: How does this current practice affect a facility's compliance with the requirements of OSHA's bloodborne pathogens standard?

Reply: OSHA's bloodborne pathogens standard prohibits the bending, recapping or removal of a contaminated needle or other contaminated sharp [29 CFR 1910.1030(d)(2)(vii)(A)]. The standard also provides an exception where an *"employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure. Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique*" [29 CFR 1910.1030(d)(2)(vii)(B)]. The preamble to the bloodborne pathogens standard notes that the administration of incremental doses of a medication is one medical procedure, among others, to which this exception refers [56 *FR* 64118 (1991)].

In the scenario you described, patients are required to be injected with medication that is not commercially available in a device with a safety engineered sharp injury protection (SESIP) system. Also, as we understand, the drug itself is not available in any other format, meaning Forteo® is not presently available from the manufacturer in a liquid format which could be drawn (like other drugs/medications) from a vial into a safety engineered (SESIP) syringe. OSHA interprets this to mean that under special circumstances where, for example, "SESIP" use is not technically feasible and the medical procedure requires the removal of a contaminated sharp, the use of a mechanical device (e.g., sharps container with an unwinder) would be allowed. Thus, under these circumstances, the needle used to administer Forteo® may be removed by a mechanical device, such as a sharps container with an unwinder, or a one-handed technique. An explanation for the medical need for needle removal must be documented in the employer's Exposure Control Plan [29 CFR 1910.1030(d)(1)(ii)(B)].

In order to limit the practice of removing contaminated needles and lessen the likelihood of employees suffering needlestick injuries, employers must train employees on the purpose of the mechanical needle removal device and ensure that it is only available for use in extreme circumstances like the use with the Forteo® Pen [29 CFR 1910.1030(g)(2)(vii)(F)]. Each employer is

responsible for ensuring that employees do not utilize needle removal procedures for situations where other methods of disposal are feasible or where SESIPs are commercially available and appropriate for use.

09/06/2005 - Applicability of the bloodborne pathogens standard to persons who self-administer injectable medications.

Question 1: Does the Needlestick Safety and Prevention Act (NSPA) apply to persons who self-administer injections at home, in their workplaces and/or in other non-medical public settings?

Response: No. Congress passed the NSPA in part to clarify the requirements under the OSHA bloodborne pathogens standard to use safer medical devices to prevent or minimize needlesticks and other sharps injuries in workplaces. See 29 CFR 1910.1030(b) (definitions of "engineering controls" and "sharps with engineered sharps injury protections") and 1910.1030(d)(2)(i) (requirement to use engineering controls). As you know, OSHA is limited to covering employers in Federal agency and private-sector places of employment (29 USC §652, 654, 668). Consumers who self-administer injections are not covered by the OSHA bloodborne pathogens standard.

Question 2: Does the requirement in 29 CFR 1910.1030(d)(2)(vii)(B), regarding one-handed recapping of needles, apply to patients who administer their own injections?

Response: No. Please see the response to Question #1.

Question 3: Do disposal procedures outlined in OSHA's bloodborne pathogens standard, such as the use of sharps containers or regulated waste bags, apply to self-injectors? What other OSHA guidelines, recommendations, specifications, or regulations are there for the disposal of used syringes in the community [i.e., at a user's home, workplace, or other non-medical public setting]?

Response: The disposal requirements at 29 CFR 1910.1030(d)(4)(iii)(A) do not apply to the disposal of needles by self-injectors in private homes. Employers whose employees are exposed to self-injected needles, such as nursing homes, are obligated to comply with these requirements. However, more than half the states in the country have developed their own public health laws addressing safe disposal of syringes used by individuals in the community. Links to the states which regulate home used syringes and other useful information on safe community needle disposal are available on the Centers for Disease Control and Prevention's (CDC's) website at http://www.cdc.gov/needledisposal/. Additionally, you may also obtain guidance from various documents published by the U.S. Environmental Protection Agency (EPA), which are available at http://www.epa.gov.

OSHA has previously written several documents addressing discarded insulin syringes as they relate to the potential for exposure to workers. Examples of these documents include the following: 1) letters of interpretation written to address exposure to needles in the solid waste industry (Hoffman, 1/2/2003; Hoffman, 5/28/2003); 2) other letters of interpretation addressing discarded insulin syringes (Ault,3/23/2001; McCaffrey, 5/28/1992); and 3) Frequently Asked Questions (FAQ) publications (Most Frequently Asked Questions Concerning the Bloodborne Pathogens Standard,

2/01/1993; Compliance Links Additional Bloodborne Pathogens FAQ). We have included copies of these documents for your information. These and other documents regarding OSHA policies are publicly available on OSHA's website.

12/22/2005 - Use of passing trays and single-handed scalpel blade remover in a surgical setting.

Question 1: In situations where a surgeon chooses to use a scalpel with a reusable metal handle, from which the used blade is removed, instead of a plastic disposable scalpel, would the use of a single-handed scalpel blade remover meet the requirements of OSHA's bloodborne pathogens standard (29 CFR 1910.1030)?

Reply 1: As you know, OSHA's bloodborne pathogens standard at 29 CFR 1910.1030(c)(1)(iv)(B) requires employers to first evaluate the efficacy of the use of safer medical devices as a means of meeting their responsibility under 29 CFR 1910.1030(d)(2)(i) to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Surgical practitioners must base their evaluation and selection of scalpels and other medical sharps on the impact a device will have on achieving the necessary balance between employee safety and the delivery of optimal healthcare to patients. If appropriate commercially available and effective safety scalpels are feasible for a particular procedure and do not compromise patient safety, then the surgeon must use them. However, if the use of a safety engineered scalpel compromises patient safety or is in some other way infeasible for use in a particular procedure, the employer must then determine what other engineering and work practice controls would effectively minimize employee exposure and implement their use.

In general, the bending, recapping or removal of a contaminated needle or other contaminated sharp is prohibited. However, the standard provides an exception where an "employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure" [29 CFR 1910.1030(d)(2)(vii)(A)]. In situations where an employer has demonstrated that the use of a scalpel with a reusable handle is required by a specific medical or dental procedure or that no alternative is feasible, the blade removal must be accomplished through the use of a mechanical device or a one-handed technique [29 CFR 1910.1030(d)(2)(vii)(B)]. The use of a single-handed scalpel blade remover meets these criteria.

Question 2: Is it correct that the use of a passing tray is considered to be "standard procedure" in operating rooms in the United States? Is it also considered to comply with OSHA standards?

Reply 2: Yes to both questions. The professional literature reflects that a no-hands-pass procedure, such as the use of a passing tray, is a frequently used work practice control for the prevention of sharps injuries in operating rooms across the United States. It complies with the bloodborne pathogens standard. OSHA's Compliance Directive, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*, CPL 02-02-069 states: "Preventing exposures requires a comprehensive program, including the use of engineering controls (e.g., needless devices, shielded needle devices, and plastic capillary tubes) and proper work practices (e.g., no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room)."

01/17/2008 - Clarification on trainer requirements and access to trainer under OSHA's bloodborne pathogens standard.

Question 1: Does 1910.1030(g)(2)(viii) require that the person conducting bloodborne pathogens training be a health care professional?

Response 1: No. The Bloodborne Pathogens Standard, 29 CFR 1910.1030, does not specify a particular job classification for qualified trainers. 29 CFR 1910.1030(g)(2)(viii) does however require that the trainer be: *knowledgeable in the subject matter covered by the elements contained in the training program. . .* In OSHA's bloodborne pathogens compliance directive (OSHA Instruction CPL 02-02-069), we state: *[p]ossible trainers include a variety of healthcare professionals such as infection control practitioners, nurse practitioners, registered nurses, occupational health professionals, physician's assistants, and emergency medical technicians. Non-healthcare professionals, such as but not limited to, industrial hygienists, epidemiologists, or professional trainers, may conduct the training provided they are knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace. One way, but not the only way, knowledge can be demonstrated is the fact that the person received specialized training.*

Question 2: Does this trainer need to physically be in the classroom or is it acceptable for the trainer to be contacted via phone, e-mail, etc. to answer any questions the students have during internet (electronic) training classes?

Response 2: The standard does not specify that the trainer be "physically" in the classroom while training is being conducted. The training requirements established under 29 CFR 1910.1030(g)(2)(vii)(N) require an employer to allow for an opportunity for interactive questions and answers with the person conducting the training session. Employers use a variety of methods to meet the intent of the standard. As an example, training conducted by compressed digital video (CDV) where the trainer is in one location but is in direct communication with the trainees would provide for an interactive exchange and is an acceptable method for meeting the requirements of the standard. Additionally, OSHA has previously stated that an employer can meet OSHA's requirement for trainees to have direct access to a qualified trainer by providing a telephone hotline. The trainer must be accessible to employees during the time of training. It is important to note, too, that employees must be trained initially **prior to** being placed in positions where occupational exposure to blood or other potentially infectious materials (OPIM) may occur.

During a phone conversation with one of our staff members, you clarified that at your workplace, there may be circumstances where an employee is completing the electronic training session at a time when the designated trainer is not readily accessible and the protocol is for the employee to leave a phone message and wait for a response. You mentioned that staff members working on evening shifts or weekends when the healthcare professional or designated trainer is not on duty would therefore not have the opportunity for interactive discussion with the trainer during the training session. This training scenario would not meet the intent of the standard and would constitute a violation of 1910.1030(g)(2)(vii)(N). Employees must have direct access to a qualified

trainer at the time the training is being conducted. For your information, we have enclosed two previously written letters of interpretation where OSHA addressed questions similar to those raised in your inquiry. [Please see letters to Mr. John Mateus, dated June 26, 2003 and; Ms. Nancy Wicklin, RN, MS, dated January 15, 1999.]

06/26/2003 - Electronic Mail Systems and Bloodborne Pathogens Training requirements.

Scenario: An employer chooses to implement non-classroom employee training programs, such as workbook or on-line programs for employees with reasonably anticipated exposure to blood or other potentially infectious materials (OPIM). With this in mind, please answer the following questions.

Question 1: *If questions are answered in a timely fashion (say in 24 business hours), could the question system be automated via email?*

The training requirements established under 29 CFR 1910.1030(g)(2)(vii)(N) require an employer to allow for an opportunity for interactive questions and answers with the person conducting the training session. Employees must be trained initially prior to being placed in positions where occupational exposure to blood or other potentially infectious materials (OPIM) may occur. Because of the critical importance of information regarding occupational exposure to potentially life-threatening bloodborne pathogens, it is critical that employees have the opportunity to ask questions and receive answers regarding material, which during training may be unfamiliar to them.

In OSHA Instruction [CPL 02-02-069 (formerly CPL 2-2.69)] *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens* (XIII.G.8), the requirement for "interactive" questions and answers has been interpreted to mean that employees must have direct access to a qualified trainer **during** the training session. The use of an electronic mail system to answer employee questions would not be considered direct access to a qualified trainer, unless the trainer is available to answer e-mailed questions **at the time the questions arise**. Frequently, a student may be unable to go further with the training or to understand related training content until a response is received. Failure to provide employees direct access to a qualified trainer would constitute a violation of this paragraph of the standard.

Question 2: *If a student sends an e-mail question as part of his training program and receives an answer 16 hours after completion of the on-line training, is the student officially trained as of the completion of the session or as of receipt of the answer to the question?*

Again, unless e-mailed questions are answered at the time that they are asked, we would not consider the student to be properly trained. This would constitute a violation of 1910.1030(g)(2)(vii)(N).

Question 3: *As a supplement to Question 2, would referral to the site's exposure control coordinator be an acceptable means of satisfying the opportunity for interactive questions and answers with the person conducting the training session?*

Employees must have direct access to a qualified trainer. A referral system does not qualify as direct access, unless the exposure control coordinator is immediately available and is a knowledgeable trainer within the meaning of 29 CFR 1910.1030(g)(2)(viii).

Question 4: *If presented with the two above options and no emailed/verbal questions are received by the employer, can the need for "an opportunity for interactive questions and answers" with the person conducting the training session be considered satisfied?*

No. A qualified trainer must be immediately available to employees regardless of whether questions are actually asked by the employees at the time of their initial and annual training.

01/20/2004 - Employer's responsibility to re-evaluate engineering controls, i.e., safer needle devices, at least annually.

Question: *If an employer has selected a particular safety-engineered device based on employee feedback, and a reduction in needlestick injuries can be shown as a result of the adoption of the current device, to what extent does an employer need to re-evaluate their chosen device?*

Reply: As you are aware, OSHA's bloodborne pathogens standard requires employers to review and update their Exposure Control Plan (ECP) at least annually [29 CFR 1910.1030(c)(1)(iv)]. It is also a requirement that: 1) annual reviews and updates of ECPs reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and 2) employers document annually their consideration and implementation of appropriate commercially available and effective safer medical devices [29 CFR 1910.1030(c)(1)(iv)(A-B)].

If, after employee input, an employer selects an engineering control that is effective in reducing needlestick injuries, it is not necessary to evaluate all newly emerging engineering controls each year. The employer must simply keep abreast of new and emerging technologies and solicit input from non-managerial employees to determine if the facility's chosen device remains preferable to any newly developed products. This should be documented in the ECP.

Since the requirements of the standard are performance-based, OSHA determines compliance with the standard on a facility-by-facility, instance-by-instance basis, based on the employer's consideration of safer medical devices, solicitation of input from employees, documentation in an employer's ECP, and employee interviews.

05/27/2004 - Bloodborne Pathogens Standard application to bifurcated needles; acceptability and appropriateness of safety bifurcated needles.

Question 1: Are employers (facilities administering the smallpox vaccine) required to evaluate commercially available safety bifurcated needles? If so, would they then be required to select and use the safety device deemed to be appropriate and effective?

Response 1: Yes, OSHA's bloodborne pathogens standard requires employers who have employees exposed to blood and/or other potentially infectious materials (OPIM) to annually document consideration and implementation of appropriate commercially available and effective safer medical devices to eliminate or minimize exposure [29 CFR 1910.1030(c)(1)(iv)(B)]. Non-managerial employees who are affected by product selections must participate in the product evaluation process [29 CFR 1910.1030(c)(1)(v)]. After soliciting input from affected non-managerial employees regarding the appropriateness of a particular engineering control, employers must select and use engineering controls (e.g., SESIPs) to eliminate or minimize employee exposure [29 CFR 1910.1030(d)(2)(i)].

Question 2: If employers are required to select and use safety bifurcated needles, is it reasonable and responsible for the federal government to provide a bifurcated needle without safety features in the National Pharmaceutical Stockpile?

Response 2: In an effort to address the appropriateness of available bifurcated needles, the CDC is organizing a research group to evaluate the acceptability and usability of safety bifurcated needles. The study was set to begin in March 2004 and will involve experienced vaccinators from state health departments who will evaluate the available safety devices.

Question 3: How will OSHA communicate to the CDC, and to those responsible for administering the smallpox vaccine, the requirements of the Needlestick Safety and Prevention Act, especially as CDC considers the procurement of additional bifurcated needles in the future?

Response 3: In January 2003, OSHA's Assistant Secretary, Mr. John Henshaw, wrote to the HHS Deputy General Counsel, Stewart Simonson, concerning OSHA's requirement for the use of engineering controls as it applies to the administration of smallpox vaccinations. In this letter, OSHA acknowledged CDC's assessment that the safety bifurcated needle available at that time was "neither appropriate nor effective" and that, "Under these circumstances, your [CDC's] determination that the [safety] device is neither appropriate nor effective for smallpox vaccination is reasonable, and the standard does not require employers to consider using it for that purpose. If, in the future, an improved safety device becomes commercially available, employers will be responsible for evaluating whether that device is appropriate for the work practices of their employees."

The FDA has since given pre-market 510(k) approval of other bifurcated needles with safety engineered features. As noted in response #2, the CDC is organizing a research group to evaluate

the acceptability and usability of the safety bifurcated needles that are currently approved and available.

01/09/2007 - Whether dental anesthetic carpules are considered to be "contaminated sharps" or "regulated waste".

Scenario: Dental carpules are small cylindrical glass tubes containing dental anesthetics which are screwed onto dental syringes and are commonly aspirated while the practitioner injects the patient. In a recent informal review, 500 anesthetic carpules were collected from 16 dentists in order to determine whether these carpules become contaminated with blood following hypodermic injections. It was discovered from this review that 10 (approximately 2%) of the carpules had visible signs of blood inside.

Question 1: Are dental anesthetic carpules considered sharps and must they be disposed of in the sharps container?

Reply 1: As you know, the bloodborne pathogens standard defines "contaminated sharps" as any contaminated object that can penetrate the skin, including but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires [29 CFR 1910.1030(b)]. Pharmaceutical containers, including anesthetics carpules used in dentistry, are generally not considered to be contaminated sharps unless they are broken and can penetrate the skin. Intact anesthetic carpules are not required by OSHA to be discarded in a sharps container.

Question 2: Are dental anesthetic carpules considered regulated waste?

Reply 2: The bloodborne pathogens standard defines regulated waste as liquid or semi-liquid blood or other potentially infectious material (OPIM); contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIM. Dental anesthetic carpules are not usually expected to become contaminated with blood. However, when there is visible blood inside the carpules, they are to be regarded as regulated waste. OSHA requires that the contaminated carpules be placed in containers that are closable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, and color-coded or labeled appropriately and closed prior to removal [29 CFR 1910.1030(d)(4)(iii)(B)]. if contaminated carpules are broken, the sharps container requirements of 29 CFR 1910.1030(d)(4)(iii)(A) would apply to the disposal of any contaminated carpules.

Question 3: If they are not contaminated sharps or other regulated waste, may they be thrown away in the trash?

Reply 3: The ultimate disposal of pharmaceutical vials must be in accordance with municipal, state and federal regulations (e.g., those of the Environmental Protection Agency, EPA). OSHA does not regulate the disposal of medical wastes which are not "regulated waste" within the meaning of the

bloodborne pathogens standard. Product material safety data sheets may provide guidance on proper disposal of anesthetic carpules.

Question 4: If they can be thrown away in the trash, would placing them inside of a plastic container (e.g., milk jug or other empty plastic container) be required, or could they simply be discarded individually?

Reply 4: Please see response #3.

08/09/2007 - Requirements for the construction of trash receptacles used in operating rooms for the containerization of regulated waste.

Question: Does a regulated waste trash receptacle that resides in an operating room need to be covered?

The Bloodborne Pathogens standard, 1910.1030(d)(4)(iii)(B)(*1*), requires regulated waste containers to be ". . . (a) Closable; (b) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping; (c) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and (d) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping." The intent of the term "closable" is to ensure that waste contained within the receptacle is not spilled during the handling and storage of the container. While the container is in use, it is not a requirement that it be closed. However, in between uses and once the container is removed from use (i.e., before transport and during storage), it must be closed.

If the exterior of the container (plastic bag) becomes contaminated, as is possible in a surgical suite, the employer must ensure a secondary containment system is available. This secondary container must also be closable and must prevent spillage during handling and transport [29 CFR 1910.1030(d)(4)(iii)(B)(*2*)].

Additionally, please remember that OSHA does not approve or endorse the use of any specific products and/or their manufacturers and suppliers. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. Thank you for your interest in occupational safety and health. We hope you find this information helpful. This letter constitutes OSHA's interpretation of the requirements discussed.

09/17/2002 - Labeling requirements for packages used to ship blood or OPIM.

Thank you for your March 15 letter to the Occupational Safety and Health Administration (OSHA) regarding the bloodborne pathogens standard, 29 CFR 1910.1030. Specifically, you are looking for confirmation of when the OSHA "BIOHAZARD" label is required on the exterior of a package used to ship blood or other potentially infectious materials (OPIM). This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any scenario not delineated within your original correspondence.

The OSHA bloodborne pathogen standard requires specimens of blood or OPIM to be placed in a container which prevents leakage during collection, handling, processing storage, transport, and/or shipping. This container must be labeled or color-coded according to paragraph 1910.1030(g)(1)(i). Further, according to paragraph 1910.1030(d)(2)(xiii) of the standard, if contamination of the outside of the primary container occurs, or if the specimen could puncture the primary container, the primary container must be placed in a secondary container which is puncture-resistant in addition to having the above characteristics.

Labeling is required on **all** containers used to store, transport, ship, or dispose of blood or other potentially infectious materials, except as noted in paragraphs 1910.1030(g)(1)(i)(F-I) of the standard. For example, if individual containers of blood or OPIM are placed in a larger container during storage, transport, shipment or disposal and that larger container is either labeled with the OSHA "BIOHAZARD" label or color-coded, the individual containers are exempt from the labeling requirement.

OSHA will accept the Department of Transportation's (DOT's) "INFECTIOUS SUBSTANCE" label in lieu of the "BIOHAZARD" label on packages where the DOT requires its label on shipped containers, but will require the BIOHAZARD label where OSHA regulates a material but DOT does not. If the DOT-required label is the only label used on the outside of the transport container, the OSHA-mandated label must be applied to any internal containers containing blood or OPIM. As you know, the BIOHAZARD label is fluorescent orange with lettering and symbols in a contrasting color.

The OSHA BIOHAZARD label is distinct from the black-and-white DOT hazard warning labels; it should not be readily confused or conflict with the DOT labels so its appearance on packages in transportation is not prohibited under 49 CFR 172.401(b). Also, its appearance on packages in transportation should not give the impression that a DOT-regulated hazardous material is in the package.

12/27/2002 - Plasma-derived products are considered "blood" within the meaning of the Bloodborne Pathogens Standard.

Your letter specifically requests an exemption from the standard for "market-ready, fully processed, plasma-derived products." You feel their inclusion under OSHA's standard *"negatively impacts your business"* and *"increases the possibility that* [Aventis] *will have to defend unfounded litigation* [from consumers] [clarification added]." We have considered your request, and after much thought and research, have decided against granting this exemption.

The standard, *". . .applies to all occupational exposure to blood or other potentially infectious materials [OPIM] as defined by paragraph (b) of this section. . ."* (29 CFR 1910.1030(a)). *"Blood" is defined as, ". . .human blood, human blood components, and products made from human blood."* (29 CFR 1910.1030(b)). Thus, since plasma-derived products are products made from human blood they are "blood" within the meaning of the standard, and occupational exposure to plasma-derived products triggers the standard operation.

It would be inappropriate to revise the standard to grant an exemption from the standard for plasma-derived products or to classify violations involving occupational exposure to such products as *de minimis*. We note that according to the Food and Drug Administration's **Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products** (January 2002), *"for plasma-derived products other than albumin, you should revise the package insert warning section to include the following statement: Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob Disease (CJD) agent."*

The material that you supplied with your request indicates that you strive to exceed the levels of testing and processing required by the FDA, and we applaud your efforts. However, as evidenced by the above recommendation, as of January 2002 it is the opinion of the FDA that a sufficient risk of bloodborne pathogens transmission exists to warrant precautionary labeling. In addition, new pathogens (e.g., West Nile virus) capable of bloodborne transmission for which there are no adequate testing guidelines, continue to arise. In view of the above, OSHA concludes that plasma derivatives pose a risk of bloodborne pathogens transmission.

02/20/2003 - Needlestick Safety and Prevention Act and the requirement to include safety-engineered sharps devices in pre-packaged surgical kits or trays.

Does compliance with the updated bloodborne pathogens directive enforced by the Needlestick Safety and Prevention Law require that pre-packaged kits include safety-engineered devices?

Note: These pre-packaged kits or trays may be prepared by outside vendors specifically for physician specialists in operating rooms and surgical centers.

The Needlestick Safety and Prevention Act (NSPA) was signed into law in November 2000. It mandated OSHA to revise its bloodborne pathogens standard to include specific additional definitions and requirements. OSHA published "*Revision to OSHA's Bloodborne Pathogens Standard -- Technical Background and Summary -- Needlestick Fact Sheet* (2001, May 9)," which clearly details the changes to the standard. We have attached it for your convenience. It is also available on our website, along with other informative outreach materials on the hazards associated with exposure to blood and other potentially infectious materials (OPIM), see [the Bloodborne Pathogens Technical Links Page].

The Needlestick Safety and Prevention Act is not enforceable on its own, but rather the Occupational Safety and Health Act of 1970, which requires compliance with OSHA standards. The OSHA bloodborne pathogens standard requires the institution of safety measures in workplaces where there is occupational exposure to blood or other potentially infectious materials (OPIM). Under the standard, as revised by the NSPA, employers are required to evaluate, select, and use engineering controls (e.g., sharps with engineered sharps injury protections or needleless systems) to eliminate or minimize exposure to contaminated sharps [29 CFR 1910.1030(d)(2)(i)].

In healthcare settings this requirement is easily interpreted to mean that employers must implement the use of "safety-engineered devices" or sharps with engineered sharps injury protection (SESIPs) when performing medical procedures with sharps, regardless how they are packaged or supplied. If, during surgical procedures, as your letter specifies, physician specialists or other healthcare personnel are using medical instruments supplied in pre-packaged kits, those packages must include engineering controls appropriate for the specific procedures being performed. Employees using these devices must have the opportunity to provide feedback on appropriate and effective safer devices [29 CFR 1910.1030(c)(1)(v)].

We understand that physician specialists (e.g., surgeons, anesthesiologists, etc.) often are not employees of healthcare facilities where they have staff privileges. Under OSHA's bloodborne pathogens compliance directive (OSHA Instruction CPL 02-02-069 [formerly CPL 2-2.69]) the status of the physician as an employer or employee is important to establish in order to determine the application of OSHA standards. According to the paragraph XI.D. in the directive, physicians "... may be cited if they create or control bloodborne pathogens hazards that expose employees at hospitals or other sites where they have staff privileges in accordance with the multi-employer worksite guidelines of CPL 02-00-124 [formerly CPL 2-0.124], Multi-Employer Citation Policy."

06/16/2006 - Wearing sandals in a medical office when feet do not contact blood or OPIM.

Question: I am a physician in an office-based pediatric center where our staff generally performs blood draws and urine checks, etc. We do not feel there is a potential for getting blood on our feet, so, as a matter of comfort, our work attire is dressy casual clothes and sandals suitable for a warm climate. We have been told OSHA requires that we wear shoes that cover our toes, or if we choose to wear sandals, we must wear socks with our sandals to make it permissible. Do the OSHA regulations permit the wearing of sandals in a medical office setting where our feet do not contact blood or body fluids?

Reply: When there is occupational exposure to blood or other potentially infectious materials (OPIM), the OSHA bloodborne pathogens standard, 29 CFR 1910.1030, requires the employer to provide, at no cost to the employee, APPROPRIATE personal protective equipment such as, but not limited to, gloves, gowns, eye protection, **shoe covers**, laboratory coats, or other equipment deemed necessary [See 29 CFR 1910.1030(d)(3)(i)]. Therefore, in circumstances where it is reasonable to anticipate that blood will contact the feet, employers must provide employees with protective gear to cover shoes which will be worn outside. (The bloodborne pathogens standard does not consider shoes worn outside the facility as personal protective equipment, regardless of whether the shoes cover the toes or not.) Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used [See 29 CFR 1910.1030(d)(3)]. As you stated in your letter, socks are not considered a protective barrier for preventing soak-through of blood or other potentially infectious materials (OPIM).

It is the employer's responsibility to ascertain whether or not there is reasonable likelihood of exposure to blood or OPIM at their workplace. Nonetheless, the determination of appropriate footwear in the absence of this (exposure to blood or OPIM) or any other recognized hazard would be up to the employer. OSHA does not forbid employers from setting protocol for prescribed work attire.

01/08/2007 - Use of rapid HIV antibody testing on a source individual after an exposure incident.

Question: Is it a violation of 29 CFR 1910.1030 for a medical facility subject to OSHA authority not to perform "rapid HIV antibody testing" on a source individual after an exposure incident?

Reply: As you may know, the bloodborne pathogens standard provides that "the source individual's blood shall be tested as soon as feasible" after an exposure incident and after consent is obtained [29 CFR 1910.1030(f)(3)(ii)(A)]. At the current time there are at least four FDA-approved tests available for "rapid HIV antibody testing," which usually can confirm negative HIV status in less than an hour after blood is drawn from a source individual. They are widely available, easy to use, and inexpensive. Standard enzyme immunoassay (EIA) testing can take a much longer time, especially if facilities to perform the tests are not available locally. Therefore, an employer's failure to use rapid HIV antibody testing when testing as required by paragraph 1910.1030(f)(3)(ii)(A) would usually be considered a violation of that provision. The use of rapid HIV antibody testing is supported by the current CDC recommendations for HIV post-exposure prophylaxis (PEP) in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis*, published on September 30, 2005. The CDC states on page 7 that having a "rapid HIV test could result in decreased use of PEP and spare personnel both undue anxiety and adverse effects of antiretroviral PEP." The document goes on to note on page 8 that "rapid HIV testing of source patients can facilitate making timely decisions regarding use of HIV PEP after occupational exposures to sources of unknown HIV status." Current guidance on the management of HBV and HCV exposure and PEP, as well as guidance for evaluation of the exposure source, is also contained in the *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis* (June 29, 2001),

01/18/2007 - The use of safety-engineered devices and work practice controls in operating rooms; hospital responsibility to protect independent practitioners under BBP standard.

Question 1: Members of our hospital operating room (OR) committee, including surgeons, nurses, and technicians, are requesting an interpretation of what the hospital's responsibility is in evaluating and implementing the use of sharps with engineered sharps injury protections (SESIPs) and safe zones for hands-free passing of sharps in the surgical suite. What does the bloodborne pathogens standard at 29 CFR §1910.1030 require in this regard?

Reply 1: OSHA's bloodborne pathogens standard requires that employers use engineering and work practice controls to eliminate occupational exposure or reduce it to the lowest feasible extent [29 CFR §1910.1030(d)(2)(i)]. One type of engineering control is a SESIP. 29 CFR §1910.1030(b) (definition of "*[e]ngineering controls*"). Therefore, where feasible, hospitals must implement the use of SESIPs and proper work practices, such as designated neutral or safe zones, which allow hands-free passing of sharps, to prevent sharps injuries in operating rooms. See CPL 2-2.69, XIII D.2 (2001) ("eliminating hand-to-hand instrument passing in the operating room" noted as engineering control in directive implementing the standard). The practitioner's preference is not an excuse for failure to use engineering controls and work practices. In many cases, surgeons may simply need additional practice or training to feel comfortable using a new and different device or work practice. However, if the use of a particular device or work practice could adversely affect the performance of a particular procedure and, ultimately, the safety of a patient, the device or practice does not have to be used. A determination not to use a particular device or work practice must be documented in the facility's exposure control plan (ECP), 29 CFR §1910.1030(c)(1)(iv).

if a hospital-selected safety device or work practice would adversely affect patient safety, the hospital must ensure that an alternative safe device or practice is implemented for the handling of sharps in the OR. For example, in a situation where all practicable engineering devices have been implemented and it is not feasible to perform the surgical procedure safely using a neutral zone, the hospital must ensure that surgeons and other staff in the operating room do not perform "hand-to-hand" passing of devices without first verbally notifying each other. In this way, operating room nurses, technicians, and surgeons will not be caught off-guard and will thus avoid "blind" retrieval of contaminated sharps.

Question 2: The surgeons in our facility are independent practitioners and are not employees of the hospital. What are the responsibilities of the hospital and the surgeons to protect hospital personnel in the OR under the bloodborne pathogens standard in this situation?

Reply 2: The hospital is responsible under the OSH Act for affording the protections of the bloodborne pathogens standard to its employees, regardless of the independent practitioners performing surgery in its operating rooms. It may not absolve itself of these responsibilities. We assume that the independent practitioners you discuss are surgeons with staff privileges at the

hospital. The relationship between a hospital and a surgeon or other physician with staff privileges at the hospital is contractual. Therefore, the practitioner has a contractual responsibility to comply with hospital procedures as set forth in the contract, and the surgeon has an obligation to follow them. Hospitals have the right to make a practitioner's adherence to the hospital's procedures a condition of staff privileges.

Furthermore, the practitioner or the medical practice with which he or she is associated, like a partnership or a professional corporation, usually would also be obligated to comply with the OSH Act and its standards, like the bloodborne pathogens standard, so as to protect employees. Surgeons or their medical practices usually employ at least one employee, such as a secretary or receptionist, and thus are employers under the OSH Act. 29 USC §652(5). Under the OSHA multi-employer worksite doctrine, an employer (here, the practitioner or his or her medical practice), that creates or controls a hazard, is obligated to comply with the standard so as not to endanger hospital employees.[1] See CPL 2-2.69 XI D (2001), which refers to CPL 2-0.124, Multi-Employer Citation Policy. These directives are available on OSHA's web site, http://www.osha.gov.

06/22/2007 - OSHA's BBP standard as it relates to laundering of surgical caps contaminated with blood from the operating room.

Question: Please clarify the requirements of the bloodborne pathogens standard (29 CFR 1910.1030). Should employees be allowed to take home reusable surgical caps contaminated with blood for laundering or is the employer required to launder such items?

Reply: As you may know, the primary use of surgical caps in operating rooms is to provide protection to the patient from any organisms that may shed from the hair or scalp of surgical staff. However, 1910.1030(d)(3)(xii) recognizes that in some circumstances surgical caps and/or hoods may be necessary to prevent splashes of blood or other potentially infectious material (OPIM) from the surgical site onto the surgeon(s) and/or others in the operating room. If it can be reasonably anticipated that the operating room employee's heads may be contaminated with blood or OPIM, appropriate surgical caps and/or hoods may be necessary PPE. Therefore, if staff members are provided surgical caps which are considered an appropriate level of protection for workplace conditions and it is worn, relied upon, and/or functions as a protective garment, then the surgical caps would be covered by the requirements of the standard and the contaminated surgical caps must be laundered by the employer at no cost to the employee. With regard to contaminated personal protective equipment, OSHA has stated in CPL 02-02-069 XIII.D.16, that *"home laundering is unacceptable because the employer cannot ensure that proper handling or laundering procedures are being followed and because contamination could migrate to the homes of employees"* Employers are responsible for cleaning, laundering and/or disposing of personal protective equipment [29 CFR 1910.1030(d)(3)(iv)].

09/25/2008 - OSHA's position on the use of Q104 needle removal device.

Dear Mr. _____:

Thank you for your letter to the Occupational Safety and Health Administration (OSHA) regarding the Q104 needle removal device as an engineering control under OSHA's bloodborne pathogens standard, 29 CFR 1910.1030. According to the information you provided, the device is designed to use electronic circuitry to heat and decontaminate a used needle and then remove the needle from its connection point to the syringe. During a phone conversation with a member of our staff, you clarified that you are requesting OSHA's written opinion on whether use of this product by employees in healthcare settings would violate the requirements of the bloodborne pathogens standard. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question(s) or scenarios not delineated within your original correspondence.

OSHA's bloodborne pathogens standard prohibits the bending, recapping, or **removal** of a contaminated needle or other contaminated sharp [29 CFR 1910.1030(d)(2)(vii)(A)]. The standard provides an exception where an, "employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure." The standard goes on to provide: "such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique" [29 CFR 1910.1030(d)(2)(vii)(B)].

For the limited circumstances where these criteria are met, the Q104 appears to be a type of mechanical removal device that could be considered. OSHA may not approve or endorse particular products.

The agency has previously responded to substantially similar questions regarding needle destruction devices (NDDs) and other products marketed as safer needle alternatives. Like sharps containers and NDDs, the Q104 is an engineering control for the point of disposal. In clinical settings, the Q104 may not always be located immediately next to the point of use and may necessitate moving across the room or work area to deposit an unprotected, contaminated sharp. This increases the potential for needlestick injuries between use and disposal.

These devices are designed to be used only with conventional syringes/sharps (i.e., those without a safety feature) that present a risk of exposure during use and prior to disposal. This is when most of the employee exposure occurs. According to 2004 data from EPINet at the International Health Care Worker Safety Center at the University of Virginia, most injuries from contaminated sharps occur during use (41%), between steps (12%), and during other activity after use, before disposal (15%). A greater proportion of the injuries documented occurred while using conventional needles.

A very compelling study was performed at Memorial Sloan-Kettering Cancer Center in New York City comparing the percutaneous injury (PI) rates at that facility prior to the intervention of sharps

with engineered safety protections (SESIPs) with PI rates following the implementation and use of SESIPs. The study found a considerable decrease in PI incidence rates after the use of SESIPs was implemented. The mean annual incidence of PIs decreased from 34.08 per 1,000 full-time-equivalent employees prior to intervention to 14.25 post-intervention (i.e., overall incidence rate of PIs was lowered by more than 50%). It should be noted also that approximately 64% of the PIs which occurred during the post-intervention period resulted from conventional (non-SESIP) device use. It was also determined that a significant proportion of PIs that did occur with the use of SESIPs could be avoided by the provision of retraining or additional training on use of those devices.

11/21/1994 - HCS as it relates to the guidelines described in OSHA's 1986 publication regarding disposal of hospital wastes contaminated with cytotoxic drugs.

Dear _____:

This is a response to your letter of August 21, 1993, concerning the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), 29 CFR 1910.1200, as it relates to the guidelines described in OSHA's 1986 publication regarding disposal of hospital wastes contaminated with cytotoxic drugs. The questions in your letter also relate to the requirements under OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030. Please accept my regret for the long delay in responding to your letter. We are providing responses to your questions in the order presented in your letter.

1. **Is [the requirement to dispose of cytotoxic waste in distinctively labelled and color-coded bags] designed to comply with the Hazard Communication Standard so that employees can define the appropriate hazard and handle the waste appropriately?**

No. Although the requirements of the HCS do apply to the storage and handling of parenteral cytotoxic pharmaceuticals, the HCS does not address proper disposal of hazardous materials and does not apply to hazardous waste. The guidelines in OSHA's 1986 document are intended to address the safety and health of workers handling cytotoxic waste while meeting the disposal requirements of EPA's National Hazardous Waste Program and equivalent state laws.

2. **[Is the requirement to place] needles, syringes, and breakable or sharp items used with cytotoxic drugs...in specially designated puncture proof boxes...designed to comply with the Hazard Communication Standard?**

Please refer to question number 1.

3. **[Could] items that are considered "empty"...or "residually contaminated" with cytotoxic drugs [by definition under RCRA]...be placed in a regular sharps container...that is used for infectious waste?**

Yes. OSHA promulgated the Bloodborne Pathogens rule after the publication of the 1986 document on safe handling practices for cytotoxic drugs. For needles, syringes, or other sharps that are contaminated with blood or Other Potentially Infectious Material (OPIM), but only residually contaminated with cytotoxic drugs, puncture-resistant receptacles meeting the requirements of the Bloodborne Pathogens standard must be used.

4. **Can empty IV bags and tubing or gowns and gloves used...be placed in with infectious waste as these are only residually contaminated? If not, do they need to be placed in specially labelled and color-coded bags or containers?**

OSHA's Bloodborne Pathogens Standard permits disposing of residually contaminated protective clothing with infectious waste, so long as such waste was labelled in accordance with 29 CFR

1910.1030. In lieu of labeling, such waste may be placed in red bags or red containers. OSHA's Hazard Communication Standard would not apply to the labeling of non-infectious waste that is contaminated with cytotoxic residues. Of course, disposal of material contaminated with cytotoxic chemicals must conform to state law. Please refer to the Medical Waste/RCRA Hotline for the State of Illinois; the hotline number is (217) 782-6760.

5. **If a hospital segregates true chemical/hazardous chemotherapy wastes such as vials with greater than 3% or the original medication remaining, or mixed infusion bags that were partially given, would only these items need to be handled in a different manner?**

Yes. Items defined as "empty" or "residually contaminated" under RCRA or applicable state law do not require handling as described in OSHA's 1986 protocols for handling cytotoxic wastes.

6. **Is it necessary to use...the above mentioned bags or containers for the segregation of residually contaminated cytotoxic waste?**

No. As discussed above, residually contaminated items may be disposed of in receptacles meeting the requirements of OSHA's Bloodborne Pathogens Standard. Sharps that are residually contaminated may be disposed of in sharps containers meeting the requirements of 1910.1030, and other residually contaminated items may be disposed of in containers that conform to 1910.1030.

05/18/1998 - Bloodborne Pathogens Standard applicability to radiopharmaceutical use.

Dear Mr. _____;

This letter is in response to your faxed request of April 24 that we re-address how the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens Standard relates to unit dose radiopharmaceuticals. In our original letter to Mr. John Z. Wang of your company, we stated that the handling of these would fall strictly under the Nuclear Regulatory Commission's (NRC) Jurisdiction. Upon further discussion with the NRC and clarification from you, we have determined that several aspects of the process you have described would fall under our bloodborne pathogens standard (29 CFR 1910.1030). OSHA would have jurisdiction over any bloodborne pathogen and other employee safety issues created by handling of the syringe. The Nuclear Regulatory Commission (NRC) would retain Jurisdiction over the actual radiopharmaceuticals and their handling.

Your letter described two systems for handling radiopharmaceuticals. In the old system, the syringe is inserted directly into a lead-lead container called a "pig" which is supplied with the radiopharmaceutical. After injecting the material into the patient, the syringe is reinserted into the pig to shield employees from radiation emitted by the drug. These pigs come into direct contact with the used needle and the inside of the container would be regarded as having direct contact with blood and would fall under [1910.1030(d)(4)(iii)(A)(4)]. This paragraph states that any containers intended for reuse may not be opened, emptied or cleaned manually or in any other manner that would expose employees to the risk of percutaneous injury. A mechanical method must be in place, so that the process of removing the contaminated syringe from the pig, as well as decontamination and cleaning of the pig are engineered to eliminate any hazard to the employee. The container must also be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

In the new system, the lead pig has a plastic insert into which the syringe is placed. A red plastic top slides over tile top of the syringe and affixes to tile lower portion of the insert creating an inner receptacle. This insert is not reused, but disposed of along with its contents. It can be removed manually as a unit with no risk of percutaneous injury. The pig, in this case, while still technically a receptacle, would need to be evaluated by the employer to determine if it does or does not have a reasonable likelihood of contamination. If it does not, then it would not have to follow a regular decontamination schedule.

In both methods, the pigs are transported in a delivery case which can hold between one and twelve pigs. To comply with the labeling requirements, the biohazard warning must be displayed on the outside of this container when the used syringes are returned to the pharmacy. The innermost container (which holds the syringe) must also be either labeled or color-coded. In the old system, the

innermost container would be the pig itself In the new system, the insert would be the innermost container. Labeling the pig in the new system would not be required, if it is determined it is not contaminated during handling and when the above procedure is being followed.

08/17/2001 - Evaluation of safer medical devices and the use of therapeutic radiopharmaceuticals.

Dear Mr. _____:

Thank you for your May 24 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Compliance Programs regarding the applicability of the Bloodborne Pathogens Standard (29 CFR 1910.1030) to nuclear medicine, specifically to the use of injectable therapeutic radiopharmaceuticals. Your letter follows a meeting that you and members of the Council on Radionuclides and Radiopharmaceuticals (CORAR) had with members of the Office of Health Compliance Assistance.

Your letter poses questions relating to the revised Bloodborne Pathogens standard (January 18, 2001) as amended by the Needlestick Safety and Prevention Act. The revised standard includes specific language regarding the requirement for employers to select safer needle devices, as they become available, for procedures where occupational exposure to blood and other potentially infectious materials (OPIM) is reasonably anticipated.

One of the new provisions of the standard is the requirement for employers to solicit input from non-managerial employees to identify, evaluate, and choose appropriate safer medical devices. The solicitation must be documented in an employer's Exposure Control Plan, which must be updated annually and as changes occur. Because the practice of nuclear medicine is unique, you are requesting an interpretation specific to this field of medicine.

Your questions are restated below followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions not delineated within your original correspondence.

Question: Should employers in healthcare facilities who handle radiopharmaceuticals take into account the hazards of radiation exposure when they conduct periodic reviews for appropriate, commercially-available safety syringes?

Yes. When evaluating safer medical devices, the employer must consider the appropriateness of each device for each procedure. In the administration of radiopharmaceuticals, the radiation itself poses an occupational hazard to employees. This must be accounted for in the evaluation and implementation of devices. The safer device must not compromise employee protection from the radiation hazard.

Question: Should such employers seek the input of nuclear pharmacists, nuclear physicians, or radiation safety officers in the evaluation and selection of safety syringes?

Yes. When employers are seeking input from employees regarding the selection of safer medical devices, the employees selected should represent the range of exposure situations encountered in the workplace (e.g., pediatrics, nuclear medicine, emergency department, etc.). The solicitation of employees who have been involved in the input and evaluation process must be documented in the employer's Exposure Control Plan.

Question: When conducting reviews for appropriate, commercially-available safety syringes to be used with radiopharmaceuticals, would it be prudent for healthcare employers to utilize [certain] criteria to determine the appropriateness of currently available safety syringes?

The criteria that you describe in your letter, which are used by some nuclear medicine practitioners to select safer medical devices, include such items as: ensuring that the "safety syringe" fits snugly into a radiation shield, ensuring that the syringe can be operated without displacing the radiation shield, and determining that the syringe does not leak or project radioactive material. In using these criteria, if a "safety syringe" fails to meet one or more of these items, it is not chosen. Using additional guidelines may also be useful. For example, "Sharps Feature Evaluation Forms" intended to be used for the evaluation of safer medical devices are available from the Training for Development of Innovative Control Technologies (TDICT) Project at http://www.tdict.org and http://www.osha.gov.

An employer's criteria for choosing appropriate medical devices are specific to each employer, facility, process, and procedure. Again, when choosing a safer medical device, it is important that the devices chosen do not cause employees to be exposed to additional hazards (e.g., radiation).

Question: What are a healthcare employer's obligations if, upon review of available safety syringes, the employer determines that there are no syringes currently on the market that are appropriate for use with radiopharmaceuticals?

How should a healthcare employer document its considerations and decisions regarding whether commercially-available safety syringes are appropriate for use with radiopharmaceuticals?

If there are currently no safer medical devices (safety syringes) available on the market for a specific procedure, the employer must document this in his or her Exposure Control Plan. As stated in OSHA's 2001 Frequently Asked Questions,

"A key element in choosing a safer medical device, other than its appropriateness to the procedure and effectiveness, is its availability on the market. If there is no safer option for a particular medical device used where there is exposure to blood or OPIM, you are not required to use something other than the device that is normally used. During your annual review of devices, you must inquire about new or prospective safer options and document this fact in your written Exposure Control Plan. With increasing medical technology, more devices are becoming available for different procedures. If no engineering control is available, work practice controls shall be used and, if occupational exposure still remains, personal protective equipment must also be used."

Question: For states and territories that operate federally-approved occupational safety and health plans, must such plans permit healthcare employers to decline to use safety syringes with radiopharmaceuticals if no appropriate syringes and syringe-radiations shields are commercially available?

As mentioned in our previous response, if no safer options are currently available, it must be documented in the facility's Exposure Control Plan. This would apply in Federal OSHA states, as well as OSHA state-plan states. Please be aware that OSHA state-plan states administer their own occupational safety and health programs under plans approved and monitored by Federal OSHA. States are required to have regulations that are "at least as effective" as the federal standards, but may also be more stringent. States are expected to adopt a standard equivalent to the revised federal standard by October 18, 2001. Employers are responsible for determining the regulations that apply in their particular states. For a list of Federal and state-plan states, log onto OSHA's website at http://www.osha.gov.

09/01/2004 - Limiting factors for implementing the use of engineering controls, i.e., safety scalpels, under the Bloodborne Pathogens standard.

Dear Ms. _____:

Thank you for your May 7, 2004 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP). Your letter addresses several issues which are restated below, followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question(s) not delineated within your original correspondence.

Question 1: Do healthcare facilities need to use reengineered safety scalpels to be in compliance with the bloodborne pathogens regulations, or can they simply evaluate?

Reply 1: OSHA's bloodborne pathogens standard at 29 CFR 1910.1030(c)(1)(iv) requires employers to evaluate safer medical devices to eliminate or minimize employee exposure to blood or other potentially infectious materials (OPIM). Employers must solicit input from non-managerial employees in the selection process [29 CFR 1910.1030(c)(1)(v)]. Engineering controls, including safety scalpels, must be implemented where their use is feasible [29 CFR 1910.1030(d)(2)(i)].

Question 2: If not, under what circumstances may they choose not to employ safety scalpels?

Reply 2: OSHA recognizes that no one medical device is appropriate for use in all circumstances and that it is important to safeguard both patients and employees during medical and surgical procedures. If the use of a particular engineering control, in this case a safety scalpel, compromises patient safety, its use would not be considered feasible. The employer, therefore, must determine what engineering and work practice controls effectively minimize hazards without unduly interfering with medical procedures. The standard also recognizes that market availability is another limiting factor in implementing the use of engineering controls and must be considered in both your choice of an engineering control and our enforcement of their use [29 CFR 1910.1030(c)(1)(iv)(B)]. However, please be aware, where exposures have been determined and where engineering controls are commercially available and feasible, they must be used.

Additionally, the bloodborne pathogens standard requires that employers "*document annually [their] consideration and implementation of appropriate commercially available and effective safer medical devices...*" [29 CFR 1910.1030(c)(1)(iv)(B)]. OSHA compliance officers have issued citations to employers at facilities where the Exposure Control Plan (ECP) did not contain such documentation. It is required, therefore, that a site choosing not to employ safety scalpels, specifically address the non-use of a safety scalpel in its ECP.

Question 3: If surgeons don't "like the new safety scalpels as well as the traditional designs," but the surgeons don't demonstrate that the newer designs would result in a negative patient outcome, is it then permissible not to use the reengineered safety scalpel devices?

Reply 3: Please see Reply #2.

Question 4: Are there definitive guidelines regarding safety scalpels listed within any of the OSHA websites?

Reply 4: While OSHA's website does not have specific guidelines regarding safety scalpels, OSHA maintains a safety and health topics page dedicated to bloodborne pathogens and needlestick prevention located at http://www.osha.gov/SLTC/bloodbornepathogens/index.html.

Question 5: What is the cost of non-compliance? Is there a schedule?

Reply 5: Section 17 of the Occupational Safety and Health Act, 29 USC §666, outlines the prescribed civil penalties and factors for consideration in the assessment of each violation cited by the agency. A willful or repeated violation may result in a penalty of up to $70,000; there is a minimum penalty of $5,000 for willful violations. Serious violations (where there is a substantial probability of death or serious physical harm) require a penalty of up to $7,000. Other-than-serious violations may result in a penalty of up to $7,000. If an employer fails to abate a violation set forth in a citation which has become a final order, the employer may be assessed a penalty of up to $7,000 for each day during which the violation continues.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at http://www.osha.gov.

12/15/2000 - Engineering controls must be used to prevent needlesticks where feasible.

Dear Ms._____:

Thank you for your October 13, 2000 letter to the Occupational Safety and Health Administration's (OSHA's) Atlanta Regional Office. Your letter was forwarded to the Directorate of Compliance Programs at OSHA's National Office for a response to your question regarding the applicability of the Bloodborne Pathogens Standard (29 CFR 1910.1030) and the newly passed Needlestick Safety and Prevention Act to biopsy needles and instruments. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any situation not delineated within your original correspondence. Your question is restated below followed by our response.

"It may not be possible to design a biopsy needle or instrument with engineered sharps injury protection (ESIP) that allows a tissue sample to be taken with the quality necessary for diagnosis. Are (biopsy needles and instruments) included in the safety needle legislation...?"
As you know on November 6, 2000 President Clinton signed "The Needlestick Prevention and Safety Act" which directs OSHA to make several changes to the Bloodborne Pathogens standard. These changes must be incorporated into the standard before May 2001. Currently however, paragraph 1910.1030(d)(2)(i) already requires the use of engineering and work practice controls where employee exposures can be eliminated or minimized to the lowest extent feasible. It further states that "(e)ngineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness." Some examples of engineering controls used to control the hazards of needlesticks include needleless intravenous (IV) systems, "self-sheathing," and/or "self-blunting" needles. OSHA Instruction [CPL 02-02-069 (formerly CPL 2-2.69)], Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, further clarifies the requirements of the standard.

[CPL 02-02-069] explains that the prevention of exposures to bloodborne pathogens requires a comprehensive program, including engineering and work practice controls. If engineering and work practice controls do not eliminate exposure, the use of personal protective equipment is required. Of course, engineering controls must be implemented where their use is feasible. If the use of an engineering control, in this case a sharp with engineered sharp injury protection (SESIP), compromises patient safety or procedural integrity, it would not be considered feasible.

The standard and the new act also recognize that market availability is another limiting factor in implementing the use of engineering controls and must be considered in both your choice of an engineering control and our enforcement of their use. The appendix of the directive has several resources designed to aid the employer in evaluating safer medical devices and SESIPs.

Again, it is important to safeguard both patients and employees during medical and surgical procedures. Therefore, the employer must determine what engineering and work practice controls effectively minimize hazards without unduly interfering with medical procedures. However, please be aware that where exposures have been determined and where engineering controls are feasible, they must be used.

Another related issue is the disposal of contaminated biopsy needles. The standard requires that, "(i)mmediately or as soon as possible after use," contaminated sharps must be placed in appropriate containers until properly reprocessed or disposed. The requirements for disposal containers are detailed in paragraph 1910.1030(d)(2)(viii).

02/09/2001 - Use of engineering and work practice controls during pouring of blood or OPIM.

Dear Mr. _____:

Thank you for your January 2001 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Compliance Programs. Your letter was a follow-up to an interpretation that we developed for you in July 2000. It asks additional questions regarding the controls used for disposing of blood and body fluids in healthcare settings, which are applicable under the Bloodborne Pathogens Standard (29 CFR 1910.1030). Your question is outlined below followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

If a hospital is interested in instituting engineering controls for pouring blood and body fluids for disposal, but cannot immediately procure one (due to temporary manufacturer s upply shortages), what do they do? Can they document their intent or provide proof of a purchase order to avoid fines and citations from OSHA until they can get the product?

As stated in our previous letter to you, according to paragraph (d)(2)(i) of the standard, where engineering and work practice controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. This would include the use of existing, feasible, commercially-available engineering controls for pouring blood or OPIM from suction canisters, in order to reduce or eliminate splashes and splatters to workers which may result in exposure to bloodborne pathogens.

During an employer's annual review of its Exposure Control Plan (ECP), as required by the standard, the employer must evaluate the practices and processes used in its facility and address the methods by which it controls specific bloodborne pathogen hazards. The employer must identify the positions for which the duties include tasks and procedures identified as having occupational exposure. The ECP must also address implementation and evaluation of proper engineering and work practice controls, personal protective equipment and employee training, among other things. Additionally, section (c)(1)(iv) of the standard requires the employer to review and update the plan **at least annually** to reflect changes in technology.

In practice, when an employer chooses the engineering control that is most effective and feasible for a particular procedure or process, it must be documented in the ECP, as stated above. If for some reason the device (or engineering control) is not commercially available (due to supply shortages, back orders, shipping delays, etc.), this must also be documented. An employer would be responsible to then implement the chosen control(s) as soon as it becomes available and adjust the ECP to illustrate such. Compliance with the requirements of the ECP, as described above, will not, in this instance, result in the employer receiving an OSHA citation for failing to implement engineering controls.

05/17/2001 - Needlestick Safety and Prevention Act amplifies the requirements to use safer needle devices.

Dear Mr. _____:

Thank you for your March 6 letter to the Occupational Safety and Health Administration (OSHA) regarding the "Needlestick Safety and Prevention Act," (NSPA) as it applies to OSHA's Bloodborne Pathogens Standard (29 CFR 1910.1030). While this Act mandated that OSHA include several new provisions into its standard, it did not change, but simply amplified, the importance of and requirements for the implementation of engineering controls (e.g., Sharps with Engineered Sharps Injury Protection) in healthcare and similar settings. For your information, we are enclosing a copy of the revised Bloodborne Pathogens Standard, 29 CFR 1910.1030, and OSHA publication 2056, **All About OSHA.**

We will restate your questions below, followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

1. Do hospitals and healthcare facilities have to use "engineered control devices" (e.g., safety needles)?

2. When do these facilities have to have "engineered control devices" safety needles in their facilities, what date?

OSHA's Bloodborne Pathogens Standard, which became effective in March 1992, requires that every employer perform a workplace exposure determination in order to identify hazards and implement proper controls. Although the requirement to implement safer medical devices is not new, the revised standard (2001) further clarifies what is meant by "engineering controls;" it adds language to the definition section of the original 1991 standard that reflects the development over the last decade of safer medical devices.

The standard requires, **"(e)ngineering and work practice controls shall be used to eliminate or minimize employee exposure."** Engineering controls are defined as, **"controls (e.g., sharps disposal container, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove a hazard from the workplace."** Examples of engineering controls most applicable in healthcare are needleless intravenous systems, retractable needles, and other sharps with engineered sharps injury protection (SESIPs).

According to ~~CPL 2-2.44D~~ **[CPL 2-2.69], Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens**, where exposures to blood and other potentially infectious materials (OPIM) are reasonably anticipated and engineering controls will reduce employee exposure either by removing, eliminating, or isolating the hazard, they must be used. Consequently, you

should already have safer devices in place. If you have not already evaluated and implemented appropriate and available engineering controls (safer medical devices), you must do so immediately.

(Correction 3/15/02)

The exposure determination, as well as the evaluation, implementation, and use of the engineering controls must be documented in the employer's Exposure Control Plan. The plan must be updated at least annually and must reflect changes in job tasks and procedures, and advances in technology.

3. Needles such as vial access needles that are used to fill syringes with either medication or flush fluid to be administered through a needleless adapter device, do they have to be a safety product?

The Bloodborne Pathogens Standard only applies where there is a reasonably anticipated employee exposure to blood or OPIM. In a case such as drawing medication from a vial which will be introduced to an area devoid of blood or OPIM, it would not be necessary to implement SESIPs.

4. Is the "Needlestick Safety and Prevention Act" enforceable? How?

Yes. As mentioned earlier, the Needlestick Safety and Prevention Act mandated changes to the Bloodborne Pathogens standard. OSHA published those changes on January 18, 2001. Therefore, enforcement of the new sections of the standard (i.e., additions to the Exposure Control Plan and recordkeeping) will be carried out just as the enforcement of any other OSHA standard would.

5. If a facility states that it has no exposure problem or needlesticks with current conventional needles or catheters, do they still have to convert to safety products?

Yes. The standard and its revisions were mandated as a means of prevention. The obligation to implement proper engineering and work practice controls is not contingent on the existence of actual needlesticks in the workplace because the purpose of the Occupational Safety and Health Act (OSH Act) is to prevent the first incident. Where conventional needles are being used, an employer is responsible for evaluating SESIPs available on the market for each particular procedure where there is reasonably anticipated exposure to blood or OPIM and using appropriate, effective devices for those procedures.

11/26/2001 - Response to the American Academy of Pediatrics regarding the Needlestick Safety and Prevention Act.

AAP Scenario: The American Academy of Pediatrics (AAP) is deeply concerned that the mandated use of safe sharps threatens the success of our nation's childhood immunization program.

AAP Suggestion 1: Exempt injections for vaccine delivery from mandated safe sharps to allow comparable studies on sharps injuries and the effectiveness of sharps with engineered sharps injury protection (SESIPs) to be conducted in ambulatory healthcare facilities where childhood immunizations are provided.

OSHA Response 1: OSHA does not generally grant exemptions from the Bloodborne Pathogens Standard. The standard applies to all occupational exposure to blood or other potentially infectious materials (OPIM) and requires an employer to determine where those exposures are reasonably anticipated. The exposure determination must then be documented and appropriate controls put in place to eliminate or minimize those hazards. The controls implemented include engineering and work practice controls, personal protective equipment, and employee training.

It would be particularly inappropriate to grant an exemption to the requirement in 29 CFR 1910.1030(d)(2)(i) to implement engineering controls, which include SESIPs after the Congress unanimously passed and the President signed the Needlestick Safety and Prevention Act (P.L. 106-430). The very purpose of that Act was to make sure that SESIPs are used as part of an overall bloodborne pathogens program to reduce accidental sharps injuries. Congress found that, **"depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices,"** on the basis of CDC findings in March 2000. They also found that the modification of the Bloodborne Pathogens Standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.

As your letter illustrates and according to the International Health Care Worker Safety Center at the University of Virginia (EPINet database), needlesticks occurring from syringes used for intramuscular/subcutaneous injections pose a risk to those administering the injections. Data collected from several hospitals indicate that needlesticks occurring from this type of procedure account for the highest number of needlesticks (17%), along with those from devices used for drawing venous blood samples (EPINet, 1998). Therefore, when performing IM/subcutaneous injections (e.g., vaccinations, administration of medication) evaluation and selection of SESIPs are required.

AAP Suggestion 2: Stand by the previous interpretation of the standard, which permitted employees and front-line employees to conduct their own risk assessments (based on the facility's history of past injuries and its comparison to sharps injuries in similar settings using similar sharps devices) and to customize their decision to switch to SESIPs. Should the work group agree that the existing work practice controls have proven sufficient to prevent sharps injuries, or that the engineering controls available would not have prevented the kinds of previous sharps injuries, then the adoption of the SESIP would be optional.

OSHA Response 2: Implementing engineering and work practice controls where there is reasonably anticipated occupational exposure to blood or OPIM has always been a requirement of the standard and has not changed. Soliciting input from non-managerial employees responsible for patient care regarding the evaluation of engineering controls (e.g., SESIPs, needleless systems) is a requirement of the revised standard (January 2001).

Non-managerial employees responsible for direct patient care must have input in employer decisions about **which** engineering controls to adopt, not whether or not to adopt them. The standard does not give the employer the option to forgo appropriate, commercially available, and effective engineering controls. If the employer determines, through device evaluation, that no available devices are appropriate for a specific procedure, that decision must be documented in the Exposure Control Plan (ECP). If the employer feels that a particular device is cumbersome or awkward, employees may need additional practice or training until they feel comfortable using a new and different device. Whether or not an engineering control is chosen for a specific procedure, an annual review of devices is required and that review must be documented in the ECP.

Again, if appropriate and effective safer options are commercially available for specific medical procedures where there is reasonably anticipated exposure to blood or OPIM, they must be used. Appropriateness and effectiveness should be based on employee feedback, industry feedback, pilot programming, and/or practical use. Engineering and work practice controls that the employer determines to be appropriate, after non-managerial employee input, must be documented in the employer's Exposure Control Plan (ECP). Of course, if using a safer medical device compromises either patient safety or medical integrity, its use would not be required.

Please keep in mind that the Bloodborne Pathogens Standard and several other new OSHA standards are written in performance-oriented language, giving the employer the opportunity to implement the controls which best suit the safety of his or her employees.

The Centers for Disease Control and Prevention (CDC) and General Accounting Office (GAO) recommend, and OSHA requires, that the use of safer medical devices be combined with a comprehensive program including reducing the use of unnecessary needles, modifying procedures where appropriate, implementing safe work practices, employee training, promoting safety awareness in the workplace, and then evaluating the effectiveness of these measures. Where the use of safer medical devices is not appropriate, it is especially important that the other components of the program be in place.

Our compliance directive, C~~PL 2-2.44D [~~CPL 2-2.69], **Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens** (s~~oon to be updated),~~ provides several internet links to websites that have information and tips on evaluating engineering controls. We encourage you to look at them as aids for your evaluation.

(Correction 3/15/02)

The purpose of the Occupational Safety and Health (OSH) Act is to prevent the first injury or illness from occurring. No proof of specific prior instances of exposure is required to trigger OSH Act obligations [Mineral Industries, Etc. v. OSHRC, 639 F.2d 1289, 1294 (5th Cir. 1981)]. Thus, a

facility's past sharps injury rates does not affect compliance with the standard. As mentioned previously, sharps injuries during the administration of vaccinations do occur. It is our mission to prevent these injuries.

AAP Suggestion 3: Delaying application of safe sharps for immunization procedures to allow "payors" time to reallocate funding resources and providers time to renegotiate contracts with medical supply vendors and "payors." This would help vaccine providers to secure adequate reimbursement for additional vaccine administration costs associated with switching to SESIPs. This delay would also help small medical groups by allowing them to purchase SESIPs after hospitals and other high volume purchasers may have caused the prices of such devices to decline.

OSHA Response 3: The requirement to use engineering and work practice controls (29 CFR 1910.1030(d)(2)) has been part of the standard since it was originally promulgated in December 1991 and has already been actively enforced since November 1999.

We will not further delay enforcement of any section of the standard. The revised standard was published in January 2001, became effective April 2001, and enforcement of the new provisions (i.e., the solicitation of input from non-managerial employees and maintaining a sharps injury log) began in July 2001 (October 2001 in OSHA state-plan states). OSHA inspections to determine compliance with this standard are performed mostly on the basis of employee complaints. During an OSHA inspection, if an OSHA compliance safety and health officer determines that an employer has not evaluated and implemented appropriate engineering and work practice controls, a citation would likely be issued.

With regard to the cost of purchasing safer medical devices, you may find that the cost is less prohibitive than anticipated. According to the November 17 GAO Report, **Occupational Safety: Selected Cost and Benefit Implications of Needlestick Prevention Devices for Hospitals**, to which you also refer in your letter, **"the greatest dollars savings resulting from a needlestick reduction program would be the reduced cost of treating healthcare workers who have sustained needlesticks... these costs include medical treatment costs for healthcare workers who become infected after sustaining a needlestick; wages and time lost by these workers; emotional distress suffered by injured workers, their colleagues, and family members; reduced quality of life and while rare, lives lost."** Some cost estimates for individual needlesticks range from $200 to $3,000 per injury according to both GAO and the International Health Care Worker Safety Center (University of Virginia). Most people find that the benefits of preventing an exposure incident far outweigh the costs of safer devices.

Additionally, if an employee had an exposure incident with a contaminated sharp, post-exposure follow-up is required. Through evaluation of the incident, an occupational health practitioner may determine that prophylaxis is not appropriate; however, follow-up still needs to be provided and paid for by the employer regardless of the type of device or the associated risk of transmission.

AAP Suggestion 4: Explore ways to make SESIP purchased in high volume at government discounts available to pediatricians through programs such as the "Vaccine for Children Program," State Medicaid program, and bulk purchase programs from private sources.

OSHA Response 4: While this may be a good suggestion for minimizing cost, we are not able to comment; this issue is outside of OSHA's jurisdiction.

AAP Suggestion 5: Phase in the implementation of the Needlestick Safety and Prevention Act (NPSA) requirements. First, target healthcare workers in high-risk setting who use sharps in high-risk procedures. Second, target procedures more likely involved in exposure to blood or OPIM. Third, include sharps used in vaccine injections.

Response 5: With regard to phasing in the enforcement of the new provisions of the standard (i.e., solicitation of input from non-managerial employees and maintaining a sharps injury log), this was already done in the period between January and July 2001 (October 2001 for OSHA state-plan states). OSHA is not targeting any industry or facility with regard to compliance with the Bloodborne Pathogens Standard. As mentioned previously, most OSHA inspections are complaint-driven. If an OSHA office were to receive a complaint regarding exposure to blood or OPIM, an inspection might result, regardless of the size or function of the facility.

Again, every process or procedure that may result in occupational exposure to blood or OPIM must be addressed and appropriate controls implemented. Though this has been a requirement since 1991, we recognize that evaluation and implementation of appropriate engineering controls can be a time-intensive task. That is why an employer is required to document his or her actions in the ECP, so that if an OSHA inspection did occur, the written plan can be consulted.

03/31/2003 - Acceptable use of antiseptic-hand cleansers for bloodborne pathogen decontamination and as an appropriate handwashing practice.

Dear Ms. _____:

Thank you for your January 3, 2003 inquiry to the Occupational Safety and Health Administration (OSHA) regarding OSHA requirements for handwashing under the bloodborne pathogens standard [29 CFR 1910.1030]. Your question has been outlined below followed by OSHA's response.

The new Centers for Disease Control and Prevention (CDC) "Guideline for Hand Hygiene in Health-Care Settings" (Morbidity and Mortality Weekly Report, October25, 2002) supports the use of alcohol-based hand rubs as an effective means for decontaminating hands in healthcare settings. Is this consistent with the requirements for handwashing established in OSHA's bloodborne pathogens standard?

Many of CDC's hand hygiene guidelines are for infection control and patient safety, which OSHA standards do not specifically address. However, we feel that these guidelines which do address *occupational* exposures to blood or other potentially infectious materials (OPIM) are consistent with OSHA's bloodborne pathogens standard. In paragraph (d)(2) of OSHA's standard, the section that most appropriately addresses "handwashing" in the scenario that you describe, the following is stated:

(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. (vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

OSHA interprets this to mean that when an employee is removing gloves and has had contact, meaning occupational exposure to blood or blood or other potentially infectious materials (OPIM), hands must be washed with an appropriate soap and running water. If a sink is not readily accessible (e.g., in the field) for instances where there has been occupational exposure, hands may be decontaminated with a hand cleanser or towelette, but must be washed with soap and running water as soon as feasible. If there has been no occupational exposure to blood or OPIM, antiseptic hand cleansers may be used as an appropriate "handwashing" practice.

Again, if there has been no occupational exposure to or contact with blood or OPIM (as defined in [29 CFR 1910.1030(b)]), the use of alcohol-based hand cleansers described in the CDC's October 2002 guidelines would be appropriate. The application of the standard and its specific elements must be put into place where there has been actual or reasonably anticipated exposure to blood or OPIM and does not apply if no occupational exposure exists.

OSHA has consistently relied on the findings and recommendations of the CDC in developing good work practices for those employees with occupational exposure to blood or OPIM and feels that the

existing standard does not compromise or contradict the recommendations included in the CDC's most recent guidelines.

01/29/2007 - Whether shielding is required when removing Becton Dickinson's blood tubes with a Hemoguard® closure.

Scenario: It is our understanding that the use of Becton Dickinson's (BD's) blood collection tubes with Hemogard® closure meets the OSHA requirement of preventing exposure to employees, and employees utilizing them do not need to wear a face shield or use a countertop shield when removing the caps from blood tubes which have the Hemogard® closure. BD makes the claim that Hemogard® closures prevent spatter, unlike the conventional rubber caps which have a tendency to spatter the blood when being removed.

Question: Is shielding required during cap removal from BD blood tubes with a Hemogard® closure?

Reply: Blood tubes with Hemogard® closure have been designed to minimize spatter during the removal of blood tube caps. The manufacturers of blood tubes with Hemogard® closure provide specific instructions on the proper technique required to ensure that the device functions as intended. It is important to keep in mind that the effectiveness of an engineering device is often dependent upon the user. Additionally, compliance with the bloodborne pathogens standard requires, among other things, the use of engineering controls **and** appropriate work practices for preventing exposure to blood or OPIM [29 CFR 1910.1030(d)(2)(i)].

As you may know, the use of eye or face protection would be based on the reasonable anticipation of facial exposure. Masks, in combination with eye protection devices such as glasses with solid side shields, goggles, or chin-length face shields, must be worn whenever splashes, spray, spatter, or droplets of blood or other potentially-infectious materials (OPIM) may be generated, and eye, nose, or mouth contamination can be reasonably anticipated [29 CFR 1910.1030(d)(3)(x)]. Employers are responsible for evaluating the need for personal protective equipment. If the evaluation shows that spattering is not occurring, then the use of a shield would not be required, provided that all employees handling the blood tubes are trained in the proper removal of the Hemogard® closures and supervisors are ensuring that the proper technique continues to be used whenever the closures are removed.

01/16/2007 - OSHA requirements for providing training for first aid, CPR, and BBP for prompt treatment of injured employees at various workplaces.

Questions: You wrote that you teach first aid, including CPR, in the Winchester, VA, area. You have been asked by several employers what OSHA's standards are for first aid, including CPR and bloodborne pathogens. Your clients are employed at various workplaces, including, but not limited to, doctors' offices, construction companies, daycare facilities, and retirement homes. Does everyone have to be trained in first aid, including CPR and bloodborne pathogens? What if there is a career rescue squad within five miles of the workplace?

Replies: OSHA's standard for first aid training in general industry, 29 CFR 1910.151(b), provides:

In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid. Adequate first aid supplies shall be readily available.

In the construction industry, 29 CFR 1926.50(c) provides:
In the absence of an infirmary clinic, hospital, or physician, that is reasonably accessible in terms of time and distance to the worksite, which is available for the treatment of injured employees, a person who has a valid certificate in first-aid training from the U.S. Bureau of Mines, the American Red Cross, or equivalent training that can be verified by documentary evidence, shall be available at the worksite to render first aid.

The primary requirement addressed by these standards is that an employer must ensure prompt first aid treatment for injured employees, either by providing for the availability of a trained first aid provider at the worksite, or by ensuring that emergency treatment services are within reasonable proximity of the worksite. The basic purpose of these standards is to assure that adequate first aid is available in the critical minutes between the occurrence of an injury and the availability of physician or hospital care for the injured employee.

One option these standards provide employers is to ensure that a member of the workforce has been trained in first aid. This option is, for most employers, a feasible and low-cost way to protect employees, as well putting the employer clearly in compliance with the standards. OSHA recommends, but does not require, that every workplace include one or more employees who are trained and certified in first aid, including CPR.

The other option for employers is to rely upon the reasonable proximity of an infirmary, clinic or hospital. OSHA has consistently taken the view that the reasonable availability of a trained emergency service provider, such as fire department paramedics or EMS responders, would be equivalent to the "infirmary, clinic, or hospital" specified by the literal wording of the standards. Emergency medical services can be provided either on-site or by evacuating the employee to an off-site facility in cases where that can be done safely.

However, the requirements that emergency medical services must be "reasonably accessible" or "in near proximity to the workplace" are stated only in general terms. An employer who contemplates

relying on assistance from outside emergency responders as an alternative to providing a first-aid-trained employee must take a number of factors into account. The employer must take appropriate steps prior to any accident (such as making arrangements with the service provider) to ascertain that emergency medical assistance will be promptly available when an injury occurs. While the standards do not prescribe a number of minutes, OSHA has long interpreted the term "near proximity" to mean that emergency care must be available within no more than 3-4 minutes from the workplace, an interpretation that has been upheld by the Occupational Safety and Health Review Commission and by federal courts.

Medical literature establishes that, for serious injuries such as those involving stopped breathing, cardiac arrest, or uncontrolled bleeding, first aid treatment must be provided within the first few minutes to avoid permanent medical impairment or death. Accordingly, in workplaces where serious accidents such as those involving falls, suffocation, electrocution, or amputation are possible, emergency medical services must be available within 3-4 minutes, if there is no employee on the site who is trained to render first aid. OSHA exercises discretion in enforcing the first aid requirements in particular cases. OSHA recognizes that a somewhat longer response time of up to 15 minutes may be reasonable in workplaces, such as offices, where the possibility of such serious work-related injuries is more remote.

The first aid training standards at 29 CFR 1910.151 and 1926.50(c) generally apply throughout the industries that they cover. Other standards which apply to certain specific hazards or industries make employee first aid training mandatory, and reliance on outside emergency responders is not an allowable alternative. For example, see 29 CFR 1910. 266(i)(7) (mandatory first aid training for logging employees), and 29 CFR 1910.269(b) (requiring persons trained in first aid at work locations in the electric power industry).

The bloodborne pathogens standard at 29 CFR 1910.1030(g)(2) requires employers to provide training to any employees who have occupational exposure to blood or other potentially infectious materials, such as employees assigned medical or first aid duties by their employers. The standard at 29 CFR 1910.1030(b) defines "occupational exposure" as "reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties." If an employee is trained in first aid and identified by the employer as responsible for rendering medical assistance as part of his/her job duties, that employee is covered by the bloodborne pathogens standard.

02/05/2007 - Clarification on providing first aid training and maintenance of medical records under OSHA's BBP standard.

Scenario: The facility, a clinical laboratory, is located an average of four minutes away from a fire department that provides first aid assistance.

Question 1: Would it be acceptable under 29 CFR 1910.151(b) in Subpart K, "Medical and First Aid," for the facility to rely on the fire department and avoid having employees trained in first aid to address emergency situations on site?

Response 1: The OSHA standard at 29 CFR 1910.151(b) states: "In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for the treatment of all injured employees, a person or persons shall be adequately trained to render first aid . . . ." The primary requirement addressed by this standard is that an employer must ensure prompt first aid for injured employees, either by providing for the availability of a trained first aid provider at the worksite, or by ensuring that emergency treatment services are within reasonable proximity to the worksite. The basic purpose of this standard is to assure that adequate first aid is available in the critical minutes between the occurrence of an injury and the availability of physician or hospital care for the injured employee.

One option this standard provides employers is to ensure that a member of the workforce has been trained in first aid. This option is, for most employers, a feasible and low-cost way to protect employees, as well as putting the employer in compliance with the standard. The other option for employers is to rely upon the reasonable proximity of an infirmary, clinic, or hospital. OSHA has consistently taken the view that the reasonable availability of a trained emergency service provider, such as fire department paramedics or EMS responders, would be equivalent to the "infirmary, clinic, or hospital" specified by the literal wording of the standard. Emergency medical services can be provided either onsite or by evacuating the employee to an off-site facility in cases where that can be done safely.

An employer who contemplates relying on assistance from outside emergency responders as an alternative to providing a first-aid trained employee must take a number of factors into account. The employer must take appropriate steps prior to any accident (such as making arrangements with the service provider) to ascertain that emergency medical assistance will be promptly available when an injury occurs. While the standard does not prescribe a number of minutes, OSHA has long interpreted the term "near proximity" to mean that emergency care must be available within no more than 3-4 minutes from the workplace. This interpretation generally has been upheld by the Occupational Safety and Health Review Commission, an independent tribunal that decides OSHA cases, and by federal courts.

Medical literature establishes that for serious injuries, such as those involving stopped breathing, cardiac arrest, or uncontrolled bleeding, first aid treatment must be provided within the first few

minutes to avoid permanent medical impairment or death. Accordingly, in workplaces where serious accidents, such as those involving falls, suffocation, electrocution, or amputation are possible, emergency medical services must be available within 3-4 minutes if there is no employee on the site who is trained to render first aid. Since your facility is an *average* of 4 minutes from the fire department and thus possibly more than 4 minutes away from the fire station in reality, you may not rely on its emergency service providers to fulfill your obligation under the standard if such serious injuries are possible at your workplace. As a matter of enforcement discretion, OSHA recognizes that a somewhat longer response time of up to 15 minutes may be reasonable in workplaces, such as offices, where the possibility of such serious work-related injuries is more remote. If that is the case in your workplace, you are allowed to rely on the fire department, which is an average of 4 minutes away from your workplace.

Question 2: Is it acceptable for the employer to provide training on first aid, including CPR, as well as first aid supplies, to employees who are not officially responsible for performing first aid, including CPR, and who would be responding on a voluntary basis?

Response 2: The OSHA standard, 1910.151(b), does not prohibit employers from providing first aid training to employees, even when the employees will not be expected to respond in workplace emergencies. However, if the company does not plan to designate employees as first aid responders, then OSHA would recommend that employees who participate in company-provided first aid training (including CPR) should be made aware of the company's plan for addressing all workplace medical emergencies.

Question 3: Under 29 CFR 1910.1030, may a company use employee numbers in place of social security numbers in the company's medical record file when the company only maintains declination forms, dates of vaccination, titer results, and dates of treatment? All other medical records and information regarding employee's medical examinations are maintained by the healthcare professional where treatment is provided.

Response 3: Section 1910.1030(h)(1)(ii)(A) of the bloodborne pathogens standard requires that employee medical records shall include the name and social security number of the employee.

Medical records must be ". . . provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director of the National Institute of Occupational Safety and Health [NIOSH] and to the Assistant Secretary of Labor [OSHA]."

if a company chooses to keep a second set of records which are identified by employee numbers in place of social security numbers, it may do so. However, whenever a record is requested by an employee, a designated employee representative, or representatives of the OSHA or NIOSH, the employer must assure access to the records containing the employee's social security number within a reasonable time, place, and manner.

08/01/2007 - Whether an employer is required to start over an incompleted Hepatitis B vaccination series.

Dear Dr. _____;

This letter is in response to your letter of January 22, 2007 concerning the potential expense involved in the administration of hepatitis B vaccinations. You ask in particular if an employer is required to start the vaccination series for a new employee over again, if the employee had not completed the scheduled shots in the series. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

Employers who have employees with reasonably anticipated exposure to blood or other potentially infectious material (OPIM) are required to provide the hepatitis B vaccination series at no cost to the employee [29 CFR 1910.1030(f)(2)(i)]. The vaccination series must be provided in accordance with the recommendations of the U.S. Public Health Service current at the time of the vaccination [29 CFR 1910.1030(f)(1)(ii)(D)]. If it can be documented that a new employee has already received part of the vaccination series, the healthcare professional responsible for the employee's hepatitis B vaccination must use this information as part of the evaluation. It is usually not necessary to restart the vaccination series if an employee misses the scheduled date for a shot. Even though the usual frequency of the shots in the vaccination series is at 0, 1, and 6 months, the U.S. Public Health Service (USPHS) provides for some flexibility in scheduling. If the series is interrupted after the first dose, the second dose must be administered as soon as possible, and the second and third doses must be separated by an interval of at least 8 weeks. If only the third dose has been delayed, it must be administered as soon as possible. This permits a certain flexibility, and there should be little or no added financial burden on a reasonably diligent employer if an employee misses a date for a shot. The employer would simply reschedule the missed shot as soon as possible.

You must also have your employee tested for antibody to Hepatitis B surface antigen, one to two months after the completion of the three-dose vaccination series. Post-vaccination testing must be completed 1-2 months after the third vaccine dose for results to be meaningful. A protective antibody response is an anti-HBs concentration of 10 or more milliInternational Units per milliliter (≥10mIU/mL). Employees who do not respond to the primary vaccination series must be revaccinated with a second three-dose vaccine series and retested, unless they are HbsAg-positive (infected).

10/26/2007 - OSHA does not regulate the final disposal of medical waste.

Dear Mr. _____:

This is in response to your letter in which you ask the Occupational Safety and Health Administration (OSHA) to comment on the disposal of unground medical waste in landfill operations. You made several assertions in favor of requiring medical facilities and other medical waste generators to ensure that all medical wastes are ground or shredded prior to being transported to landfills. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any situations not delineated within your original correspondence. We apologize for the delay in providing a response to your concerns.

OSHA agrees with your comments that medical waste can indeed present numerous potential dangers to downstream handlers (e.g., employees in landfills, recycling facilities, etc.). The hazards include the potential for lacerations and other percutaneous injuries as well as the risk of exposure to bloodborne pathogens. However, OSHA does not regulate the final disposal of medical waste. OSHA stated in the Bloodborne Pathogens Standard at 29 CFR 1910.1030(d)(4)(iii)(C): *disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.*

The OSHA standard provides that regulated waste containing contaminated sharps be discarded in containers which are: a) closable, b) puncture resistant; c) leakproof on sides and bottom; and d) labeled or color-coded in accordance with the standard [29 CFR 1910.1030(d)(4)(iii)(A)]. OSHA established these provisions for the protection of employees within the facility that generates the contaminated sharps as well as for those who must handle the waste downstream. These measures are generally consistent with the requirements of most state regulations with regard to the handling (i.e., segregation, containment, and labeling) of used sharps. As you may already know, there may be variation among different states with regard to acceptable measures of treatment of medical waste prior to final disposal. You may want to contact individual states for clarification on the requirements enforced within their jurisdiction.

04/18/2008 - Placement of sharps containers and requirement to ensure they are maintained in an upright position.

Question: In a laboratory where sharps containers are kept close to employees' workstations with lids and are positioned so that they are kept upright, is it necessary to have "mechanisms" to restrain the containers as a precaution from spillage?

Reply: As you may know, 29 CFR 1910.1030(d)(4)(iii)(A)*(2)(ii)*, requires that during use, containers for contaminated sharps must be: "[m]aintained upright throughout use. . ." The use of mechanisms to restrain sharps containers is one way of preventing spillage during use; however, the Bloodborne Pathogens Standard does not specify the use of restraining mechanisms for all situations of sharps container use. For example, if a workplace assessment reveals that sharps containers can be maintained in an upright position during use with no danger of being knocked over or spilled, or that the containers **must** remain unrestrained to accommodate mobility needs, or employees or patients might be endangered by fixed sharps containers (e.g., in a mental health or correctional facility), the use of restraining mechanisms would not be mandatory. The placement of sharps containers, as well as the measures used to maintain them in an upright position during use, must be based on the site-specific hazard assessment of the area of intended use.

The National Institute for Occupational Safety and Health's (NIOSH's) document, *Selecting, Evaluating, and Using Sharps Disposal Containers*, makes recommendations on several important components of a site-specific hazard analysis in the selection of sharps containers. Among other things, NIOSH recommends that the employer consider: i) container transport or mobility needs; ii) clinician and procedural variability and movement; and iii) laboratory equipment variability and movement.[1] If, after evaluating the work environment, an employer determines that restraining mechanisms are not required, but makes the decision to install them as an added measure to ensure the sharps containers are maintained upright, doing so should not, in itself, create an unsafe or unhealthful condition. [See 29 CFR 1910.1030(c); exposure control plan.]

09/09/2008 - OSHA's position on the use of lancets or lancing devices without safety-engineered features for finger prick blood sampling in the workplace.

Scenario: There are two basic types of lancing devices for workplace use; standard exposed blade lancets and safety type lancets (typically with a spring-loaded auto-retracting blade.)

Question: What is OSHA's position on the use of lancet or lancing devices without safety-engineered features in the performance of finger prick blood sampling in the workplace? Is the use of standard exposed blade lancets acceptable in the workplace for finger prick blood sampling, assuming all other precautions for the use and disposal of sharps devices are followed?

Response: OSHA's bloodborne pathogens standard requires that employers use engineering and work practice controls to eliminate occupational exposure or reduce it to the lowest feasible extent [29 CFR 1910.1030(d)(2)(i)]. In order to prevent accidental needlestick injuries, employers must provide lancets with safety-engineered features for employees who perform finger prick blood sampling in the workplace (e.g., healthcare workers), unless the use of those devices is somehow contraindicated in a particular disease. As always, if using a safer device compromises either patient safety or medical integrity, its use would not be required.

As you may know, the Bloodborne Pathogens Standard, 29 CFR 1910.1030, does not apply to the self-administered personal tests by employees or residents of an establishment. An employee who is diabetic, for instance, may have the need to self-administer finger pricks to periodically test his/her own blood glucose level. Likewise, in some residential settings (e.g., group homes, assisted living or, in certain situations, nursing care facilities), the residents themselves may also self-test and have the need to use lancets. Self-testing with standard lancets, whether done by employees or residents at a workplace setting, would not be covered. The improper disposal of standard lancets or other needles used by those who self-test and/or self-administer medication however, can create a safety hazard for maintenance workers, waste handlers, and other staff placing them at risk for exposures to bloodborne pathogens including HIV/AIDS, hepatitis B, and hepatitis C from needlestick injuries. Therefore, OSHA recommends that employers require employees and residents to appropriately discard of their used sharps, rather than allowing them to be discarded in regular office trash. Providing sharps containers for proper disposal or encouraging the use of commercially available sharps containers manufactured and marketed for home use would be appropriate ways to assure safe disposal.

08/11/1995 - Permanent variance from the labels and signs requirements of the Bloodborne Pathogens standard.

Dear Mr._____:

This is in response to your letter of June 20, addressed to Ms. Ruth McCully, Director of the Occupational Safety and Health Administration (OSHA) Office of Health Compliance Assistance, concerning your request for a permanent variance from the labels and signs requirements of the Bloodborne Pathogens standard [29 CFR 1910.1030(g)(1)(i)]. Your letter has been forwarded to the Directorate of Technical Support for a response.

In your letter you requested a permanent variance on behalf of the member companies of the International Society of Blood Transfusions (ISBT) Working Party on Automation and Data Processing. Our evaluation of OSHA's Bloodborne Pathogens standard indicates that blood products are exempted from the labeling requirements. Paragraph 29 CFR 1910.1030(g)(1)(i)(F) negates the need for a variance. This standard states that "Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g)." Therefore, no variance is required from the requirements of 29 CFR 1910.1030(g)(1)(i).

10/29/1996 - Clarification of OSHA's Bloodborne Pathogens Standard as it relates to syringes and needles contaminated with both a bloodborne pathogen and radioactive nuclear medicine.

Dear Mr. _____:

This is in response to your letters of August 9, and the April 9, from Mr. Haig S. Bagerdjian concerning the status of a request for clarification of the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030) as it relates to syringes and needles contaminated with both a bloodborne pathogen and radioactive nuclear medicine. The primary question related to OSHA's jurisdiction over nuclear medicine, and the remaining questions were a followup based on the assumption that OSHA has jurisdiction. Please accept our regret in the delay in responding to your inquiry.

The Nuclear Regulatory Commission (NRC) has jurisdiction over the disposal of syringes and needles containing a mixed waste. The NRC and OSHA have jurisdiction over occupational safety and health at NRC-licensed facilities. OSHA and the NRC have a memorandum of understanding (MOU) that delineates the general areas of responsibility of each agency. The intent of the MOU was to minimize duplication of regulation and efforts. Each agency has its place in worker protection. NRC typically covers hazards associated with the following: radiation risk produced by radioactive materials; chemical risk produced by radioactive materials; and facility conditions which affect the safety of radioactive materials and thus present an increased radiation risk to workers. OSHA typically covers hazards associated with "facility conditions which result in an occupational risk, but do not affect the safety of licensed radioactive materials." Therefore, NRC has jurisdiction over the conditions and practices that affect the safety of licensed radioactive materials. In the case of syringes contaminated with a mixed waste, such as radioactive materials and bloodborne pathogens, if the components are covered by the NRC license, OSHA does not have jurisdiction.

10/05/1998 - Bloodborne Pathogens standard: Group purchasing agreements in healthcare facilities; engineering controls.

Dear Mr. _____:

This is in response to your letter dated June 19. We apologize for the long delay. You have requested that the Occupational Safety and Health Administration (OSHA) provide an interpretation of CFR 1910.1030, Bloodborne Pathogens standard. Specifically you have asked if the use of group purchasing agreements in healthcare facilities is a violation of the Bloodborne Pathogen standard.

OSHA's Bloodborne Pathogen standard has a provision that requires an employer to evaluate medical devices that may eliminate or minimize employee exposure 29 C.F.R. §1910.1030 (c)(1)(iv). In accordance with this provision, the employer is not automatically required to institute the most sophisticated engineering controls, but it is the employer's responsibility to evaluate existing controls and to review the feasibility of instituting more advanced engineering controls. This section of the standard is performance oriented. That is, OSHA does not mandate what products must be evaluated or purchased. The standard provides the necessary flexibility for the employer to choose the most suitable products to fit the needs of the facility. OSHA also requires that employers examine and maintain or replace on a regular schedule engineering controls to ensure their effectiveness 29 C.F.R. §1910.1030(d)(2)(ii).

OSHA requires employers to eliminate or minimize employee exposures through reasonable and feasible engineering and work practice controls; but OSHA does not have jurisdiction over contract agreements and therefore cannot determine the legality of GPO arrangements. OSHA would require compliance with the BBP standard regardless of these contractual obligations between the GPO and the hospitals.

The Food and Drug Administration (FDA) approves medical devices for marketing. Since the Bloodborne standard took effect, there has been a great surge in medical device manufacturing. There are currently many safe needle devices on the market. As you know, OSHA cannot and does not endorse, review, or approve medical devices. The real test of compliance with OSHA standards comes about by observation in the workplace. Medical devices generally have specific instructions that must be followed when using them. The safety features that they provide may become more of a hazard if the employee is not using the device correctly. The compliance with the OSHA standard must be established at the time of inspection.

As a point of further information, OSHA has recently published a Request for Information (RFI) relative to prevention of percutaneous injuries (enclosed). If you would like to submit information or comments in response to the RFI, they should be submitted in quadruplicate to the Docket Officer, Docket No. H370A, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW, Washington, DC 20210. Additional information on submission of comments can be found under the "Addresses" section of the notice.

Employer's responsibility to provide time and transportation for Hepatitis B vaccinations. [07/07/1999]

Thank you for your April 14, 1999 letter to the Occupational Safety and Health Administration (OSHA). We apologize for our delay in responding to your important questions. We hope that this letter will serve as a useful resource in addressing the concerns of your affiliates regarding the employer's obligation in the Hepatitis B vaccination process.

The issue regarding employee vaccinations for bloodborne pathogens is clearly documented in 29 CFR 1910.1030, Bloodborne Pathogens, and its current directive, OSHA Instruction [CPL 2-2.69, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens]. Your questions are outlined below, followed by OSHA's interpretation.

1. Must the employer either provide or pay for transportation to and from the site where the Hepatitis B vaccination will be administered?

According to the standard, "the employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are: (A) Made available at no cost to the employee; (B) Made available to the employee at a reasonable time and place." Employees may incur "no out of pocket expense" for the vaccine and vaccination series. While transportation may not need to be provided by the employer, its cost must be covered by the employer.

2. Are all activities associated with obtaining a Hepatitis B vaccination, in fact, work functions and, consequently, is all time associated with receipt of the vaccination work time?

The current directive specifically states in Section (f)(1)(ii)(B) that, "The term 'reasonable time and place' requires the medical procedures and evaluations to be convenient to the employee. They*shall be offered during normally scheduled work hours*. If participation requires travel away from the worksite, the employer must bear the cost." Plainly, this would mean that when receiving the vaccine or commuting to have it administered, employees must be considered "on-duty."

You mention that this issue of compliance is being debated between your affiliates in New York State. We must inform you that since New York is an OSHA state plan state, this is something that needs to be resolved within the jurisdiction of that state plan. The state plan covers state and local employees and must institute and enforce employee safety standards that are at least as effective as those at the national level. If you have not already done so, you may reach the New York State Plan at:

New York Department of Labor
John E. Sweeney, Commissioner
W. Averell Harriman State Office
Building 12, Room 500
Albany, NY 12240
(518) 457-2741

10/29/1999 - Employers must ensure that post-exposure follow-up procedures are provided.

Dear Mr. _____:

We apologize for the delay in our response to your letter of June 23, 1999 which was forwarded to the Occupational Safety and Health Administration's (OSHA's) Office of Health Compliance Assistance (OHCA) by the Chicago Regional Office. You requested a clarification regarding the standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The bloodborne pathogen standard requires that an employer provide the vaccination series and post exposure follow-up procedures to an employee in the event of an exposure. You asked for an interpretation of "who is responsible for the follow-up when an employee of one facility has a blood exposure in another facility." As described in your scenario, the physicians are the employees, the Clinic is the employer and the Hospital is a host employer. The employer, in this case the Clinic, would be responsible for providing follow-up procedures at no cost to the employee.

Contractual agreements between the employees and the host employer, such as you have described, are not part of OSHA's jurisdiction. OSHA's requirement simply states that it is the employer's (the Clinic's) duty to ensure that follow-up procedures are accomplished. The employer (the Clinic) would be subject to citation if follow-up procedures were not provided.

You also asked if the Hospital, who will do all the testing, acting as a healthcare professional, must abide by §1910.1030(f)(5) and provide the Clinic with the information as described in paragraph (f)(5). As stated in the standard, the employer (the Clinic) must obtain a written opinion from the healthcare professional (the Hospital) and provide it to the employee within 15 working days. The employer (the Clinic) is allowed access specifically to the healthcare professional's written opinion in order to comply with this paragraph of the standard.

12/05/2007 - Clarification on the requirement for a written opinion from an examining physician.

Dear Mr. _____:

Thank you for your May 5, 2006 letter to the Occupational Safety and Health Administration (OSHA), Directorate of Enforcement Programs, requesting clarification on the requirement for a written opinion from an examining physician. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions or situations not delineated within your original correspondence.

As you stated in your letter, there are a number of expanded health standards that require the employer to provide the employee with a medical examination and "obtain a written opinion from the examining physician." In each of these standards, OSHA considers the physician supervising the medical examination to be the "examining physician." A healthcare professional person who works under the supervision of a licensed physician and performs a medical examination may write a medical opinion for the physician, but the physician must review the opinion, concur with the opinion, and assume responsibility for the opinion. Therefore, the signature on the opinion must be the physician's signature.

Recent standards allow for written opinions from other healthcare professionals (PLHCPs), but only when they are legally permitted by their professional license to independently conduct the type of medical evaluation required. In many cases, however, the required signature on the opinion would still be the physician's. This can vary state by state according to their licensing laws and what scope of practice is permitted for each healthcare professional.

11/01/1999 - Bloodborne Pathogens: Handwashing facilities must be readily accessible.

Dear Dr. _____:

This is in response to your letter of August 10, 1999, requesting an interpretation of the Federal Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens standard with regard to the need for handwashing facilities in exam rooms.

Basic handwashing remains a fundamental element of infection control practices. Facilities for proper handwashing need to be readily available in all areas where occupational exposure to bloodborne pathogens is anticipated, since gloves may not provide complete protection against bloodborne pathogens. All medical examinations do not have to assume contact with blood or Other Potentially Infectious Material (OPIM). Exam rooms, where procedures are limited to taking blood pressures and temperatures or other simple non-invasive procedures, would not require handwashing facilities or even gloves. However, for a medical practice which routinely performs pelvic and rectal examinations such as you described, contact with blood or OPIM can more than reasonably be anticipated.

Paragraph 1910.1030(d)(2)(iii) of the standard requires employers to provide handwashing facilities where employees have easy access to them. This increases the likelihood of use, minimizes the amount of time that contamination must remain in contact with the skin, reduces contaminant migration resulting from employees traveling to remote locations in order to wash hands, and fosters an attitude of compliance due to accessibility of proper facilities.

"Readily-accessible" was not defined in the standard. However, an employee must not have to travel through several doorways, halls, and stairways to wash his/her hands. This would greatly increase the risk of surface contamination in a far broader area than is generally considered the "work area." Since all work areas must be decontaminated after contact with blood or OPIM, OSHA would expect wash facilities to be suitably located to eliminate contamination of surfaces beyond the appropriate work area.

06/11/2001 - Decontamination and labeling requirements for BBP-contaminated equipment and sharps.

Dear Mr. _____:

Thank you for your March 23 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Compliance Programs regarding the applicability of the Bloodborne Pathogens standard (29 CFR 1910.1030) to labeling and shipping contaminated medical devices. We appreciate your continued correspondence and contact with our staff regarding this rather complicated matter. We hope that this letter suits your needs. We have restated your scenarios and questions below and added our responses. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any scenario not delineated within your original correspondence.

Scenario 1: In some instances, equipment that is contaminated with blood or other potentially infectious materials (OPIM) needs to be returned to the manufacturer in an un-tampered condition... The items are prepared for shipment (e.g., primary and secondary packaging, labeled, etc.) in such a way that there is no reasonably anticipated employee contact with the blood or OPIM. The employees who handle the equipment upon receipt are trained to do so in a safe manner (e.g., engineering controls, personal protective equipment, in-house decontamination, etc.).

Question 1: Would such measures be in compliance with the OSHA (Bloodborne Pathogens) Standard?

Response: Yes. If conscious efforts are made to decontaminate the equipment to the greatest extent feasible, proper labels are applied, employees are trained with regard to the handling of the equipment, and packaging is done in such a way that potential employee exposure is minimized, compliance would be achieved. In the scenario that you describe, it appears that the proper precautions and controls were implemented for shipping contaminated equipment.

It is OSHA's intent to protect all employees, on the packing, shipping and receiving ends, from potential exposures to blood and other potentially infectious materials (OPIM). If shipping and labeling contaminated medical equipment are done in accordance with the requirements of the standard, exposures are minimized and compliance is achieved. Paragraph (d)(2)(xiv) of the standard states that **"(e)quipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible."**

Specifically, for equipment prepared for shipment, the standard requires that **"...(A) readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated. (B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken."** With respect to sections or entire parts of equipment that

cannot be decontaminated, paragraph (g)(1)(i)(H) states, **"(l)abels required for contaminated equipment shall... state which portions of the equipment remain contaminated."** Where decontamination is not feasible for certain equipment, controls must be in place to protect employees, both of which must be documented in the employer's exposure control plan (ECP), as explained further below.

Scenario 2: Consider the situation where a shipment of equipment contaminated with residual human blood is being prepared for transport. It is my understanding that the Agency's hazard warning labeling requirements are only applicable to the actual container (e.g., bag, bottle, box, etc.) holding the shipped item. In the event that the outside of the primary container becomes contaminated, a biohazard label would also be required on a secondary container. OSHA regulations would not, however, require any labeling on the outer, tertiary shipping carton provided that the product is fully contained by the inner containers and there is no reasonably anticipated employee contact with blood.

Question 2: Is this understanding correct? Would it also apply to shipping blood specimens?

Response: Yes. The intent of the labeling requirements under the standard is to communicate the hazard of the blood or OPIM to the employees. If the primary and secondary containers are labeled appropriately, it is assumed that the hazard has been communicated and the employees would be protected on the packing, shipping, and receiving ends. Further, any labeling of tertiary or outermost containers would not be mandated by OSHA, but rather by the Department of Transportation.

Scenario 3: ...At least one medical equipment manufacturer... has not yet identified a chemical sterilant or tuberculocidal disinfectant that is compatible with a particular type of equipment that performs numerous automated immunodiagnostic assays... The employer's exposure control plan explains the limitations of the decontamination process and includes protective measures to be followed when the equipment is serviced or shipped.

Question 3: Is this an acceptable interim measure while a chemically compatible EPA-registered tuberculocide is being identified and validated?

Response: Yes. In the scenario that you describe, complete decontamination of equipment may not be feasible. Therefore, it is important that the employer document all methods of compliance relating to potential blood and OPIM hazards in its exposure control plan (ECP), specifically those related to methods of decontamination and proper handling of contaminated equipment. The ECP must be reviewed and updated at least annually. When an appropriate decontaminant for this equipment becomes available, the employer would be required to use it and include that information in the ECP.

Question 4: If the item to be shipped is a contaminated sharp, would OSHA agree that the sharp is required to be deposited directly into a puncture resistant container for shipping, and that prior to shipment decontamination is not necessary? Assume that the consignee is aware of the shipment, the shipper and consignee employers have incorporated instructions into their exposure control plans and trained employees, and the sharp is decontaminated upon receipt - prior to any manual handling.

Response: According to paragraph (d)(4)(iii)(A)(1) of the standard **"(c)ontaminated sharps shall be discarded immediately or as soon as feasible in containers that are: (i) closable; (ii) puncture resistant; (iii) leakproof on sides and bottom; and (iv) labeled or color-coded in accordance (with the standard)."** The purpose for this requirement is to prevent occupational needlesticks and other percutaneous injuries from contaminated sharps. Therefore, OSHA requires that contaminated sharps (e.g., reusable scalpels, needles, etc.) be put directly in a sharps container after use, without individual device decontamination. This minimizes employee handling of devices, thereby decreasing the risk of an injury.

If a reusable sharps container is shipped to another facility to be decontaminated or reprocessed, of course, all the aforementioned labeling and shipping requirements would apply. When opening and emptying a container in order to decontaminate or clean the reusable items in it, the process to open that container must be done in a manner that is not manual, as discussed in paragraph (d)(4)(iii) of the standard. The procedures and protocols used for the disposal of and/or decontamination of reusable sharps must also be included in the ECP.

09/10/2001 - Plasma derivatives are covered by the Bloodborne Pathogens Standard.

Dear Mr. _____:

This letter is in response to the Plasma Protein Therapeutics Association's (PPTA's) February 15, 2000 and August 27, 2001 correspondence. The February 15, 2000 letter from PPTA's then-Director of Regulatory Affairs, Mr. Jason Bablak, to the Occupational Safety and Health Administration's (OSHA's) [Office of Health Enforcement] pertained to the coverage of plasma derivatives under the Bloodborne Pathogens Standard ("the standard" or "BPS"), 29 CFR §1910.1030. His letter followed an informal meeting he had with Mr. Craig Moulton of this office.

Within the last year and a half, we sent two interim letters to Mr. Bablak explaining the extensive research that would be necessary to formulate our response. Again, we apologize for the delay and hope that this letter serves as an answer to PPTA's request. We appreciated his including the background and supplemental information along with his request for an exemption under the standard.

We have carefully reviewed PPTA's package. PPTA's request is outlined below, followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any situations not delineated within the original correspondence.

Plasma Protein Therapeutics Association (PPTA) is a trade association representing the major commercial processors of plasma derivatives. PPTA requests that, "OSHA limit its interpretations that include plasma derivatives in the BPS definition of 'blood,' and provide an exemption from the standard for FDA-approved, US-licensed plasma derivatives that have undergone viral inactivation and/or removal processes."

Your request deals only with plasma derivatives after they have been fully processed, such as when they are used in a health care facility. As you know, the Bloodborne Pathogens Standard is intended to protect workers in diverse settings from occupational exposure to blood and other potentially infectious materials (OPIM). The standard's definition of blood includes, *"human blood, human blood components, and products made from human blood"* [29 CFR §1910.1030(b)]. Clearly, because plasma derivatives are derived from human blood, they would be considered to be *"products made from human blood"*; plasma derivatives are covered by the standard.

Although it is true that OSHA exempts certain human cell lines from the BPS, human cell lines do not come under the definition of "blood." They are covered under subparagraph (b) of the definition of "Other Potentially Infectious Materials," which applies to cell or tissue cultures *only* if they actually contain a pathogen.

Your letter raises the question of whether occupational exposure to fully processed plasma derivatives in the absence of the precautions prescribed in the standard should be regarded as a *de minimis* violation, which would not require abatement or trigger a penalty. (According to 29 U.S.C. §658(a), the Secretary of Labor may issue *de minimis* notices *"...with respect to de minimis violations which have no direct or immediate relationship to safety or health."*) Please be aware that for the reasons listed

below we do not consider violations of the standard based on exposure to fully processed plasma derivatives to be de minimis; we expect full compliance with the standard for these products.

Although the FDA requires blood testing for hepatitis B, HIV, and syphilis (21 CFR §§610.40, 610.45, 640.5), and has also proposed to require testing for hepatitis C and human T-lymphotropic virus [64 FR 45340 August 19, 1999], the FDA has no actual or proposed regulations on testing for parva-virus B19 and other pathogens, such as those causing arboviral infections, Creutzfeldt-Jakob disease, and viral hemorrhagic fever. Also, new viruses, for which there are no testing procedures, may arise. It should be remembered that HIV was once a new virus; AIDS appeared in blood transfusion recipients and others before the HIV virus was isolated in 1983 and 1984 [Preamble to OSHA Bloodborne Pathogen Standard, 56 FR 64013 (December 6, 1991)].

It can not be stated with certainty that FDA testing protocols for viral inactivation of plasma derivatives will protect workers from ***all*** occupational exposure to bloodborne pathogens. While most "finished product" plasma derivatives may be free from the pathogens listed above, even the FDA recognizes that *"...despite multiple precautions, there are occasions when problems are identified which may increase the potential risk that the plasma derivative may transmit a communicable disease."* [(Plasma Derivatives and Other Blood-Derived Products) 64 FR 45384 (June 15, 1999) (Requirements for Trucking and Notification)].

The FDA also states in its "Blood Action Plan" that many of its requirements for the U.S. blood supply are obsolete and in need of revision. Also, studies indicate that, though small, there is a risk of transmission of the pathogen causing Creutzfeldt-Jakob disease (CJD) or other currently unrecognized human viruses from blood products that may be corrected by improving viral and bacterial inactivation procedures (Mary E. Chamberland et al., *Blood Safety, Emerging Infectious Diseases*, Vol 4, 1998).

We would also like to point out that not applying the standard to plasma derivatives will have no appreciable effect on the BPS compliance responsibilities of the health care industry. Health care workers, such as nurses, who would handle plasma derivatives, already have occupational exposure to human blood and other potentially infectious materials; their employers must comply with the BPS for these exposures.

08/22/2002 - Universal precautions application to elective Surgeries.

Dear Senator_____:

This letter is in response to the letter you forwarded from your constituent, Dr. Joseph W. Hayhurst. His letter conveyed some concerns about performing elective cosmetic surgery on HIV-positive patients. Dr. Hayhurst wanted to know how OSHA's enforcement of the bloodborne pathogens standard, 29 CFR 1910.1030 would affect this issue. Most of Dr. Hayhurst's letter deals with issues involving the Americans with Disabilities Act, patients' rights, and actions of the state medical association. Since none of these issues falls within OSHA's jurisdiction we will not address them here.

The issue in Dr. Hayhurst's letter that does concern OSHA is occupational exposure to bloodborne pathogens during surgery. Dr. Hayhurst feels that, because of the possibility of contracting the Human Immunodeficiency virus (HIV), health care personnel should not perform medical procedures on known HIV patients if the procedure is not medically necessary. However, neither the OSHA bloodborne pathogens standard nor any other requirement under the Occupational Safety and Health Act of 1970 prohibit employees from performing such procedures.

The basis of infection and exposure control philosophy as well as for the bloodborne pathogen standard is that all blood or other potentially infectious materials must be handled with universal precautions. Specifically, in its 1987 document, "Recommendations for the Prevention of HIV Transmission in Health-Care Settings," the Centers for Disease Control state:

Since medical history and examination cannot reliably identify all patients infected with HIV or other bloodborne pathogens, blood and body-fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC and referred to as "universal blood and body-fluid precautions" or "universal precautions" should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown.

Applying this concept, the bloodborne pathogen standard applies to all occupational exposure to blood or other potentially infectious materials (OPIM). The standard defines "Universal Precautions" as "...an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens."

Therefore, blood and tissue must be handled in the same manner regardless of a patient's perceived or known risk. Thus, if refraining from performing elective surgery were an abatement method under the bloodborne pathogens standard, all elective surgery would be barred; this was clearly not the intent of the standard. OSHA found that the standard, which requires engineering and work practice controls and personal protective equipment, among other things, "...will result in a substantial reduction of significant risk." (56 FR 64036).

OSHA specifically found, "...the above listed provisions of the standard will also reduce exposure to HIV infected body fluids and other materials thus reducing the risk of infection to HIV." 56 FR 64038 (Dec. 6, 1991). Finally in the Needlestick Safety and Prevention Act, PL 106-430, 114 Stat. 1901, passed in 2000, Congress found in Section 2: "(3) Compliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work;" and "(7) Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are a part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries."

Dr. Hayhurst also specifically expresses concern about the possibility of HIV infection due to vaporization of tissue during liposuction. In the preamble to the bloodborne pathogen standard OSHA extensively discussed aerosolization of blood and other potentially infectious materials. Although two experts from the University of California at San Francisco presented data about a potential respiratory hazard from the inhalation of blood-containing aerosols and others supported their views, many experts, including those from CDC and the National Institute of Occupational Safety and Health (NIOSH), stated there were no cases of bloodborne disease traceable to airborne transmission. These conflicting opinions, coupled with the lack of information, prevented OSHA from regulating aerosols (56 FR 64120-22).

Dr. Hayhurst may wish to contact the National Institute for Occupational Safety and Health (NIOSH) to obtain further information from them on any studies they may be conducting regarding aerosolization exposure to infectious material during surgical procedures. NIOSH can be reached by calling 1-800-35-NIOSH.

As opposed to aerosols, solid or liquid particles, ranging in size from submicrometer to multi-micrometer which are suspended in a gas (56 FR 64120), the standard does regulate the generation of droplets. It states at 29 CFR 1910.1030(d)(2)(xi): "All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances."

01/23/2003 - Evaluation of sutureless catheter securement devices to prevent needlestick hazards.

Dear Congressman _____:

This is in response to your letter of November 21, in which you expressed your concern about the needlestick hazard which healthcare professionals face when securing catheters with sutures. The Occupational Safety and Health Administration (OSHA) shares your concern about the hazards of needlesticks and has demonstrated this by revising the Bloodborne Pathogens Standard (29 CFR 1910.1030) in response to the Needlestick Safety and Prevention Act of 2000.

The revised Bloodborne Pathogens Standard requires employers whose employees have occupational exposure to blood and other potentially infectious materials (OPIM) to implement appropriate and available safer medical devices designed to eliminate or minimize occupational exposure. Employers must solicit the input of frontline employees in the identification, evaluation, and selection of safer devices. Sutureless catheter securement devices are one type of the safer devices that may be evaluated in this required process. According to OSHA's traditional adherence to a hierarchy of controls and basic industrial hygiene practice, engineering and work practice controls must be instituted as the primary means of eliminating or minimizing employee exposure. Suture needles used to secure catheters on a patient constitute a hazard regulated by the standard. OSHA recognizes that eliminating the need to use suture needles decreases the risk of a potentially hazardous procedure. The use of sutureless securement devices is one method an employer can use to eliminate this potential needlestick hazard.

During an employer's annual review of his Exposure Control Plan (ECP), he must evaluate the practices and processes used in the facility and address the methods by which exposure to blood and OPIM will be controlled (29 CFR 1910.1030(c)). The ECP must also address implementation and evaluation of proper engineering and work practice controls, personal protective equipment, and employee training. If an employer determines that an alternative to using sutures to secure catheters is appropriate and feasible, he must implement it. If, however, an employer determines that no alternative is feasible (e.g., it compromises patient safety or the medical procedure), then he must document that in his ECP and re-evaluate alternative engineering controls or substitution methods the following year.

In your letter you ask that OSHA consider issuing an information bulletin regarding needlestick hazards associated with suture securement of catheters. We try to be very cautious about taking any action that might be perceived to be an endorsement of aspecific product. For this reason, OSHA does not provide a list of safer devices or recommend specific types of devices. Apparently, there is currently only one manufacturer who produces a catheter securement device that reduces or eliminates the need for suturing. We will continue to evaluate whether an information bulletin is

appropriate as resources permit. We are sharing information about this device with our compliance assistance staff to ensure that they are aware of this device as an option to employers.

01/29/2004 - Concern of potential adverse affects from latex by consumers and health care patients with Hevea Natural Rubber Latex Allergy.

Dear Ms. _____,

Thank you for your July 27, 2003 letter to the Occupational Safety and Health Administration's (OSHA) Directorate of Enforcement Programs. You letter summarizes several objections and concerns that you had regarding two proposals before ASTM that involved the color-coding of latex gloves and the prohibition on their use by food handlers. Your concern stems from the potential adverse effects from latex by consumers and health care patients with Hevea Natural Rubber Latex Allergy (HNRLA).

While we are familiar with the hazards associated with latex allergy, OSHA rules and regulations do not cover consumers or health care patients, rather employers and employees in occupational settings. In a workplace, an employer is required to assess the potential hazards present, select the appropriate personal protective equipment (PPE), communicate their selection decisions to employees, and train them on the use, limitations, and care of the equipment. These general requirements for PPE are found at 29 CFR 1910.132.

The use of gloves in food service is intended to maintain a proper level of sanitation to ensure food safety for consumers. The gloves are not chosen to protect the worker from the food, but rather the food from the worker. Gloves selected in the scenarios that you describe in your letter are not for the purpose of worker safety, but rather consumer safety, therefore OSHA requirements would not apply.

OSHA does have specific requirements for glove use under 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens, which applies to workplaces where there is occupational exposure to blood or other potentially infectious materials. Employers covered under this standard must provide and make accessible hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives to those employees allergic to the type of gloves normally provided [29 CFR 1910.1030(d)(3)(iii)]. However, in the situation you are concerned with, this standard would not apply. Additionally, while there are requirements to provide hypoallergenic gloves or other alternatives, there is no requirement for color-coding to facilitate the differentiation of glove types.

If you need further information on these issues, you may wish to contact ASTM, the U.S. Food and Drug Administration, or the U.S. Product Safety Commission.

09/08/2005 - Acceptability of DOT labeling requirements in lieu of OSHA's labeling requirements for shipments of biohazardous materials.

Question: Are human samples (e.g., whole blood, plasma, serum, urine and tissue), which are shipped to a research laboratory, exempted from the biohazard labeling requirement under 29 CFR 1910.1030(g)(1)(i)(G) if the outer container is labeled with the IATA UN3373 Diagnostic Specimens marking?

Reply: Labeling is required on **all** containers used to store, transport, ship, or dispose of blood or other potentially infectious materials (OPIM), except as noted in paragraphs 1910.1030(g)(1)(i)(F-I) of the standard. Regarding the specific exemption provided by 29 CFR 1910.1030(g)(1)(i)(G), OSHA has provided clarification in a previously written letter of interpretation with regard to interplay between OSHA labeling requirements and those of the Department of Transportation (DOT). OSHA has stated:

[I]f individual containers of blood or OPIM are placed in a larger container during storage, transport, shipment or disposal and that larger container is either labeled with the OSHA "Biohazard" label or color-coded, the individual containers are exempt from the labeling requirement.

OSHA will accept the Department of Transportation's (DOT's) "INFECTIOUS SUBSTANCE" label in lieu of the [OSHA] "BIOHAZARD" label on packages where the DOT requires its label on shipped containers, but will require the BIOHAZARD label where OSHA regulates a material but DOT does not. If the DOT-required label is the only label used on the outside of the transport container, the OSHA-mandated label must be applied to any internal containers containing blood or OPIM. The BIOHAZARD label is fluorescent orange with lettering and symbols in a contrasting color. (Letter to Mr. Jon Carter, September 17, 2002)

You should consult with the United States Department of Transportation to determine what it requires for the outside labeling of packages containing these human samples. An identifying label that is acknowledged by the DOT as being sufficient may be used in lieu of the OSHA "BIOHAZARD" label on the shipping container; however, any internal containers containing blood or OPIM would still be required to be labeled with the OSHA-mandated label or color coding. It should be noted that not all diagnostic specimens are included in OSHA's definitions of blood or OPIM (e.g., urine and feces are not considered OPIM unless they contain visible blood) and, therefore, OSHA's labeling requirements are not applicable to all diagnostic specimens.

11/09/2005 - Periodic serologic testing to monitor antibody concentrations after completion of the hepatitis B vaccine three-dose series is not recommended.

Dear Mr. Thomas:

Thank you for your letter addressed to the Occupational Safety and Health Administration regarding the requirements of our Bloodborne Pathogens Standard, 29 CFR 1910.1030. Specifically, you had a question regarding whether your employer must provide another series of hepatitis vaccine shots if your blood test results show you no longer have a detectable titer. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

According to the standard and our enforcement directive, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, (CPL 02-02-069), an employer's responsibility for providing the hepatitis B vaccination series is clear. Paragraph 1910.1030(f)(1)(i) of the standard states, "the employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure follow-up to all employees who have had an exposure incident." This includes employer provision of, "the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis... at no cost to the employee, ...at a reasonable time and place, and ...according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place."

Regarding your letter, neither a new series of shots nor a hepatitis B vaccination booster is currently required in the current U.S. Public Health Service (USPHS), Centers for Disease Control and Prevention's (CDC's) guidelines. Because the USPHS does not recommend routine booster doses of hepatitis B vaccine, they are not required by the Bloodborne Pathogens Standard at this time. The CDC has said that vaccine-induced antibodies to HBV decline gradually over time, and less than or equal to 60 percent of persons who initially respond to vaccination will lose detectable antibodies over 12 years. Studies among adults have demonstrated that, despite declining serum levels of antibody, vaccine-induced immunity continues to prevent clinical disease or detectable viremic HBV infection. Therefore, booster doses are not considered necessary. Periodic serologic testing to monitor antibody concentrations after completion of the three-dose series is not recommended. If a routine booster dose of hepatitis B vaccine is recommended by the USPHS at a future date, such booster doses must be made available at no cost to those eligible employees with occupational exposure.

04/02/2007 - Clarification of OSHA's policy on changing disposable gloves between patient contacts.

Scenario: On December 6, 2006, Kettering Hospital's operating room (OR) staff was informed by the Infection Control personnel that it was no longer acceptable for the OR employees to wear clean exam gloves while transporting patients, nor was it acceptable to wear clean exam gloves when transporting trash and linen to the decontamination area. The rationale offered for this policy was that if the patients were provided and are using clean gowns and linen, there was no need for gloves. Also, if the trash and linen bags were not soiled, then there was no need for gloves either. However, it is your belief that you and your fellow co-workers should protect yourselves by using clean gloves during **all** transport. Further, you were advised by your supervisor that you will be counseled on your behavior should you continue to wear clean exam gloves while performing the above mentioned duties.

Response: The personal protective equipment requirements of OSHA's Bloodborne Pathogen standard at 29 CFR 1910.1030(d)(3), are performance-oriented. As such, it is the employer's responsibility to evaluate the tasks and the types of exposure expected at his or her workplace and, based on the determination, select the "appropriate" personal protective equipment in accordance with paragraph 1910.1030(d)(3)(i) of the standard.

At a minimum, gloves must be used where there is reasonable anticipation of employee hand contact with blood, other potentially infectious material (OPIM), mucous membranes, or non-intact skin and when handling or touching contaminated surfaces or items. Please bear in mind that the term "contaminated" is defined as the presence or the reasonably anticipated presence of blood or other potentially infectious materials, rather than just "visibly" contaminated.

OSHA requires that disposable gloves be changed as soon as practical when contaminated and as soon as feasible when they are torn or punctured. These requirements protect the employee from exposure to the hazards of bloodborne pathogens. OSHA does not require that gloves be changed between patients if they are not contaminated and their barrier properties have not been compromised. However, as stated in the preamble to the standard, changing gloves between patient contacts is good infection control practice to eliminate patient-to-patient transmission of disease. Additionally, if the conditions you described in your letter are anticipated to occur, such as the chance of patients' tubes and catheters splashing employees during transport, then certainly, gloves must be used, to protect the employee from exposure to blood or OPIM. Further, employees who have contact with contaminated linen and trash must wear protective gloves which must be changed when contaminated.

In addition, please be aware that, should the situation arise where you or your fellow co-workers **have** to change your gloves and are denied and/or your supervisor retaliates, you may wish to contact the local OSHA Area Office. OSHA, in addition to investigating safety and health complaints, has authority under Section 11(c) of the Occupational Safety and Health Act to

investigate and take appropriate action on an employee reprisal, if it resulted from filing a safety or health complaint with OSHA or a complaint to an employer.

10/04/2007 - Applicability of OSHA's bloodborne pathogens standard to the use of safety needles with self-infuse bleeding products.

Scenario: A hemophilia home healthcare company supplies bleeding products to patients nationwide. Many patients with bleeding disorders self-infuse their products while other patients have professional nursing services provide in-home assistance with venipuncture and infusion.

Question 1: Does OSHA's bloodborne pathogens standard, 29 CFR 1910.1030, require that safety needles be sent to patients who self-infuse?

Reply 1: No. Your company is not required to send safety needles to persons who self-infuse bleeding products or who self-inject any other medication. The Occupational Safety and health Act of 1970 (OSH Act) only protects employees. 29 USC §653(a) states that the OSH Act applies to employment.

Question 2: Does OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030, require us to provide safety needles when an outside party (e.g., home healthcare professional) uses our products to infuse a patient in his/her home?

Reply 2: The standard applies to employers having employees with occupational exposure to blood or other potentially infectious materials (OPIM). During a phone conversation with a member of our staff, you mentioned that your company, a pharmacy which supplies medical products and equipment, does not employ nor contract with in-home healthcare professionals to assist patients in infusing bleeding products. Since your company does not have employees with occupational exposure to blood or OPIM, you do not have a responsibility under OSHA's Bloodborne Pathogens Standard to supply your customers with safety-engineered sharps.

However, it is advisable that patients who rely on the services of healthcare professionals to be supplied with sharps with engineered sharps injury protections (SESIPs) and/or needleless devices for the protection of healthcare workers.

09/16/2008 - Whether written programs may be kept solely in an electronic format.

Dear Mr. _____:

Thank you for your April 8, 2008 letter regarding the requirements of various standards for a written program. Your letter specifically asks whether written programs may be kept solely in an electronic format. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

As you pointed out in your letter, a number of standards require programs that are written and accessible to all employees on site. Examples of these provisions are 29 CFR 1910.1030(c)(1)(i) and 1910.1030(c)(1)(iii) (bloodborne pathogens), 29 CFR 1910.1200(e)(1) and 1910.1200(e)(4) (hazard communication), and 29 CFR 1910.146(c)(4) (permit-required confined spaces). Traditionally, these programs have been kept in separate binders in appropriate work areas in order to comply with the standards. Maintaining multiple copies of these manuals can be both challenging and time-consuming.

You have also stated that placing safety materials, programs, checklists, and forms on a company intranet can provide significant benefits in consistency, ease of use, and accuracy in maintaining and updating these materials in a timely manner. And, just as hard copy programs can be photocopied upon request, so can an electronic version be printed out upon request.

Computers are much more common in the workplace now than when most OSHA standards were written. We agree that in many instances electronic access to programs could be beneficial. Therefore, OSHA would allow a written program to be in either paper or electronic format, as long as the program meets all other requirements of the standard in question.

Where the standard requires that the written program must be made available to employees, the employer must ensure that employees know how to access the document and that there are no barriers to employee access.

12/15/1992 - Biohazard labeling.

Dear Ms. _____,

This is in response to your letter of September 22 and to provide you with written confirmation of phone conversations you have had with a member of my staff. You requested an interpretation of the acceptability of your company's biohazard label under the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, the Occupational Exposure to Bloodborne Pathogens Standard. We apologize for the delay in this written response.

The bloodborne pathogens standard requires that the biohazard label be affixed to containers of regulated waste and other containers used to store, transport, or ship blood or other potentially infectious materials; a red container may be substituted for the biohazard label. The design and coloring of the warning label which you submitted appears to be consistent with the requirements of 1910.1030(g)(1)(i)(B) and (C) which require that the biohazard symbol and legend be in a contrasting color to a fluorescent orange or orange-red background.

03/31/1994 - Secondary container for a specimen.

Dear Mr._____:

This is in response to your letter of October 26, regarding the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." Specifically, you asked whether the secondary container into which a specimen is placed is allowed to leak. We apologize for the delay in this response.

According to section (d)(2)(xiii)(B), the second container shall be closable; constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and properly labeled or color-coded.

04/15/1996 - Doctors required to wear gloves while fitting patients with contact lenses.

Dear Mr. _____:

Thank you for your letter of March 15, concerning the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, 29 CFR 1910.1030. You asked whether doctors are required to wear gloves while fitting patients with contact lenses.

The standard defines occupational exposure as reasonably anticipated contact with blood or other potentially infectious materials. In OSHA's view, the situation that you describe is routine contact lens care where there is no occupational exposure to bloodborne pathogens, and personal protective equipment is not required. However, in rare cases, such as one involving traumatic injury to the eye where occupational exposure to bloodborne pathogens is reasonably anticipated, the wearing of gloves is necessary to be in compliance with 1910.1030.

04/15/1996 - The potential for the transmission of HIV from contact with urine specimens.

Dear_____:

This is in response to your letter of January 9, addressed to the Occupational Safety and Health Administration (OSHA) concerning the potential for the transmission of the human immunodeficiency virus (HIV) from contact with urine specimens during handling and transport.

The Bloodborne Pathogens Standard, 29 CFR 1910.1030, lists a number of body fluids, in addition to blood, that are reasonably likely to transmit bloodborne pathogens. OSHA provides the basis for including the body fluids listed in the June 1988 Centers for Disease Control (CDC) Guidelines (MMWR, Volume 37, Number 24, 1988), under the definition of "other potentially infectious materials" at page 64102 in the Federal Register, Vol. 56, No. 235, published December 6, 1991. Under these guidelines, urine is not classified as a body fluid that could reasonably transmit bloodborne pathogens. In order for urine to be classified as potentially infectious, blood must be visibly present or the presence of blood reasonably anticipated due to the patient having a medical condition that would lead to blood in the urine.

Under section 1910.1030(d)(2)(xiii), OSHA requires that "specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipment." Therefore, if test tubes are used to transport blood, then the test tubes must be capable of preventing leakage during transport. Urine that does not contain visible blood would not be regulated under this standard and would not be required to be placed in containers that prevent leakage.

The bloodborne pathogens standard is designed to protect the nation's workers, particularly healthcare workers, from exposure to the hepatitis B virus (HBV), the human immunodeficiency virus (HIV), and other bloodborne pathogens. OSHA believes that all potential sources of bloodborne pathogens are covered under this standard and that healthcare workers, such as yourself, are adequately protected from bloodborne pathogens.

05/07/1996 - OSHA Guidelines for Medical Practices.

Dear Senator _____:

This is in further response to your letter of January 31, on behalf of your constituent, Dr. David M. Mokotoff, of Bay Area Heart Center concerning the Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030).

Dr. Mokotoff's employees attended a symposium on OSHA guidelines for medical practices. The information provided in the symposium raised concerns for the doctor. Dr. Mokotoff's concerns center on the designation of appropriate areas for eating, drinking, applying cosmetics or lip balm, and handling contact lenses; handwashing procedures; and information and training requirements for non-employees and employees. Also, the doctor raised concerns about the assessment of penalties for cited violations.

The Bloodborne Pathogens standard, paragraph (d)(2)(ix), prohibits these activities such as eating, drinking, applying cosmetics or lip balm, and handling contact lenses, only in work areas where employees have a reasonably anticipated exposure to blood or other potentially infectious materials (OPIM). The prohibition against food and drink and the use of personal items in such a work area is consistent with other OSHA standards and is good industrial hygiene practice. The employer/practitioner is free to designate an area where it is reasonable to anticipate that occupational exposure will fail to occur, and to allow the consumption of food and drink in those areas.

Dr. Mokotoff has been mistakenly informed that handwashing after patient contact for a bloodpressure check is an OSHA requirement. The bloodpressure check is a non-invasive procedure, and as such, employees would not have a reasonable likelihood of exposure to blood or OPIM. Hence, with bloodpressure checks, there is no requirement for handwashing by employees after patient contact.

In contrast, handwashing becomes a critical concern when the employee has occupational exposure to blood or OPIM, or when occupational exposure can be reasonably anticipated. OSHA recognizes this concern with paragraphs (d)(2)(v) and (d)(2)(vi) of the standard, stating employees must wash their hands after the removal of gloves and other personal protective equipment. Employees must also wash their hands or skin following contact with blood or other potentially infectious materials.

The Occupational Safety and Health Act extends protection only to employees, not to patients. Therefore, the Bloodborne Pathogens standard is applicable only to Dr. Mokotoff's employees. Dr. Mokotoff's concerns regarding this matter are unfounded since employers have no obligation under the Act to provide or implement any protective measures required under this standard, or any other standards to patients.

Dr. Mokotoff also expresses concern regarding training employees who have occupational exposure. Paragraph (g)(2) details employee training requirements, but essentially the standard emphasizes that

the employer must provide information and training to those employees that have occupational exposure at the time of initial assignment and at least annually thereafter. Therefore, if the employee's initial assignment occurs on the first day of employment, the employer must provide the required training at that time.

Violations cited under OSHA's standards are classified as willful, serious, other-than-serious, and a notification of de minimis. These violations are assessed penalties based on the gravity of the violations. Each willful violation can carry a penalty of not more than $70,000. Serious and other-than-serious violations can carry a penalty of not more than $7,000. Although these are the maximum penalty amounts OSHA can issue, please bear in mind that OSHA's average penalty for a serious violation is less than $900. Factors such as employer work history and employer size are factored into determination of the penalty.

04/01/1997 - Disinfectants claiming efficacy against the Hepatitis B virus.

Dear Mr. _____:

This is in response to your letter of December 10, 1996. You have requested a clarification of the Occupational Safety and Health Administrations (OSHA) position on disinfectants claiming efficacy against the Hepatitis B virus. You have asked if the products with the EPA approval meet the requirements of the Bloodborne Pathogens Standard without a registered tuberculocidal claim.

A review of the initial intent of the Bloodborne Pathogens Standard that specifically deals with the cleaning of contaminated work surfaces, i.e., 1910.1030(d)(4)(ii)(A), reveals that OSHA intended to provide a performance-based provision that would allow for future development of "appropriate disinfectant" products. OSHA has reviewed the information on the disinfectants and has reconsidered its position on EPA-registered disinfectants that are labeled as effective against HBV and HIV. OSHA's current stance is that EPA-registered disinfectants for HIV and HBV meet the requirement in the standard and are "appropriate" disinfectants to clean contaminated surfaces, provided such surfaces have not become contaminated with agent(s) or volumes of or concentrations of agent(s) for which higher level disinfection is recommended.

It is important to emphasize the EPA-approved label section titled "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 AND HBV Of SURFACES\OBJECTS SOILED WITH BLOOD\BODY FLUIDS." On the labels that OSHA has seen, these instructions require:

1. personal protection devices for the worker performing the task;
2. that all the blood must be cleaned thoroughly before applying the disinfectant;
3. that the disposal of the infectious waste is in accordance with federal, state, or local regulations;
4. that the surface is left wet with the disinfectant for 30 seconds for HIV-1 and 10 minutes for HBV.

OSHA would expect all such disinfectants to be used in accordance with their EPA-approved label instructions.

11/18/1992 - Requirements for the bloodborne pathogens standard, 1910.1030.

This is in response to your recent inquiries regarding requirements in the Occupational Exposure to Bloodborne Pathogens Standard, 29 CFR 1910.1030.

As you are aware, the personal protective equipment requirements of the standard are performance oriented. That is, it is the employer's responsibility to evaluate the task and type of exposure expected and, based on that determination, select the "appropriate" personal protective equipment in accordance with paragraph (d)(3)(i) of the standard.

At a minimum, gloves must be used where there is reasonable anticipation of employee hand contact with blood, other potentially infectious materials, mucous membranes, or non-intact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items.

In general, OSHA agrees with you that gloves are not necessary when giving intramuscular injections as long as hand contact with blood or non-intact skin is not anticipated. However, if the employee administering the vaccine is expected to hold pressure over the site of injection (e.g., with a cotton ball) or apply a bandage to the site, gloves are required since it could be reasonable anticipated that the employee's fingers could contact blood. If the patient receiving the immunization is responsible for applying pressure or a bandage (e.g., patient hold cotton ball and applies pressure as needle is withdrawn), the employee administering the vaccine need not wear gloves. It must be understood, however, that if such an employee is expected to provide assistance to the patient should an adverse reaction occur (e.g., the employee holds pressure on site or provides other assistance if patient loses consciousness), then that employee should be prepared for such an occurrence. Part of such preparation would be the donning of gloves before initiating vaccine administration.

Your second inquiry regarded payment for Hepatitis B vaccine required to be offered by employers. The 3 scenarios you presented are as follows:

1. A dental employee has health coverage through a spouse's health plan, and such plan requires the employee's spouse to contribute a portion of the premium. Such a method would not constitute "at no cost" to the employee.

2. A dental employee has health coverage through a spouse's health plan, and such plan does not require any employee contribution. Regardless of monetary aspects of the spouse's contribution to such a health plan, it is the labor of the spouse which earns the benefits of such a plan, and therefore such a plan cannot be considered noncontributory on the part of the dental employee.

3. A dental employee has health coverage through a health plan which is entirely (100%) paid for by the dentist employer. If the plan is truly non-contributory by the employee (e.g., no premium charge, deductible, copayment, or other form of payment required of the employee), then certainly the dentist employer can use such a plan to cover the vaccination expenses, provided such expenses are part of the plan coverage.

The message in the above examples is clear: It is the employer's responsibility to pay for the Hepatitis B vaccine offered to employees.

Your third concern was the qualifications of trainers for employees under 1910.1030. The language of the standard [section (g)(2)(viii)] is "The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address."

As explained in the Summary and Explanation of the Standard published in the Federal Register along with the Standard, flexibility has been incorporated into the Standard. The National Institute for Occupational Safety and Health submitted a comment that "the trainer should have expertise in the subject area, as documented by objective evidence such as satisfactory completion of relevant training courses or degree programs". However, the Standard does not suggest completion of particular courses since workplaces where exposure can occur are varied. Rather, the trainer should be knowledgeable in the contents of the training program the employer is required to provide. A dentist or nurse in the dental office certainly should be able to train employees provided he or she gains familiarity with the Standard and understands the topics to be covered in a training program.

01/15/1999 - Trainer accessibility during training.

Dear Ms. _____:

This is in response to your letter of December 7, 1998, addressed to the Occupational Safety and Health Administration's (OSHA's) Office of Health Compliance Assistance (OHCA), regarding training requirements in 29 CFR 1910.1030, the Occupational Exposure to Bloodborne Pathogens rule. Your company offers interactive computer courses to clients. You've requested that we provide a letter that restates OSHA's policy on the issue of whether or not the trainer must be physically present in the room when employees are taking a training course on-line.

During training, it is critical that trainees have an opportunity to ask and receive answers to questions where material is unfamiliar to them. Frequently, a trainee may be unable to go further with the training or to understand related training content until a response is received. OSHA has previously stated that a training provider can meet OSHA's requirement for trainees to have direct access to a qualified trainer by providing a telephone hotline. The trainer must be accessible to employees during training.

While you have not stated in what manner you currently provide trainers to your clients, for your information, it is OSHA's policy that using the E-mail system to answer employee questions is not considered to be direct access to a qualified trainer, unless the trainer is available to answer e-mailed questions at the time the questions arise. This is essential since a trainee may require an interactive discussion with the trainer to clarify the question or to ask additional questions. Therefore, if access to a qualified trainer is provided through E-mail, the trainer must be available for an interactive on-line exchange whenever a trainee question arises. A "timely manner," in this case, means at the time the question arises.

03/10/2000 - HBV antibody testing is required after vaccination series;HBV booster not required.

Dear Dr. _____:

Thank you for your February 10 letter addressed to the Occupational Safety and Health Administration's (OSHA's) [Office of Health Enforcement]. You have a question regarding whether a Hepatitis B vaccination booster is required by OSHA under the Bloodborne Pathogens Standard, 29 CFR 1910.1030. This letter supplements our phone conversation and we hope it better serves your needs.

According to the standard and the recently published directive, *Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens*, [CPL 2-2.69], an employer's responsibility for providing the hepatitis B vaccination series is clear. Paragraph (f)(1)(i) of the standard states, *"the employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure follow-up to all employees who have had an exposure incident."* This includes employer provision of, *"the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis... at no cost to the employee,...at a reasonable time and place, and...according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place."*

Regarding your letter, a hepatitis B vaccination booster is not currently required by the U.S. Public Health Service, Centers for Disease Control and Prevention's (CDC's) *Guidelines for the Immunization of Health-Care Workers*. However, the December 26, 1997 CDC *Guidelines* does indicate that *"postvaccination testing for antibody to hepatitis B surface antigen (anti-HBs) response is indicated for healthcare workers who have blood or patient contact and are at ongoing risk for injuries with sharp instruments or needlesticks."* This means that a titer or antibody testing is required approximately two months after the employee finishes the vaccination series. The indicated guidelines can be found in [Appendix E of CPL 2-2.69], which is available on OSHA's website at http://www.osha.gov.

01/11/2001 - Labeling requirements under the HAZCOM and Laboratory standards; use of safe needle devices.

Question 1: Is it necessary to label each bottle of reagent even if it will be used in a timely manner?

Reply: The labeling requirement depends on the OSHA standard which covers your facility. OSHA's Hazard Communication Standard (HCS), at 29 CFR 1910.1200(f)(5) states ***"... the employer shall ensure that each container of hazardous chemicals in the work place is labeled, tagged or marked with... (i) Identity of the hazardous chemicals...and (ii) Appropriate hazard warnings, or alternatively, words, pictures, symbols or combination thereof,...to...provide the employees with the specific information regarding the physical and health hazards of the hazardous chemicals."*** Paragraph 6 allows an employer to use signs, placards, process sheets, batch tickets, operation procedures, or other such written materials in lieu of labels, providing the required information is conveyed.

OSHA's Laboratory Standard, at 29 CFR 1910.1450(h)(1)(i) states that, ***"Employers shall ensure that labels on incoming containers...are not removed or defaced."*** Furthermore, if chemicals are developed in the laboratory, the employer need only provide the appropriate training as outlined in the standard. This standard covers only those facilities meeting the criteria of "laboratory use" and "laboratory scale" as defined therein.

The HCS requirements apply to all hazardous chemicals, defined as ***"... any chemical which is a physical or a health hazard."*** The Laboratory Standard applies to all hazardous chemicals meeting the definition of "laboratory use" and **having a potential for employee exposure.**

Paragraph (b) of the Laboratory Standard, 29 CFR 1910.1450, defines the "laboratory use of hazardous chemicals" to include the handling or use of hazardous chemicals where all of the following conditions are met: multiple chemical procedures or chemicals are used; the procedures involved are not part of a production process, nor in any way simulate a production process; and the chemical manipulations are carried out on a "laboratory scale." The definition of "laboratory scale" specifically excludes those workplaces which function to produce commercial quantities of materials.

Question 2: Are coding systems acceptable in place of writing precautionary information on secondary containers?

Reply: Please see our reply to your first question. Also, 29 CFR 1910.1200(f)(7) states, ***"The employer is not required to label portable containers into which hazardous chemicals are transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer...."***

For further information on labeling requirements, see OSHA's Compliance Instruction on the HCS, CPL 2-2.38D, which will provide further guidance on chemical labeling and other aspects of the HCS. You can search for this document on OSHA's website at http://www.osha.gov.

Question 3: Does this requirement apply only to hazardous chemicals or all chemicals used by the laboratory?

Reply: Please see our reply to your first and second questions above.

Scenario: "At an on-site inspection, an OSHA compliance Officer (CSHO) notices a laboratory NOT using safe needle devices. The laboratory claims that this is too costly and justifies their practice by stating there has been zero needlestick incidents."

Question 4: Would OSHA consider this a citation with an associated fee?

Reply: The fact that the facility has "zero needlestick incidents" and such devices are too costly, does not prevent the issuance of a citation. OSHA's Bloodborne Pathogens Standard, 29 CFR 1910.1030, states at (d)(2)(i) that, ***"Engineering and work practice controls shall be used to eliminate or minimize employee exposure...."*** **Citations will be issued to any employer that has not implemented engineering controls where feasible.** OSHA's Compliance Instruction on the Occupational Exposure to Bloodborne Pathogens Standard is [CPL 2-2.69]. This document states: "Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they must be used." If the employer is using one engineering control but there are other controls, such as "safe needle devices," available, then OSHA **may** issue a citation based on specifics of the investigation and the Compliance Safety and Health Officer's review of the exposure control plan. Employers must institute engineering **and** work practice controls as the primary means of eliminating employee exposure or reducing it to the lowest extent feasible. The key is to prevent potential employee exposure to needlesticks.

06/27/2001 - Means of reducing needlestick exposure hazards.

Dear Congressman _____:

Thank you for your letter of April 2, addressed to Mr. Richard E. Fairfax, Director of the Occupational Safety and Health Administration's (OSHA's) [Directorate of Enforcement Programs (DEP)]. Your letter conveyed some concerns that you and Mr. Joe Adkins had about OSHA's enforcement of the Bloodborne Pathogens Standard, 29 CFR 1910.1030. Specifically, you expressed concerns about how needle destruction devices are viewed by our compliance program.

Let us reassure you again that needle destruction devices are indeed considered engineering controls as described by the standard. However, it is not the intent of the standard, as Mr. Adkins was quoted in the article that you enclosed, "that **any** device is acceptable if it decreases needlestick injuries." The intent of the standard is to eliminate the hazard of the needle. OSHA requires employers to use safer devices even if they have not yet had needlestick injuries; employers must not wait until their employees have been injured by contaminated needles before they attempt to eliminate their exposures.

The key to the prevention of needlesticks is using engineering controls to remove the hazard of a contaminated needle from the workplace. Congress acknowledged these preventative steps and purposely added the two key methods of doing this to the definition section of the standard: needleless systems and sharps with engineered sharps injury protection.

Ideally, the most effective way of removing the hazard of a contaminated needle is to eliminate the needle completely by converting to needleless systems. If this is not possible, removal of the hazard as soon as possible after contamination is required. This is best accomplished by using a "sharp with engineered sharps injury protection," which shields the sharp from exposure as soon as it is withdrawn from the patient.

However, simply using **any** device may not be appropriate. The device that most effectively eliminates the exposure can vary by procedure. The employer and employees must consider which device is best suited for a specific procedure. For some procedures a safer device may not be commercially available. In this case, the employer must use another method to remove the hazard from the workplace as soon as feasible. This is frequently done by placing the needle directly into a sharps container located as close to the patient as possible.

If a safer medical device is not available for a specific procedure, an employer could choose to use a needle destruction device to destroy the needle before placing it in a sharps container. Nonetheless,

there are still 600,000 to 800,000 injuries occurring each year, many of which occur immediately after use and prior to placement in a sharps box.

Again, OSHA is aware that needleless systems or sharps with engineered sharps injury protection cannot be used in all situations. However, if their use is feasible for a given procedure, then they must be used.

In the article you sent, Mr. Adkins has identified home use of needles as another sector where there is a risk of needlesticks. The domestic use and disposal of needles has become an area of increasing concern for OSHA and several other agencies. Needles used in the home do not follow the same waste stream as the regulated waste from doctor's offices and hospitals; they are discarded in regular trash posing potential exposures to trash haulers downstream. Although the homes of self-injecting insulin patients are beyond OSHA's jurisdiction, this device may be useful in preventing these downstream exposures.

12/03/2002 - Sharps injury logs are intended to track departments, devices, and/or procedures causing injuries, not injured employees.

Dear Ms. _____:

Thank you for your August 22 letter to the Occupational Safety and Health Administration (OSHA). Your letter was forwarded to OSHA's Office of Health Enforcement to answer a specific question regarding the enforcement procedures for the Bloodborne Pathogens Standard in the Nursing and Personal Care Facility National Emphasis Program (NEP). Specifically, you inquired about the direction given to our field staff for evaluating an employer's sharps injury log. Your concern is restated below followed by OSHA's response.

AHCA Concern: The AHCA believes that there is no regulatory requirement that generally prohibits names to appear on the sharps injury log; rather it is circumstances that trigger the requirement to remove personal identities to maintain privacy.

AHCA Suggestion: We encourage OSHA to take quick action to correct its NEP directive to accurately reflect that the sharps injury log may contain names when appropriate.

Response: The sharps injury log is used to track devices that are causing injuries and may need to be replaced; it is not intended to track employees having injuries. The log is a valuable surveillance tool for healthcare facilities to identify departments, devices, and/or procedures where injuries are occurring.

The Bloodborne Pathogens Standard as revised by the Needlestick Safety and Prevention Act (NSPA) sets forth the elements that must be included in the log. These are:

> Type and brand of device, if known;
> Department or work area where exposure occurred; and
> An explanation of how the incident occurred.

OSHA's Compliance Directive for the Bloodborne Pathogens Standard, CPL 2-2.69, at paragraph XIII.H.3, further explains that additional information may be included; however the confidentiality of the injured employee must be maintained [Needlestick Safety and Prevention Act; Pub. L. No. 106-430, Sec. 3, 114 Stat. 1901, 1903 (2000)]. Since neither the NSPA nor the Bloodborne Pathogens Standard specifies the format of the log, OSHA included a sample log in the directive's appendix. You will note that the sample log does not include a column for an employee's name, but rather one for "case/report numbers." This is because OSHA believes the addition of an employee's

name jeopardizes that employee's confidentiality and increases his or her hesitancy to report an incident. Also, it does not fulfill the intent of the log.

An establishment may keep sharps logs with employees' names on them. However, if the log is made available to any other persons, the establishment must withhold any information that directly identifies an employee or that could reasonably be used to identify the employee. Therefore, OSHA will direct its compliance staff and the public that if the sharps injury logs include employee names, the names and all other personal identifiers must be removed before the log is made available to others.

As AHCA mentioned in its letter, it is aware of some long-term care facilities that are including names on the log. In order to ensure required confidentiality, facilities must remove names prior to the record being turned over to any other person(s). Employers may keep a separate confidential list of the case numbers and employee names, as suggested by CPL 2-2.69, paragraph XIV.A.

In addition, AHCA suggested that the sharps injury log be maintained, "in the employee's medical file" (and then) "identifiers would not have to be removed." This is not possible, since any "log" containing more than one name could not be maintained in an individual's personal medical file without breaching the confidentiality of any other named individual.

05/17/2006 - Requirements for covered beverages at nurses' stations.

Question: Is it against OSHA regulation to keep a covered beverage at a nurse's station in a hospital?

Reply: OSHA does not have a general prohibition against the consumption of beverages at hospital nursing stations. However, OSHA's bloodborne pathogens standard prohibits the consumption of food and drink in areas in which work involving exposure or potential exposure to blood or other potentially infectious material takes place, or where the potential for contamination of work surfaces exists [29 CFR 1910.1030(d)(2)(ix)]. Also, under 29 CFR 1910.141(g)(2), employees shall not be allowed to consume food or beverages in any area exposed to a toxic material. While you state that beverages at the nursing station might have a lid or cover, the container may also become contaminated, resulting in unsuspected contamination of the hands.

The employer must evaluate the workplace to determine in which locations food or beverages may potentially become contaminated and must prohibit employees from eating or drinking in those areas. An employer may determine that a particular nurse's station or other location is separated from work areas subject to contamination and therefore is so situated that it is not reasonable under the circumstances to anticipate that occupational exposure through the contamination of food and beverages or their containers is likely. The employer may allow employees to consume food and beverages in that area, although no OSHA standard specifically requires that an employer permit this. OSHA standards set minimum safety and health requirements and do not prohibit employers from adopting more stringent requirements.

01/24/2007 - Acceptable time lapse for "annual" training.

Scenario: Various OSHA standards address frequency of employee training. Some standards are very explicit on frequency, stating "no later than 12 months from the date of the previous training," while others simply state that training must be performed "at least annually."

Question: Could you please clarify OSHA's interpretation of training requirements and what is expected when training must be conducted "at least annually"?

Reply: You are correct in stating that the language may vary in certain OSHA standards. However, wherever OSHA standards require that employee training be conducted "at least annually," OSHA interprets that to mean that employees must be provided re-training at least once every 12 months (i.e., within a time period not exceeding 365 days.) This annual training need not be performed on the exact anniversary date of the preceding training, but should be provided on a date reasonably close to the anniversary date taking into consideration the company's and the employees' convenience in scheduling. If the annual training cannot be completed by the anniversary date, the employer should maintain a record indicating why the training has been delayed and when the training will be provided.

Please keep in mind that the term "at least annually" is generally regarded as indicating that circumstances which warrant more frequent training may occur. It is extremely important that employees are trained to protect themselves from all known workplace hazards, including new hazards which may result from changes in workplace practices, procedures, or tasks. For example, OSHA's bloodborne pathogens standard at 29 CFR 1910.1030(g)(2)(v), provides for "additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupation exposure." More frequent training may also be required when employee performance suggests that the prior training was incomplete or not fully understood.

07/16/2008 - Whether an employee can waive right to have untested blood maintained for 90 days.

Background: OSHA's Occupational Exposure to Bloodborne Pathogens standard addresses the requirement for blood testing as part of a post exposure evaluation at 29 CFR 1910.1030(f)(3)(iii)(B). The standard states: "If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for **at least 90 days**. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible" (boldface added).

Question: It is our experience that laboratories will typically only store a blood sample for 7-30 days. Following a work-related bloodborne pathogens exposure incident, if an employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, is it permissible for the employer to have the employee sign a consent verifying their understanding of the lab's procedure of the 30-day storage time frame?

Reply: No, an employer may not have employees sign a consent form waiving the right to have untested baseline blood maintained for the minimum time limitation of 90 days.

According to the preamble to the final rule, the Centers for Disease Control and Prevention (CDC) stated, "the worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may be indicative of recent HIV infection." The preamble adds: "CDC has further stated that the first 6-12 weeks are 'when most infected persons are expected to seroconvert' (Ex. 15, MMWR 1989; 38 [No. S-6]:13)." The final rule specifically provides that untested baseline blood samples be preserved for at least 90 days in order to account for the 12 week post-exposure period when an acute retroviral illness may develop and to afford the employee the opportunity to know his/her immediate post-exposure HIV status even if consent for HIV testing was initially withheld. [56 *Federal Register* 64159 (1991).]

03/21/1992 - Eating and drinking in area where potentially infectious material exists.

Dear Senator _____:

This is in response to your letter of March 2, addressed to the former Assistant Secretary for the Occupational Safety and Health Administration (OSHA), Gerard Scannell. You wrote on behalf of your constituent, Dr. S. C. Taylor.

Dr. Taylor was concerned that 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens", prohibited "drinking of coffee and eating of food in our office".

This regulation prohibits the consumption of food and drink in areas in which work involving exposure or potential exposure to blood or other potentially infectious material exists, or where the potential for contamination of work surfaces exists. The prohibition against eating and drinking in such a work area is consistent with other OSHA standards and is good industrial hygiene practice.

In addition to contamination of the food itself, one must consider that food and beverage containers may also become contaminated, resulting in unsuspected contamination of the hands. Food and drink may be contaminated by such processes as the leakage or spillage of specimen containers, or the performance of activities that could generate splashes, sprays, or droplets of blood or other potentially infectious materials.

Dr. Taylor is free to designate areas in which it is not reasonable to anticipate that occupational exposure will occur and to allow the consumption of food and beverage in those areas. OSHA will evaluate such designations on a case-by-case basis and anticipates that such areas will be separated from contaminated work areas.

04/04/1992 - Infectious materials and nail and tissue clippers as sharps.

1. Are nail clippers, tissue clippers, etc. considered as sharps?

2. Are toenail clippings and skin shavings from bottom of feet considered hazardous?

3. Orthopedic discards - casts?

Dear Dr. _____:

This is in response to your letter of March 2, in which you requested clarification concerning the requirements of 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

This regulation states that the body substances to which universal precautions must be applied are blood and other potentially infectious materials. Toenail clippings and skin shavings are included if they are contaminated with blood or blood components, such as exudates from wounds.

Similarly, nail clippers and tissue clippers which are contaminated with blood or other potentially infectious materials would be considered sharps which must meet the handling and labeling requirements of the standard if they are capable of penetrating the skin. "Contaminated" means the presence or reasonably anticipated presence of blood or other potentially infectious material on an item or surface.

The Occupational Safety and Health Administration (OSHA) expects that these instruments would be disinfected regardless of their coverage under this regulation due to the possibility of transmission of non-bloodborne diseases.

04/09/1992 - Handwashing requirements.

Dear Mr. Thompson:

This is in response to your letter of January 20, regarding the acceptability of the Nebucid 880 "No Touch" Hand Disinfecting System and Dermocol Disinfectant Solution. Please accept our apologies for the delay in our response.

The Occupational Safety and Health Administration (OSHA) regulation on Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030, requires in sections (d)(2)(iii) and (v) that "employers shall provide handwashing facilities which are readily accessible to employees" and "ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment".

In section (d)(2)(iv), the standard permits an alternative to the standard handwashing facility: "When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleaner in conjunction with clean cloth/paper towels or antiseptic towellettes. When antiseptic hand cleaners or towellettes are used, hands shall be washed with soap and running water as soon as feasible".

These requirements are based on testimony resulting from OSHA's proposed regulation and on the Centers for Disease Control's "Guidelines for Handwashing and Hospital Environmental Control". The latter states that handwashing is the preferred method of infection control and that the recommended technique involves a vigorous rubbing together of all surfaces of lathered hands for at least 10 seconds, followed by thorough rinsing under a stream of water.

The above-mentioned antiseptic alternative is allowed as an interim measure where an employer can show that soap and water are not a feasible means of handwashing, e.g. for ambulance-based paramedics, firefighters, or mobile blood collection personnel.

The Nebucid 880 may be acceptable as an alternative handwashing technique and may certainly be used following regular handwashing as a supplementary cleanser. However, where handwashing facilities are feasible, OSHA expects employers to provide them and ensure their use.

08/07/1992 - Bloodborne pathogen standard's requirement of social security number on medical records.

Dear Dr. _____:

This is in response to your letter of April 30, requesting clarification concerning the Occupational Safety and Health Administration (OSHA) regulation, 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." Specifically you were concerned about the recording of employees' social security numbers on their medical records. We apologize for the delay in this response.

The Bloodborne Pathogens Standard addresses recordkeeping and medical record access in section (h) of the regulation. Section (h)(1)(i) requires that the employer establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records." Further, section (h)(2)(ii)(A) states that this record shall include the name and social security number of the employee. These are mandatory requirements.

In your letter, you referred to a Supreme Court decision addressing the right of an individual to prevent disclosure of social security numbers. After thorough research, we were unable to find such a 1959 United States Supreme Court case involving a requirement imposed on applicants for airline pilot licenses to disclose their social security numbers. In any event, we have received a legal opinion that OSHA can enforce the disclosure provisions of the standard because no action is taken by OSHA against the individuals whose social security numbers are on the records.

08/12/1992 - Request to waive requirement for hand washing between patients when gloves are removed.

Dear Dr. _____:

This is in response to your letter of June 1, regarding the Occupational Safety and Health Administration (OSHA) standard on "Occupational Exposure to Bloodborne Pathogens," 29 CFR 1910.1030, section (d)(2)(v). Specifically, you requested that OSHA "reconsider this section and waive the requirement for hand washing when a phlebotomist removes gloves between patients and there is no visible contamination of the gloves with blood or OPIM."

Section (d)(2)(v) of the standard very specifically requires handwashing after removal of gloves or other personal protective equipment. OSHA believes the benefits of this practice far outweigh the concerns you presented of excessive handwashing and delays in performing procedures. Please note that this requirement was presented to, and supported by, a number of commentors to the public record following publication of the proposed regulation in May, 1989.

Please bear in mind, however, that while it is sound public health policy to do so, OSHA does not have a requirement that gloves be changed between patients. We hope this information is responsive to your concerns.

08/25/1992 - Eating and drinking in doctors' waiting rooms.

Dear Senator _____:

This is in further response to your letter of June 23, on behalf of your constituent, Dr. Robert McKeeman, in which you requested information on the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

With respect to Dr. McKeeman's first question regarding OSHA requirements to prohibit all eating and drinking in the waiting room, we can clarify for him that OSHA's jurisdiction covers only employees of an establishment, not patients or clients. Paragraph (d)(2)(ix) of this regulation prohibits the consumption of food and drink by employees in areas of the establishment in which work involving exposure or potential exposure to blood or other potentially infectious materials (OPIM) occurs, or where the potential for contamination of work surfaces exists.

OSHA, therefore, does not require that a doctor prohibit patients from eating or drinking, or mothers from feeding hungry babies, in the waiting room. Further, assuming that under the specific conditions in a given establishment it is not reasonably anticipated that a waiting patient could contaminate cups or other serving utensils which the employees would handle, serving those patients coffee would likewise not be prohibited.

Regarding Dr. McKeeman's concern that OSHA's compliance officers "... have to generate enough fines to pay for their wages, and for the expenses of the department ...," OSHA is funded through the normal governmental budgetary process, not through generation of fines. Section 17(1) of the Occupational Safety and Health Act of 1970 states, "... Civil penalties owed under this Act shall be paid to the Secretary for deposit into the Treasury of the United States and shall accrue to the United States ...."

04/30/1993 - Dental workers exposed to disinfectants as part of decontamination.

Dear Mr_____:

This is a final response to your letter of October 15, 1992, regarding the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." We apologize for the delay in this response.

Your specific concern was that members of the dental healthcare workforce are now being exposed to more disinfectants than ever before, as a result of decontamination requirements of the bloodborne pathogens standard. You felt that these increased chemical exposures and resulting respiratory illnesses and associated health problems that we may see in 5 or 10 years may outweigh the benefits of the decreased risk of human immunodeficiency virus (HIV) or hepatitis B virus (HBV) transmission.

The bloodborne pathogens standard is designed to protect the nation's workers, particularly health care workers, from exposure to HBV, HIV, and other bloodborne pathogens. Of the diseases caused by these viruses, hepatitis B is the most common, with 8700 cases per year among workers in the health care profession. Hepatitis B infection may result in serious illness, potential long term disability and death. HIV causes AIDS, for which there currently is no cure and which eventually results in death. These viruses, as well as other organisms that cause bloodborne diseases, are found in human blood and certain other human body fluids. Therefore, employers have a particular responsibility to ensure that workers do not come into direct contact with blood or other potentially infectious materials while performing their job. Part of this responsibility includes proper disinfection of contaminated items.

The U.S. Environmental Protection Agency (EPA) is the governmental agency which is responsible for overseeing the registration of sterilants, tuberculocidal disinfectants, and anti-microbial products. Under the bloodborne pathogens standard, OSHA requires that contaminated items and surfaces be decontaminated with an appropriate disinfectant. EPA-registered tuberculocidal disinfectants and solutions of 5.25 sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water are considered appropriate for this purpose.

As required by the 29 CFR 1910.1200, "Hazard Communication Standard," manufacturers and distributors of hazardous materials, including tuberculocidal disinfectants and bleach, are to send a material safety data sheet (MSDS) to the purchaser of the product. In turn, the employer who receives the MSDSs is responsible for communicating the hazard information therein to the employees who will be using the product(s). In this way, employees can take the appropriate measures necessary to prevent health problems related to use of the disinfectants.

04/26/1994 - Is a physician's order required before performing blood testing on a source individual after consent is obtained.

Dear Ms. _____:

This is in response to your letter received November 29, 1993, regarding the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030 "Occupational Exposure to Bloodborne pathogens." We apologize for the delay in this response.

Specifically, you asked whether a physician's order is required before performing blood testing on a source individual after consent is obtained, or whether the hospital may state in its policy that tests shall be performed following the patient's consent.

You also state that you understand that consent must be obtained from the source individual. This is the situation in some states. However, in others, the third sentence in Section (f)(3)(ii)(A) applies. This sentence states, "When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented." This stipulation was included for employee protection. That is, in some states, if an employee has been exposed to blood, the employee has the right to know the infectious status of the source person. Such knowledge enables the employee to make informed treatment decisions. The blood of such a source individual is to be tested even without consent in those circumstances. The Indiana Board of Health Office of Legal Affairs (telephone (317) 633-8540) should be able to assist you in this determination.

A separate physician's order is not required before testing a source individual's blood. It is permissible for the hospital policy to simply state that such testing will be performed after consent is obtained, unless the hospital is located in a state where consent is **not** required. In that case, such a statement by the hospital would not be in compliance with OSHA's Bloodborne pathogens standard.

11/24/1993 - Extracted teeth potentially infectious materials.

Dear Senator _____:

This is in response to your letter of September 25, which you wrote on behalf of your constituent, Mr. Gordon Sorum. Mr. Sorum contacted you because his oral surgeon refused to return an extracted tooth to him and informed him that "OSHA prohibits him from returning teeth that have been extracted from patients." The Occupational Safety and Health Administration (OSHA) appreciates the opportunity to clarify this matter.

Under the Occupational Exposure to Bloodborne Pathogens standard (29 CFR 1910.1030), OSHA considers extracted teeth to be potentially infectious material when they are being disposed of, used as diagnostic specimens, or sent to dental schools for student use. As such, they are to be handled in a particular manner in order to prevent occupational transmission of disease to employees who come into contact with them.

However, there is nothing in the standard which would prevent a dentist from giving patients their own extracted teeth when the patient desires them, since the intent of the standard is to prevent exposure of employees to the blood of other individuals, not to protect individuals from their own blood. At the same time, it would be unacceptable for a healthcare provider to require that a patient take all of the contaminated items generated during their care in order to circumvent the standard's regulated waste requirements.

07/01/1994 - Appropriate quality standards for PPE.

Dear Mr. _____:

This if in further response to your letter of April 19, addressed to Assistant Secretary of Labor for OSHA, Joseph A. Dear, regarding your concerns about the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens." You expressed concerns about appropriate quality standards for personal protective equipment, in particular, clothing.

OSHA has not established specific standards for personal protective clothing resistance against biological agents.

OSHA's Bloodborne Pathogen Standard requires appropriate PPE to be used to prevent blood or OPIM from passing through to, or contacting the employees' work or street clothes, undergarments, skin, eyes, mouth, or other mucous membranes, unless engineering controls and work practices have eliminated occupational exposure. The type and amount of PPE shall be chosen to protect against contact with blood or OPIM based upon the type of exposure and quantity of these substances which can be reasonably anticipated to be encountered during the performance of a task or-procedure. A gown which is frequently ripped or falls apart under normal use would not be considered "appropriate PPE".

Use of protective body clothing, such as gowns, aprons, laboratory coats, clinic jackets, surgical caps, or shoe covers, and the degree to which such PPE must resist penetration, are performance based. The employer must evaluate the task and the type of exposure expected and, based on the determination, select the "appropriate" personal protective clothing in accordance with section **(d)(3)(i)** of the standard. For example, laboratory coats or gowns with long sleeves shall be used for procedures in which exposure of the forearm to blood or OPIM is reasonably anticipated to occur. However, if the amount of blood exposure is such that the blood penetrates the clothing and contaminates the inner surface, the penetration itself would constitute exposure and the clothing would be inappropriate.

OSHA directs compliance officers to evaluate the task being performed and the degree of anticipated exposure by direct observation, employee interview, or review of written standard operating procedures.

Regarding the use of gloves as PPE, gloves of appropriate sizes must be made available in accordance with section **(d)(3)(iii)** of the standard.

At a minimum gloves shall be used where there is reasonable anticipation of employee hand contact with blood, OPIM, mucous membranes, or non-intact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items. Studies have shown that gloves provide a barrier, but that neither vinyl nor latex procedure gloves are completely impermeable. Thus, OSHA requires hand- washing after glove removal.

While disposable gloves shall be replaced as soon as practical when contaminated, obviously some critical procedures (i.e., surgery, delivery) cannot be interrupted to change gloves. The key words to evaluate are "practical" and "feasible".

Disinfecting agents may cause deterioration of the glove material; washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected pores thereby transporting potentially infectious materials into contact with the hand. For this reason, disposable (single use) gloves may not be washed and reused. Plastic film food handling gloves ("cafeteria" or "baggie" gloves) are not considered to be appropriate for use in exposure-related tasks. They are not strong enough to provide protection to the hands nor would they fit the employee as required by paragraph **(d)(3)(ii)** of the standard.

There are currently no available standardized methods of testing and classification of performance specifications for resistance of clothing to biological hazards. However, we appreciate your efforts in providing to customers products that have met other agencies' guidelines and regulations with safety in mind.

12/07/1994 - The mandate to use one of two pharmacies and whether or not the time it takes to attend a medical appointment is compensable.

Dear Mr. Mottram:

This is in response to your letter of September 8, concerning two administrative practices that you questioned. One is that your members who are under the care of an infectious disease physician are limited in the pharmacies they can use and the other is whether a worker is entitled to compensation for the time it takes to attend appointments for work related medical evaluations, consultations, follow-ups, and other similar activities.

The first practice you mention concerning the mandate to use one of two pharmacies is not addressed anywhere in any Federal Occupational Safety and Health standard. The Occupational Exposure to Bloodborne Pathogens Standard, CFR 29, 1910.1030, does not require any such restriction.

The second concern you have is whether or not the time it takes to attend a medical appointment is compensable. Workers compensation rules and regulations following an occupational illness or injury occurs is under the jurisdiction of the Office of Worker's Compensation Programs (OWCP). We suggested that you contact your local OWCP office for further information. Federal OSHA has several substance-specific standards that require employers to pay for medical examinations in connection with those substances, such as lead, arsenic and cotton dust.

02/15/1996 - Classification of saliva in dental procedures under the bloodborne pathogens standard.

Dear Dr. _____:

This is a full response to your correspondence of September 29, 1995, regarding classification of saliva in dental procedures under the bloodborne pathogens standard.

The Occupational Safety and Health Administration's (OSHA) Bloodborne Pathogens standard is directed toward protecting employees against occupational transmission of bloodborne disease. The pathogens encompassed by the standard include, but are not limited to, human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus, and non-A non-B hepatitis virus.

The standard lists a number of body fluids in addition to blood that are reasonably likely to transmit bloodborne pathogens. OSHA based this list on the Center for Disease Control and Prevention (CDC) guidelines. These body fluids, along with several substances, have been collectively referred to in the standard as "other potentially infectious materials." With regard to saliva, the CDC guidelines state the following:

Universal precautions do not apply to saliva...Gloves need not be worn when feeding patients and when wiping saliva from skin...Special precautions, however, are recommended for dentistry. Occupationally acquired infection with HBV in dental workers has been documented, and two possible cases of occupationally acquired HIV infection involving dentists have been reported. During dental procedures, contamination of saliva with blood is predictable, trauma to health care workers' hands is common, and blood spattering may occur. (MMWR, 1988; 37:379)

In addition, these CDC guidelines recommend the use of gloves for examination of mucous membranes (including the mucous membranes of the mouth).

While the study attached to your letter concludes that saliva may have some anti-HIV activity, the provisions of the standard would still need to be followed to protect employees against other bloodborne pathogens. Based upon the recommendations of the CDC with regard to precautions in dentistry and the necessity for assuring employee protection against all bloodborne pathogens, we have concluded that retaining "saliva in dental procedures" as an "other potential infectious material" is appropriate and correct.

07/03/1997 - OSHA's standard for exposure to bloodborne pathogens.

Dear Dr. _____:

Thank you for your letter dated May 8, regarding concerns about the Occupational Safety and Health Administration's (OSHA) standard for Occupational Exposure to Bloodborne Pathogens. In your letter you have stated an objection to wearing latex gloves while performing procedures in your orthodontic practice. You state that there is no contact with the teeth, gums or salvia of a patient in many of your procedures.

As you know, the standard requires that employees use gloves in the dental setting when there is hand contact with blood or "other potentially infectious material" (OPIM) which includes saliva in dental procedures as well as any body fluid that is visibly contaminated with blood. The use of gloves for examination of mucous membranes (including the mucous membranes of the mouth) was first recommended by the Centers for Disease Control and Prevention (MMWR, 1988; 37:379). Based on this recommendation, OSHA included this provision in the final standard. At a minimum, gloves must be used where there is reasonable anticipation of employee hand contact with blood or OPIM, or non-intact skin.

A section of the standard requires that employers provide gloves in the appropriate size. You state that "cheap, ambidextrous latex gloves" has caused two problems, allergic reactions to latex and carpal tunnel syndrome. Using the correct sized glove would help to eliminate some of the discomfort and help to promote employee participation. Some employees are allergic to latex. The alternatives to latex gloves include vinyl gloves, hypoallergenic gloves, glove liners, and pow[d]erless gloves.

Employees who are allergic to the gloves should be provided with one of these alternatives. The U.S. Food and Drug Administration (FDA) is finalizing a new labeling regulation to address the allergen problem with latex gloves in the health care setting. The use of gloves as means of protecting employees in the dental setting is not a new concept. According to the information provided to OSHA during the rulemaking, disposable gloves were in use by 96% of the direct patient care workers in dentists' offices before the standard became final.

02/16/1993 - Sterilization of spirometry tubing.

Dear Mr. _____:

This is in response to your letter of August 31, 1992, requesting clarification of the Occupational Safety and Health Administration (OSHA) regulation 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens". We apologize for the delay in this response.

Specifically, you inquired about the sterilization of spirometry tubing between patients and whether your sterilization procedures were adequate. You, however, are operating under an incorrect belief that "saliva is considered as a potentially infectious material in the bloodborne pathogens law". The definition of "other potentially infectious materials" includes saliva in dental procedures as well as any body fluid that is visibly contaminated with blood. Saliva that is not the product of a dental procedure or which is not visibly contaminated with blood (or for which it would not be reasonable to anticipate that it could be contaminated with blood) would not be considered to be a potentially infectious material and would, therefore, not be covered under 29 CFR 1910.1030.

In general, OSHA does not believe that spirometry tubing presents a bloodborne pathogens hazard to employees. The recommendations of the Joint Council of Allergy and Immunology that the tubing be sterilized between patients is sound public health policy but does not fall within OSHA's jurisdictional mandate to protect the health and safety of **employees**. If employees were to handle tubing which was contaminated with blood or other potentially infectious materials, decontamination by means of bleach or an EPA-registered disinfectant would be necessary.

04/18/1996 - Hazards of Smoke Generated from Surgical Procedures.

Dear Ms_____:

Thank you for your letter addressed to John Miles of the Occupational Safety and Health Administration (OSHA) concerning the agency's requirements addressing hazards of smoke generated from surgical procedures. Specifically, you inquired if there is a specific OSHA guideline that mandates the evacuation of surgical smoke generated by electrosurgery during operative procedures.

OSHA does not have a specific standard that addresses inhalation hazards related to smoke from surgical procedures. Related to your question, OSHA does have a regulation that addresses the hazards of bloodborne pathogens (29 CFR 1910.1030). A copy has been enclosed.

Please understand that in cases where a particular hazard is not addressed by any OSHA standard, the general duty clause may be cited. The general duty clause, Section 5(a)(1) of the Occupational Safety and Health Act of 1970, applies to all employers and requires each employer to provide employees with a place of employment which is free of recognized hazards that may cause death or serious physical harm. Section 5(a)(1) citations must of course meet the requirements outlined in OSHA's Field Inspection Reference Manual (FIRM) Chapter III. C., and will only be issued where there is a serious and recognized hazard in the workplace which can be feasibly abated.

08/28/1996 - Appropriateness of the usage of video presentations in meeting the OSHA bloodborne training requirements.

Dear Mr. _____:

Thank you for your inquiry regarding the appropriateness of the usage of video presentations in meeting the Occupational Safety and Health Administration (OSHA) bloodborne training requirements.

29 CFR 1910.1030(g)(9)(2)(vii)(N) of the Bloodborne Pathogens Standard specifically requires that there be an opportunity for **interactive** questions and answers with the **person** conducting the training session.

Training the employee solely by means of a film or video without the opportunity for a discussion, constitutes a violation of the above referenced regulation. While video training programs are certainly appropriate for use as an **aid** in training, they must be supplemented with the required site specific information, and a person must be accessible for interaction.

Please bear in mind that many of the requirements of Bloodborne Pathogens Standard in particular are performance oriented. Compliance officers, therefore, will determine on a case-by-case basis, whether the training that has been provided is effective and adequate. This is accomplished through observations of work practices and employee interviews in an effort to determine that the training (including written material, oral presentations, film, videos, computer programs, or audiotapes) is presented in a manner that is appropriate to the employees' education, literacy level, and language.

12/02/1996 - Requirement to obtain a healthcare professional's written opinion in the "pre-exposure vaccination setting."

Dear Dr. _____:

Thank you for your letter dated October 15, where you raised an issue relating to the Occupational Safety and Health's Administration (OSHA) standard on Occupational Exposure to Bloodborne Pathogens. You have asked about the specific requirement to obtain a healthcare professional's written opinion in the "pre-exposure vaccination setting."

The Bloodborne Pathogens standard, 29 CFR 1910.1030, requires the employer to obtain and provide the employee with a healthcare professional's written opinion of a medical evaluation prior to the initial inoculation of the Hepatitis B vaccine. This requirement can be found in paragraph (f)(5)(i). The written opinion shall be limited to whether Hepatitis B vaccination is indicated for an employee and if the employee has received such a vaccination. The second circumstance that requires a written opinion, and the one you are familiar with, is found in paragraph (f)(5)(ii). This written opinion must be obtained for post-exposure evaluations.

The purpose of obtaining an evaluation prior to receiving the vaccine is that some employees may be allergic to a component of the vaccine. Following the evaluation, the healthcare professional can proceed to administer the first inoculation on this same visit. The written opinion ensures the employer that an evaluation was done, informs the employer regarding the employee's HBV vaccination status, and allows the employer to provide a copy to the employee.

09/23/1997 - The Bloodborne Pathogen Standard and the Enforcement Procedures for TB.

Dear Mr. _____:

This is in response to your letter dated June 27. We apologize for the long delay. Your letter presented specific questions concerning the Occupational Safety and Health Administration's (OSHA) Occupation Exposure to Bloodborne Pathogen Standard and the Enforcement Procedures for Occupational Exposure to Tuberculosis (TB).

The first question you ask concerns when an employer hires a new employee who has been previously vaccinated, does OSHA require the employer to send this employee for a "current" evaluation by a healthcare professional? Paragraph (f)(2)(i) states that an employer must make an evaluation and vaccine available to all employees with reasonably anticipated occupational exposure. If the complete hepatitis B series was previously received, the employer can claim the exemption as stated in paragraph (f)(2). If the employer claims this exemption, it must be documented in the employee's medical record. This establishes a new medical record for the employee and it must be maintained for the duration of employment and for thirty years. This documentation does not require the employer to obtain a "current written opinion" from a professional healthcare provider. Evidence provided by the employee or their previous employer is acceptable for the purposes of recordkeeping. It would be beneficial for the employer to have a copy of the employee's vaccine information to include in the new record. It is suggested that one way to obtain the information would be to ask the employee if they would voluntarily provide a copy. The employer is encouraged to ask the employee for documentation of their vaccine status. The previous employer, who provided the vaccine, maintains the original medical record for the duration of employment plus thirty years.

Your second question pertains to tuberculosis skin testing and which employees are required to be tested. OSHA's position is that employers, in covered workplaces, shall offer Mantoux TB skin tests (at no cost to employees) to all current potentially exposed employees and to all new employees prior to exposure. A two-step baseline shall be used for new employees who have an initially negative TB skin test result and who have not had a documented negative TB skin test result during the preceding 12 months. Periodic skin testing frequency is to be based on the results of the employer's risk assessment, utilizing the methodology outlined in the Centers for Disease Control and Prevention's (CDC) document "Guideline for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994."

Using this methodology, the employer must offer TB skin testing every three months for workers in certain high risk categories, every six months for workers in intermediate categories, and annually for low risk personnel. In addition, OSHA requires that all other employees who "share the air" in the same building or facility be offered an annual TB skin test. Employees who do not work in the same building or facility where suspected or confirmed infectious TB patients are encountered or provided treatment and who do not "share the air" with such an area would not be required to have the TB skin offered to them. Workers with documented positive TB skin test who have received treatment for disease or preventive therapy for infection are exempt from the TB skin test but must be informed periodically about the symptoms of TB and the need for immediate evaluation of any

pulmonary symptoms suggestive of TB by a physician or trained healthcare provider to determine if symptoms of TB disease have developed. In addition, if a facility has not encountered or treated any individuals with suspected or confirmed infectious TB, then there is no occupational exposure and TB skin test do not have to be made available. Finally, be aware that participation in the employer's skin testing program is voluntary on the part of the employee. OSHA does not require that employees participate in TB skin testing, only that the employer make such skin testing available to employees.

OSHA FAQs

08/05/2009 - OSHA's position on the requirements for TB screening for employees who have a documented allergy to PPD

Dear Mr. Rowe:

Thank you for your letter of May 6, 2009, to the Occupational Safety and Health Administration (OSHA). Your letter has been forwarded to the Directorate of Enforcement Programs (DEP) for a response. You specifically asked what OSHA's policy is regarding annual employee tuberculosis (TB) skin testing for health care workers (HCWs) who have a documented allergy to purified protein derivative (PPD) tuberculin. This letter constitutes OSHA's interpretation only of the requirements herein, and may not be applicable to any questions not delineated within your original correspondence.

Scenario: Your facility has had several employees who have had allergic reactions in the past to the TB skin test (TST)/PPD. Many facilities have chosen to do only an annual screening questionnaire for these employees, while your facility has opted for QuantiFERON-TB Gold (QFT-G) blood test in lieu of a PPD for those employees who have a documented allergy to the PPD.

Question: What is OSHA's position on the requirements for TB screening for employees who have a documented allergy to PPD?

Reply: OSHA's current compliance directive (CPL 02-00-106) references the 1994 Centers for Disease Control and Prevention (CDC) guidelines, which, as you are aware, do not address a recommended TST for individuals who have had an allergic reaction to a TSTPPD. The Agency's current means of enforcement of worker protection from TB in large part falls under the provisions set by Section 5(a)(l) of the Occupational Safety and Health (OSH) Act, the general duty clause. Your facility, which administers the QFT-G, a type of blood assay for *Mycobacterium tuberculosis* (BAMT), would adhere to the recommendations of the most recent CDC guidelines (*Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005*) and would be considered to meet the provisions of the general duty clause.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Our enforcements guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult the OSHA website at http://www.osha.gov. If you have any further questions, please feel free to contact the Office of Health Enforcement at (202) 693-2190.

10/21/2004 - Respiratory protection medical evaluations: additional evaluations; use of employee's physician; testing; medical removal; and confidentiality.

Dear Mr. _____:

Thank you for your letter of August 15, 2003 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs regarding the medical evaluation section of the respiratory protection standard 29 CFR 1910.134. Your questions are restated below, followed by OSHA's response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

Question 1: Does OSHA require the medical questionnaire to be filled out on a yearly basis or may it just be amended as job or health conditions warrant?

Answer: The respiratory protection standard requires an initial medical evaluation to determine the employee's ability to use a respirator before the employee is fit tested or required to use the respirator in the workplace. At a minimum the employer must provide additional evaluations if an employee shows signs or symptoms that are related to their ability to wear a respirator. There is not a specific annual requirement for medical evaluations in the standard. However, the physician or other licensed healthcare provider (PLHCP) may prescribe annual tests to ensure employees' continued ability to wear a respirator.

Question 2: Is it allowable for an employee to go to their own doctor for a medical evaluation of their ability to wear a respirator if the employee is willing to cover the costs?

Answer: The standard requires the employer to select a PLHCP to perform the medical evaluations. Usually the employer has the evaluation performed by a company physician or through an arrangement with a local health care facility. The employer may also choose to use the employee's own physician to evaluate the employee's ability to wear a respirator, in which case, both the physician's fees and the employee's time must be paid by the employer. However, this arrangement is usually difficult to administer since the employer would need to establish a relationship with each physician and provide each physician with the necessary information. If the employer does not select the employee's own doctor or any physician the employee prefers as the PLHCP and the employee goes to a physician of his own choosing, the employer would not be required to accept the evaluation or pay for the evaluation.

Question 3: What information must the company provide to the employee for the physician to make a medical determination as to the employee's ability to wear a respirator?

Answer: The employer must provide the PLHCP with the information in paragraph (e)(5) of the

standard. This information includes: the type and weight of the respirator to be used by the employee; the duration and frequency of respirator use; the expected physical work effort; additional protective clothing and equipment to be worn; and the temperature and humidity extremes that may be encountered. The PLHCP must also be provided with a copy of the company's respiratory protection program and a copy of the standard.

Question 4: Can the company dictate to the employee which type of testing must be done by their doctor in order to determine the employee's ability to wear a respirator?

Answer: Most employers use the medical questionnaire to determine an employee's ability to wear a respirator but the standard also allows employers to use a medical examination instead. OSHA requires that the content of the examination include, at least, the items covered in the questionnaire, but this is considered the minimum requirement for the medical evaluation. Any additional testing would be left to the discretion of the company's PLHCP.

Question 5: Does any provision exist to prevent employees from being disqualified or displaced if their ability to use the current type of company-provided respiratory protection is diminished?

Answer: The standard does not provide medical removal protection. However, if the PLHCP determines that an employee has a medical condition that places the employee's health at increased risk if a negative pressure respirator is worn, but the employee could wear a powered air purifying respirator (PAPR), then the employer must provide one. OSHA believes many workers who are medically unable to wear a negative pressure respirator will be able to use a PAPR. However, if it is determined that the employee cannot wear a PAPR either, then the employer cannot assign the employee to a position that would require the employee to wear a respirator.

Question 6: I am aware of at least one instance where the information provided by an employee on Appendix C (The OSHA Respirator Medical Evaluation Questionnaire) was shared with the human resources department. How can the issue of confidentiality be formally addressed to ensure the practice of sharing personal medical information is not ongoing and will not happen in the future?

Answer: The information in the medical questionnaire is considered a medical record and, like all medical records, it must not be shared with management personnel. The medical questionnaire clearly states "To maintain your confidentiality, your employer or supervisor must not look at or review your answers, and your employer must tell you how to deliver or send this questionnaire to the health care professional who will review it."

Your employer's Human Resources may have a policy on who may access employee medical records and for what reasons. You should check with your State professional boards to find out if there are any relevant state laws regarding confidentiality of employee medical records. Also, some National and State Health Care Professional organizations like the American Medical Association have ethics statements for healthcare professionals who are members of their organizations in regard to the confidentiality of medical records, and these organizations may serve as resources for you on this issue of confidentiality.

02/05/1996 - The OSHA interpretation of respiratory protection requirements with regards to tuberculosis (TB) exposure.

Dear Ms. _____:

This letter is in response to your request for the Occupational Safety and Health Administration's (OSHA) interpretation of respiratory protection requirements with regards to tuberculosis (TB) exposure.

Under the new respirator certification and testing guidelines issued by the National Institute of Occupational Safety and Health (NIOSH), several new categories of particulate respirators are now available on the market. These include the Type 100, the Type 99, and the Type 95. According to the NIOSH certification document, all three classes of these respirators are acceptable for use during workplace tuberculosis exposure. The Type 95 is regarded as the minimally acceptable level of respiratory protection. OSHA will still accept the use of the high efficiency particulate air (HEPA) respirator or any of these newly certified respirator classes.

There are several questions on the use of respirators that continue to be asked. These include use limitations of disposable respirators and fit testing and fit checking requirements for respirator fit. Regarding the reuse of disposable respirators, NIOSH has stated that the disposable masks can be reused for multiple uses provided the integrity of the mask has not been compromised. OSHA accepts this view. On fit checking and fit testing, our standards require that each worker assigned to wear a respirator must receive either a qualitative or quantitative fit test. Once assigned a respirator, each employee must perform a fit check of the mask every time the respirator is put on. The purpose of the fit check is to assure that the respirator is properly situated on the face and is providing a face to respirator seal comparable to when the mask was fit tested.

The last point raised in your correspondence addresses the assigned protection factor (APF) of the N-95 respirators. When a quantitative fit test is conducted, the wearer of the mask is assigned a fit factor that is based upon the APF plus a safety factor of 10. The combination of the APF and the safety factor is the derivation of the fit factor (100). OSHA has not assigned a protection factor to these masks. The section of the proposed standard covering APFs is currently open and under review. The agency cannot at this time state what the protection factor for these respirators would be. Nevertheless the agency will expect that for a quantitative fit test that the wearer of the respirator must achieve a fit factor of at least 100.

03/04/1996 - Fit testing and fit factors for the N-95 respirators for protection against TB exposure.

Dear Dr_____:

This letter is in response to your request for written information regarding fit testing and fit factors for the N-95 respirators recently certified by the National Institute of Occupational Safety and Health (NIOSH). The Occupational Safety and Health Administration's (OSHA) [Respiratory Protection Standard], [29 CFR 1910.134], requires that fit tests be conducted for those workers required to wear respiratory protection. Under this standard either a quantitative (QNFT) fit test or a qualitative (QLFT) fit test is acceptable. Your use of a Portacount to conduct quantitative fit testing is acceptable provided the tests are conducted according to the recommendations of the manufacturer of the respirator.

You are correct in your letter when you state that a fit factor of 100 should be used when conducting a quantitative fit test. In your earlier discussion with Mr. Richard Fairfax of my staff, Mr. Fairfax was discussing the generally accepted assigned protection factor (APF) of 10 for disposable respirators. As you are aware, when a quantitative fit test is conducted, the wearer of the mask is assigned a fit factor that is based upon the APF plus a safety factor of 10. The combination of the APF and the safety factor is the derivation of the fit factor (100). The agency has not taken a formal position on the APF for these respirators. OSHA is engaged in rulemaking on a final respiratory protection standard, and until a final standard is issued OSHA will not be assigning protection factors to respirators. Nevertheless OSHA continues to require that, for a quantitative fit test, the wearer of the respirator must achieve a fit factor of at least 100.

The agency also requires, as addressed in [29 CFR 1910.134], that wearers of respirators conduct a fit check each and every time they don a respirator. The fit check may be conducted according to the manufacturer's instructions.

06/03/2002 - Tuberculosis testing procedures for the home health care industry.

Dear Mr. _____:

Thank you for your November 13, 2001 letter regarding two-step purified protein derivative (PPD) testing for Tuberculosis and its implementation by the home-health care industry. In particular you asked whether the two-step TB testing for new potentially exposed employees, explained in the Occupational Safety and Health Administration's (OSHA's) compliance directive, CPL 2.106, *Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis*, is mandated for the home healthcare industry.

OSHA's compliance directive, CPL 2.106, *Enforcement Procedures and Scheduling for Occupational Exposure to Tuberculosis* focuses on the workplaces identified by the Centers for Disease Control and Prevention (CDC) as those wherethe risk was considered the highest. This instruction is not a "mandate," nor is it a final OSHA standard applicable to any particular segment of the health care industry. Rather, it was written as a directive to our field offices to clarify the application of the General Duty Clause when inspecting facilities identified as belonging in these high hazard groups.

The General Duty Clause is paragraph 5(a)(1) of the Occupational Safety and Health (OSH) Act of 1970. It requires each employer to, "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious harm...."

In paragraph L.1. the directive sets forth General Duty Clause policy in regard to TB exposure, including feasible abatement methods, such as TB skin testing. (See paragraph L.1.e.2.) However, section 5(a)(1) citations are issued only, "...to employers with employees working in one of the workplaces where the CDC has identified workers as having a higher incidence of TB infection than the general population...." (See paragraph L.1.c.) Paragraph H.1. of the directive lists those workplaces as follows:

a. Health care facilities,
b. Correctional institutions,
c. Long-term care facilities for the elderly,
d. Homeless shelters, and
e. Drug treatment centers.

Home health care clearly does not fall into categories b through e. It also does not take place in "health care facilities" (category a). A "facility" is "something created to serve a particular function," e.g., "a new mental health facility" (*Webster's II New College Dictionary*, 1995, p.401). Thus OSHA would not cite home health care employers for not conducting TB testing.

However, the CDC's *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities*, 1994, upon which the OSHA directive was largely based, does recommend several measures for healthcare workers who perform home health care to patients who have suspected or confirmed infectious TB.

03/29/2004 - Fit testing is not required for employees not exposed to a hazardous atmosphere and not required to wear a respirator.

Dear Ms. _____:

Thank you for your February 13, 2004 letter to the Occupational Safety and Health Administration (OSHA), Directorate of Enforcement Programs, concerning annual fit testing requirements for employees potentially exposed to tuberculosis. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions or situations not delineated within your original correspondence.

In your letter you state that your business provides home health care and your most recent TB Risk Assessment found that all but one location had very low risk. You also state your current practice for those employees that may be occupationally exposed to tuberculosis is to have them fit tested prior to assignment to a patient with suspected or actual TB. Other employees are not exposed and are not required to wear a respirator.

The practice you have outlined above appears to be in compliance with OSHA standards. OSHA standards require any employee required to wear a respirator to be fit-tested before wearing it in a hazardous environment. If there is no hazardous atmosphere and the employee has no need to wear a respirator, then there would be no need for that employee to have an annual fit test.

01/03/1994 - Hazard communication standard and pharmaceuticals.

Dear Mr. _____

This is a response to your letter of July 20, concerning the application of the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), 29 CFR 1910.1200, to pharmaceutical products. We regret the delay in responding to your inquiry.

Your questions will be answered in the order they were presented in your letter.

[Question 1.] Does the HCS apply to all pharmaceuticals — or only to pharmaceuticals that the manufacturer has determined as hazardous?

[Reply 1.] The HCS only applies to pharmaceuticals that the drug manufacturer has determined to be hazardous and that are known to be present in the workplace in such a manner that employees are exposed under normal conditions of use or in a foreseeable emergency. The pharmaceutical manufacturer and the importer have the primary duty for the evaluation of chemical hazards. The employer may rely upon the hazard determination performed by the pharmaceutical manufacturer or importer.

The HCS provides workers exposed to chemicals with the right to know the chemicals' hazards and associated protective measures. This is accomplished through implementations of a hazard communication program in each workplace where employees are exposed to hazardous chemicals. Employers are required to ensure that hazardous chemicals are labeled with chemical identity, appropriate hazard warnings, and name and address of the manufacturer, importer or responsible party; maintain MSDSs for hazardous chemicals in the workplace and make them readily accessible to exposed workers; provide training for employees to understand the chemicals hazards and be able to us the information on the labels and MSDSs to know how to protect themselves.

The employer is required to develop a written hazard communication program for their workplace that includes an inventory of all the hazardous chemicals in the workplace. The labels and MSDS are developed by the chemical manufacturer or importer of the product. MSDS are to be provided with the initial shipments to downstream users for any item that would expose employees to hazardous chemicals. Labels are required on containers of hazardous chemicals for every shipment.

[Question 2.] Are pharmaceuticals in a retail establishment which are packaged for sale to consumers exempt from the HCS?

[Reply 2.] Yes, Section 1910.1200(b)(6) (1910.1200(b)(6)(v) and 1910.1200(b)(6)(vi)) of the HCS exempts, "food, drugs, cosmetics, or alcoholic beverages in a retail establishment which are packaged for sale to consumers," and "foods, drugs, or cosmetics intended for personal consumption by employees while in the workplace."

[Question 3.] Must the pharmacy keep MSDSs for hazardous chemical containing products in a solid dosage form (e.g., tablets and capsules) intended for direct administration to the patient — or — are these products exempt from the MSDS requirements?

[Reply 3.] Drugs, as defined in the Federal Food, Drug and Cosmetic Act, in solid, final form for direct administration to the patient (i.e., tablets, pills, capsules) are exempt from coverage under Section 1910.1200(b)(6)(viii) of the HCS. MSDSs are required far all other hazardous drugs.

[Question 4.] Must the pharmacy keep MSDSs for hazardous chemical containing products in a solid dosage form (e.g., tablets and capsules) that are intended to be crushed or mixed prior to administration?

[Question 5.] Must the pharmacy keep MSDSs for hazardous chemical containing products in solid dosage form (e.g., tablets and capsules) that are NOT intended to be crushed or mixed prior to administration — even though it is possible that a nurse might choose to crush or mix them prior to administration?

[Question 9.] Are pellet-filled and powder-filled capsules considered to be solid dosage forms?

[Question 10.] Is a liquid-filled gelatin capsule considered to be a solid dosage form?

[Replies to Questions 4, 5, 9, and 10.] Tablets, capsules, or pills which are designed to be dissolved or crushed by employees prior to administration to a patient are not in "final form"" and are covered by the HCS. There may be situations where the tablet, capsule, or pill is dissolved or crushed to facilitate patient administration when that is not typically the way it is dispensed. The "final form" exemption would apply in this situation.

[Question 6.] Must the pharmacy keep MSDSs for products that DO NOT contain hazardous chemicals and that are intended to be crushed or mixed prior to use?

[Reply 6.] MSDSs are not required for non-hazardous drugs. MSDSs are required to be prepared and transmitted with the initial shipment of all hazardous chemicals including drugs and pharmaceutical products, except for drugs as defined by the Federal Food, Drug and Cosmetic Act which are in solid, final form for direct administration to the patient (i.e., tablets, pills, or capsules) or which are packaged for sale to consumers in a retail establishment.

[Question 7.] Must the pharmacy keep MSDSs for liquid pharmaceuticals (e.g., injectable products and oral liquid products) that DO NOT contain hazardous chemicals?

[Reply 7.] Liquid drugs which are hazardous chemicals would be covered if there is a potential for employee exposure to them. Non hazardous liquid drugs are not covered by the HCS.

[Question 8.] Must the pharmacy keep MSDSs for ointments, creams, and other topical preparations that do not contain hazardous chemicals?

[Reply 8.] If the active ingredients in this dosage form are, indeed, non-hazardous, then these chemical containing products are not covered by the HCS and do not require MSDSs.

[Question 11.] If the manufacturer will not or cannot provide a MSDS for a covered drug, must the pharmacy document its attempt to obtain a MSDS?

[Reply 11.] Yes, the pharmacy is to contact the drug manufacturer, importer, or distributor to request a MSDS. This action should be documented in the form of a letter. Section 1910.1200(g)(1) of the standard states that "the employer shall have a MSDS for each hazardous chemical they use." However, employers are not to be held responsible for inaccurate information on the MSDS which they did not prepare and they have accepted in good faith from the chemical manufacturer, importer, or distributor.

Please bear in mind that the package inserts and the Physician's Desk References cannot be accepted in lieu of MSDSs, as these documents do not meet the specification requirements of MSDSs under the present rule.

02/08/2005 - MSDS's must be provided to employees who package/process drugs for distribution into final form if they contain hazardous chemicals.

Dear Ms. _____:

Thank you for your April 6, 2004 letter to the Occupational Safety and Health Administration's (OSHA's) Office of Evaluation and Analysis. Your letter was forwarded to OSHA's Directorate of Enforcement Programs (DEP), we received it on April 28, 2004. We apologize for the delay in responding to your request for clarification. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any statement or scenario not delineated within your original correspondence. Specifically, you requested information regarding 29 CFR 1910.1200, OSHA's Hazard Communication Standard (HCS), as it relates to drugs and Material Safety Data Sheets (MSDSs). Your paraphrased question and our response are provided below.

Question: Stericycle Pharmaceutical Returns Center (SPRC) processes prescription and over the counter drugs in their final form for distribution. These drugs are in the forms of tablets, pills, capsules, ointments, creams, gels, injections, and liquids. Would SPRC be exempt from the MSDS requirement under 29 CFR 1910.1200(b)(6)(vii)?

Response: SPRC is not exempt from the MSDS requirement and must provide MSDSs to those employees exposed to drugs containing hazardous chemicals, as defined by the HCS. In your letter you stated that SPRC employees are engaged in activities such as pouring and measuring liquid drugs and counting tablets and pills for packaging and processing.

SPRC is therefore considered a "chemical manufacturer" under the HCS, which defines this term as "an employer with a workplace where chemical(s) are produced for use or distribution." The term "produce" under the HCS means to "manufacture, process...or repackage" [29 CFR 1910.1200(c)]. Because SPRC is considered a chemical manufacturer under the HCS and the potential for exposure exists, employees are entitled to the information that is contained on the MSDSs.

In addition, the exemption under paragraph (b)(6) of the standard states that the HCS does not apply to "Any drug...in solid final form for direct administration to thepatient..." The intent of the HCS is to protect employees from hazardous exposures. In the situation you described, employees are counting tablets, pills, and capsules in preparation for packaging and are, therefore, handling the drugs in a manner that would potentially result in exposure to the dust from crumbled pills, tablets, or capsules. Where there is potential for exposure, employees are covered by the standard and have the right to know the hazards of the chemicals to which they are exposed. The same principle applies to the processing of any liquids, injections, gels, and ointments, for which there is no exemption under the HCS.

03/07/2007 - Use of generic MSDSs written by third-party companies and employer responsiblities when using an online MSDS service.

Dear Mr. _____:

This is in response to your correspondence dated May 2, 2006 to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions not delineated within your original correspondence. In your letter you requested an interpretation regarding the material safety data sheet (MSDS) provisions of OSHA's hazard communication standard (HCS), 29 CFR 1910.1200. You specifically asked about the legitimacy of using generic MSDSs and MSDS locator services to comply with the applicable portions of the HCS. Your scenarios are paraphrased with your questions below, followed by OSHA's response.

Scenario 1: You describe companies that provide employers with electronic MSDS access services. These services are provided either online or on CD-ROM. You state that these companies provide generic MSDSs for chemical products and that these MSDSs do not contain the name of any specific chemical manufacturer, and that they may contain incomplete information regarding the chemical composition and hazards of the substance. Your concern is that these types of generic MSDSs and the associated supply services do not meet the intent of the HCS.

Question 1: Do generic MSDSs written by third-party companies meet the requirements of the hazard communication standard?

Reply 1: A material safety data sheet must be specific to each manufacturer's product. Each MSDS must contain, at a minimum, the information required by the HCS; 29 CFR 1910.1200(g)(2)(i)-1910.1200(g)(2)(xii). Included in those provisions are requirements for the manufacturer/importer to provide their name, address, and telephone number or the same information for someone designated as a "responsible party." The "responsible party" would then be obligated to be the primary contact, as opposed to the manufacturer, for providing additional information about the chemical product to include product hazards and appropriate emergency procedures. Therefore generic MSDSs, which are not specific to the manufacturer and to the chemicals being used in the workplace, and which do not contain the name and contact information of the responsible party for the content of the data sheet, do not meet the intent of the HCS. Please be aware that OSHA does allow for manufacturers to prepare "generic" MSDSs for different products which contain the same chemical in different proportions and that otherwise conform to the requirements of 29 CFR 1910.1200(g).

Your letter also stated that "generic" MSDSs may contain health and safety hazard information that may not be indicative of the latest available heath information for those substances and that the information reflected on the generic MSDSs may be "substantially different or lacking." As previously stated, the "generic MSDSs" described in your letter would not meet the intent of the HCS if it lacks critical identifying information. The HCS is a performance-oriented standard, however, and although there are specific requirements for MSDS content, there is some variability in terminology that may be found on MSDSs from different manufacturers for chemical products with

primarily the same content. The scientific accuracy of the information provided is the essential requirement.

Scenario: Your letter describes situations where employers use on-line MSDS access services. You indicate that, in your opinion, it would be impossible for a third-party electronic MSDS repository to maintain copies of MSDSs for every chemical that is potentially used by an employer. Your concern is that on-line MSDS access services may not meet the intent of the HCS, if an MSDS for the specific chemical being used is not available at the time it is requested.

Question 2: Under what conditions can employers rely on on-line MSDS services to make available to them the MSDS for a specific chemical used by that employer when the employer has not provided the service with the MSDS document?

Reply 2: OSHA's hazard communication standard requires MSDSs for the chemicals used in the workplace to be readily accessible to employees. A letter of February 18, 1999 (to Senator Ron Weyden), states ". . . OSHA interprets "readily accessible" to mean immediate access to MSDSs. The employer has flexibility to determine how this will be accomplished and may provide the data sheets via paper copies, computer terminal access, or some other means of providing readable copy on-site." If an employer chooses to use an on-line MSDS service, it is the **employer's** obligation (under the HCS), not that of the access service, to ensure that the MSDSs for the specific products being used are available, accurately represent the same hazards as those being used, and that there are no barriers to employee access to the MSDSs.

The following scenario provides further clarification to your question. If an employer had supplied an on-line MSDS service with copies of the MSDSs for the specific chemicals being used at his or her workplace, and the service was able to make that specific MSDS information immediately accessible pursuant to an on-line request, then those conditions would ensure that the intent of the standard was being met. Please note that OSHA has allowed electronic access to MSDSs for many years, and there are several existing letters of interpretation that provide additional discussion on this issue.

12/24/1992 - Guidance on whether "patch test kits" are exempt from the labeling requirements of HCS.

Dear Dr. _____:

This is in further response to your inquiry of October 9, concerning the Occupational Safety and Health Administration's (OSHA) Hazard Communication Standard (HCS), 29 CFR 1910.1200.

You requested guidance on whether "patch test kits" are exempt from the labeling requirements of HCS. If the patch test kit and its contents are subject to the labeling requirements of the Federal Food, Drug and Cosmetic Act and are labeled in accordance with the Food and Drug Administration, the kit would be exempt from the labeling requirements of HCS. This exemption, found in 29 CFR 1910.1200(b)(5)(ii), only applies to labels; employers must still comply with all other provisions of the standard.

You also list several instances that you feel would be exempt from all of the requirements of HCS, which we will address in the order that you presented them:

1) manufacturer supplied general office supply products, e.g., copier toner;

Chemicals such as copier toner in a business office, that are only used by employees incidentally in non-routine and isolated instances, are not covered by the standard. HCS would apply if copier toner was used by an employee whose job involves routine work with the toner. For example, employees who work in a copy room of an office or in a business establishment that professionally duplicates documents, must be trained and informed of hazards in accordance with HCS.

2) manufacturer supplied consumer supply products, e.g., daily use of Windex to clean surfaces;

Consumer products are only covered by HCS if the employees who use them experience exposures that are of greater duration and frequency than those of normal consumers, or if the product is not used in a manner that is consistent with normal consumer use.

A bottle of Windex could fall under the scope of chemicals that are covered by the company's HCS program if employees use the cleaner more frequently than normal consumer use, or if it is not used in the same manner that a normal consumer would use Windex. For example, cleaning staff who use the product repeatedly on a daily basis would need information on the hazards of Windex because they use the product more frequently than a normal consumer would.

3) FDA approved drugs and emergency medical kits; and

MSDSs must be readily accessible to all workers who may be exposed to hazardous chemicals during normal conditions of use or during foreseeable emergencies at their workplaces, including FDA approved drugs. Such drugs are not subject to the labeling requirements of HCS when they are

labeled in accordance with FDA guidelines, as per 29 CFR 1910.1200(b)(5). Unless otherwise exempted, they are subject to all other requirements of the standard.

Drugs that are in solid and final form for direct administration to the patient (i.e. tablets, pills or capsules) are completely exempt from the requirements of HCS, as per 29 CFR 1910.1200(b)(6). Vaccines, whose hazards are biological rather than chemical, are also exempt from the standard.

Medical kits are exempt from the HCS requirements because they are intended for employee consumption, as per 29 CFR 1910.1200(b)(6)(vi).

4) pharmaceutical sample medications.

Please see our answer to the question above. Sample medications are comparable to other FDA approved medications, and would be covered in the same manner.

4/18/2008 - Clarification of the requirement to provide accurate and current hazard information on an MSDS.

Dear Ms. _____,

This is in response to your correspondence dated December 11, 2007 to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions not delineated within your original correspondence. In your letter you requested clarification of the material safety data sheet (MSDS) requirements under OSHA's Hazard Communication standard (HCS), 29 CFR 1910.1200. Your paraphrased inquiry and OSHA's response follow.

Question: Some of the MSDSs maintained by our system include a statement that the information contained on the MSDS is "valid on the date of printing only." If a MSDS is printed containing the aforementioned quoted statement on one day, and then one wants to refer to the same MSDS on the next day, would the document be deemed valid on the day subsequent to printing? You specifically ask if an MSDS with the above quoted statement would be considered to be in compliance with OSHA regulations.

Answer: OSHA's hazard communication standard (HCS), 29 CFR 1910.1200(g)(2)(xi) states that MSDSs shall contain ". . .[t]he date of preparation of the material safety data sheet or the last change to it . . . " A material safety data sheet is intended to be a reference document that reflects the most accurate and current information about a specific hazardous chemical (product) that is available at the time that the MSDS is developed. It is imperative that an MSDS is a correct reflection of current scientific information related to the hazardous chemical or product, again, as of the date that the MSDS is prepared. Failure to include a preparation date on the document would be a violation of 29 CFR 1910.1200(g)(2)(xi). It is the chemical manufacturer's (or the responsible party's) obligation to ensure that the information contained on an MSDS is accurate and meets the requirements of the HCS. The document would be deemed in violation of the HCS if the dates required by the standard were not included on the document.

As you may know, the MSDS must accompany the initial shipment of a hazardous chemical to the downstream user. MSDSs must be updated whenever the required information on the data sheet changes and the updated data sheet must then be sent with thenext shipment of the chemical to the downstream user. MSDSs are therefore tied to the initial shipment of the chemical, and the information on the data sheet would be considered current for that particular shipment of the chemical, and remains valid until such time that the information gets updated.

Thus, a statement that the information is "valid on the date of printing only" is inconsistent with the requirements of the HCS. The MSDS is valid until the information is superseded, and without the date of preparation or last change, it is difficult for the user to know whether it is a correct reflection of current scientific information. This statement also inappropriately attempts to place the duty of learning about updates on the user; the HCS places the duty of providing updated MSDSs on manufacturers, importers, and distributors.

05/23/2008 - Storage and use of compressed gas cylinders; whether cylinder is considered an oxidizing compressed gas or oxygen cylinder.

Dear Mr. _____:

Thank you for your letter of September 18, 2007, to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP). You had questions concerning standards applicable to the storage and use of compressed gas cylinders. Your paraphrased questions and our response follow.

Scenario: I have two compressed cylinders used for laboratory calibration of gas detectors. One cylinder contains 20.9% oxygen (balance nitrogen); the other contains 100% methane. The volume of each cylinder is approximately 2 cubic feet, and they are pressured at 2000 psi.

Question #1: What standards apply to the use, storage, and handling of these cylinders?

Response #1: The handling, use, and storage of compressed gas cylinders in applications other than welding and cutting in general industry workplaces is governed by OSHA's Compressed gases standard, 29 CFR 1910.101. The standard, at 29 CFR 1910.101(a), requires that gas cylinders be visually inspected to determine that they are in safe condition.

The standard further states, in §1910.101(b), that "the in-plant handling, storage, and utilization of all compressed gases in cylinders . . . shall be in accordance with Compressed Gas Association (CGA) Pamphlet P-1-1965." We note that there are more recent versions of the industry consensus standards that are referenced in §1910.101.2 If the more recent consensus standards address hazards associated with compressed gases that are not addressed in the CGA pamphlets referenced in the standard, §1910.101, §1910.1200, or any other applicable OSHA standard, the more recent consensus standards may provide support for a citation alleging a violation of the OSH Act's general duty clause, 29 USC 651(a)(1). If an employer is not in compliance with the requirements of an OSHA standard but is complying with the requirements of a current consensus standard that clearly provides equal or greater employee protection, the violation of OSHA's requirement will be treated as a de minimis violation. De minimis violations are those having no direct or immediate relationship to safety and health and result in no citation, penalty, or requirement to abate.

You stated in your letter that you are using these cylinders in a laboratory environment. OSHA's laboratory standard, §1910.1450, Occupational exposure to hazardous chemicals in laboratories, defines "hazardous chemical" as one that has been established to produce acute or chronic health effects in exposed employees. While methane is an asphyxiant, it does not produce the acute or chronic health effects described in 1910.1200 Appendix A to which the lab standard refers. However, methane does present an explosion or flammability hazard. Therefore, OSHA's Hazard communication standard, §1910.1200, would apply. The Hazard communication standard requires, among other things, that employees receive training with regard to the hazards associated with the chemicals with which they work, how to detect the presence of those chemicals in the workplace, and the measures required to protect themselves from those hazards.

Question #2: Is a cylinder that contains 20.9% oxygen (balance nitrogen) considered an oxygen cylinder or an oxidizing compressed gas?

Response #2 The cylinder contains 20.9% oxygen and 79.1% nitrogen, which is essentially compressed air.3 While air is technically an oxidizer, compressed air presents no greater oxidation hazard than that of the atmospheric air already present in the workplace. This position was reflected in OSHA's comparison of its Hazard communication standard, 29 CFR 1910.1200, with the Global Harmonization System (GHS) for the Classification and Labeling of Chemicals (available on OSHA's website at http://www.osha.gov/dsg/hazcom/GHSOSHAComparison.html). This document notes, in Section 2.4.2, that "[a]rtificial air containing up to 23.5% vol. oxygen % may be regarded as not oxidizing for some regulatory purposes (e.g. [sic] transport)." Therefore, the cylinder containing 20.9% oxygen would not be considered an oxygen cylinder or an oxidizing compressed gas for the purposes of 29 CFR 1910.101.

2/22/2008 - Requirements of the HCS and the employer's ability to rely on a manufacturer's hazard determination.

Dear Mr. _____:

This is in response to your correspondence dated April 22, 2008 to the Occupational Safety and Health Administration (OSHA). Your letter was forwarded to OSHA's Directorate of Enforcement Programs for response. You are requesting clarification of OSHA's Hazard Communication Standard (HCS), 29 CFR 1910.1200. You specifically ask about the requirements of the HCS as they relate to an employer's ability to rely on a manufacturer's hazard determination and the subsequent reporting of those hazards on the material safety data sheet (MSDS). Your scenario and related question are paraphrased below, followed by OSHA's response.

Scenario: An employer is using a chemical product in its facility, and a material safety data sheet for that product is present. The employer performed air monitoring and the results revealed that use of the product generated a "**toxic gas**." The physical and health hazards associated with employee exposure to the toxic gas are not included on the MSDS.

Question: If an employer is using a product and discovers a health hazard during its use that is not discussed on the MSDS, can that employer ignore the existence of the unreported health hazard and proceed based solely on the hazard information presented on the MSDS (provided by the manufacturer of the product)?

Response: The HCS requires a chemical manufacturer/importer or employer to conduct a hazard determination for each hazardous chemical they produce or import. The results of the hazard determination are then reported by the manufacturer on an MSDS for that product. The manufacturer must develop an MSDS that reflects all of the physical and health hazards associated with the chemical which may occur under normal conditions of use as well as those hazards that may exist during foreseeable emergencies. Under OSHA's HCS, an employer using the chemical (if that employer is different from the manufacturer who performed the hazard determination) is not responsible for making corrections to a deficient or inadequate MSDS.

A manufacturer is only obligated to report on an MSDS those hazards associated with its chemical under normal conditions and those that may occur during a foreseeable emergency. If the product is being used in a manner not intended by the manufacturer, then the manufacturer would not be expected to have any knowledge about this "toxic gas" and would, therefore, not be required under the HCS to include such information on the MSDS.

The HCS allows a downstream employer to rely on the results of the hazard determination performed by the manufacturer or importer which are reported on the MSDS for that chemical (or chemical product). In your scenario, an employer who uses a chemical performs air monitoring and discovers that his employees are exposed to a "toxic gas" whose hazards are not reported on the MSDS. Under these circumstances, the downstream employer may not ignore the newly discovered exposure hazards associated with use of the chemical product.

An employer may contact the product manufacturer directly to notify them of the possibility of the presence of hazards associated with the use of their chemical that are not accurately reflected on the MSDS. A chemical manufacturer that becomes newly aware of significant information regarding the hazards of a chemical has a duty to update its MSDS (29 CFR 1910.1200(g)(5)). Additionally, OSHA has policies and procedures for the field staff to address MSDSs that are deemed to be deficient. For example, an employer may contact the closest OSHA enforcement office and bring the alleged deficiency to their attention. OSHA Instruction 02-00-038, "Inspection Procedures for the Hazard Communication Standard" outlines the procedures to be used by an OSHA office when they are made aware of an MSDS that is believed to be deficient.

Additionally, if an employer has sufficient information about a potential health hazard for which no information is provided on the MSDS, it must provide employees with additional information and training regarding those new hazards. Based on the performance oriented nature of the HCS, if employers have this information, they must provide it to their employees, including information related to how employees can recognize exposures and measures to protect themselves against the workplace hazards. 29 CFR 1910.1200(h).

Lastly, OSHA's standard for General Requirements for Personal Protective Equipment (PPE), 29 CFR 1910.132(d)(1), requires employers to, ". . .assess the workplace to determine if hazards are present, or are likely to be present, which necessitate the use of personal protective equipment (PPE). . ." If the employer's hazard determination results in findings that PPE would protect employees from hazards present in the workplace, then this equipment must be provided by the employer.

9/16/2008 - Whether written programs may be kept solely in an electronic format.

Dear Mr. _____:

Thank you for your April 8, 2008 letter regarding the requirements of various standards for a written program. Your letter specifically asks whether written programs may be kept solely in an electronic format. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence.

As you pointed out in your letter, a number of standards require programs that are written and accessible to all employees on site. Examples of these provisions are 29 CFR 1910.1030(c)(1)(i) and 1910.1030(c)(1)(iii) (bloodborne pathogens), 29 CFR 1910.1200(e)(1) and 1910.1200(e)(4) (hazard communication), and 29 CFR 1910.146(c)(4) (permit-required confined spaces). Traditionally, these programs have been kept in separate binders in appropriate work areas in order to comply with the standards. Maintaining multiple copies of these manuals can be both challenging and time-consuming.

You have also stated that placing safety materials, programs, checklists, and forms on a company intranet can provide significant benefits in consistency, ease of use, and accuracy in maintaining and updating these materials in a timely manner. And, just as hard copy programs can be photocopied upon request, so can an electronic version be printed out upon request.

Computers are much more common in the workplace now than when most OSHA standards were written. We agree that in many instances electronic access to programs could be beneficial. Therefore, OSHA would allow a written program to be in either paper or electronic format, as long as the program meets all other requirements of the standard in question.

Where the standard requires that the written program must be made available to employees, the employer must ensure that employees know how to access the document and that there are no barriers to employee access.

10/20/1999 - Using "stick-on" labels to meet the requirements of 1910.1200.

Dear Dr. _____:

We are in receipt of your letter of March 22, 1999 regarding labeling provisions under the Hazard Communication Standard (HCS), 29 CFR 1910.1200. You described a labeling system used by your client and asked if this system meets the requirements of the HCS. This letter follows up on a phone conversation you had with a member of my staff. Please excuse this delay in providing these written comments.

The labeling system you described is designed for four different solvents with similar hazards. These solvents are used rotationally in one piece of equipment. You have proposed to label the equipment permanently with the manufacturer's name and the products' appropriate hazard warnings, including target organ effects. The solvent identity would be adhered to the equipment using stick-on labels. Differences in health effects that the solvents present (such as carcinogenicity) would be printed on the stick-on label.

The labeling requirements of the HCS include the identity of the hazardous chemical(s); appropriate hazard warnings; and the name and address of the chemical manufacturer, importer, or other responsible party. The labeling system you have proposed appears to meet these requirements.

09/03/2004 - OSHA has no specific standard on autoclaving used medical instruments.

Dear Ms. Rios:

Thank you for your January 16, 2004 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP) regarding the applicability of OSHA standards in processes involving autoclaving on dental instruments on private property. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions or situations not delineated within your original correspondence. The scenario and specific question you raised in your letter and through phone conversation with a member of the [DEP] staff have been rephrased below, followed by OSHA's response. We apologize for the delay in providing you a response.

Scenario: Dental Hygiene Onsite, Inc. employs dentists and dental hygienists who do not work in fixed dental office settings. Our services are entirely mobile, and our employees provide dental services to residents in long-term care facilities. Currently, the used instruments are being transported to our central office after being scrubbed, placed in an ultrasonic cleaner, bagged and sealed, and placed in a sealed plastic container. Autoclaving [steam sterilization] is currently being performed at our central office. As our business expands, our employees will be expected to be located in different counties and soon in different states. We would like to continue our mobile dental services by providing our practitioners with sterilization equipment that they may maintain in their homes for the sterilization of reusable instruments.

Question: What are the [OSHA] guidelines concerning autoclaving of used [dental] instruments on private property?

Response: There is no specific OSHA standard on the autoclaving of instruments. We would note that the Centers for Disease Control and Prevention (CDC) have developed guidelines and recommendations on the use and monitoring of sterilization equipment in dental healthcare settings, and the Food and Drug Administration (FDA) may also have relevant information in connection with that agency's approval of autoclaves.

02/06/1997 - The dental industry's concerns regarding compliance with certain provisions of the Hazard Communication Standard (HCS).

February 6, 1997

Linda M. Chatwin, Esq.
General Counsel
Ultradent Products Incorporated
505 West 10200 South
South Jordan, Utah 84095

Dear Ms. Chatwin:

The Occupational Safety and Health Administration (OSHA) has, over the past year and a half, undergone extensive discussions with the American Dental Trade Association (ADTA) in an attempt to resolve the dental industry's concerns regarding compliance with certain provisions of the Hazard Communication Standard (HCS).

One such concern was the necessity of MSDSs for dental devices, as these devices are already regulated under Food and Drug Administration (FDA) labeling provisions. As fully explained in the enclosed letter to Mr. Thomas Fise of the American Dental Trade Association (ADTA), OSHA has determined that MSDSs are required for dental devices which are not exempt from coverage under the "article" or "consumer products" provisions of the HCS.

As you correctly note, the agency's stay of enforcement was lifted on December 16, 1996, and the dental industry is therefore expected to comply with the provision of the HCS. OSHA does not envision a change in its position on this issue, which resulted from a thorough and exhaustive analysis of the issues raised by the ADTA. If we may be of further assistance, please do not hesitate to contact us.

Sincerely,

Stephen Mallinger, Acting, Director
Office of Health Compliance Assistance

December 11, 1996

Ms. Ruth McCaulley
OSHA Office of Health Compliance Assistance
200 Constitution Avenue N.W.
Washington D.C. 20210

Dear Ms. McCaulley:
I would appreciate receiving an update of OSHA's position regarding MSDS requirements for dental devices. I understand that the 120 day stay of enforcement as to FDA regulated dental devices has now passed. Please let me know whether OSHA is now in a position to make this stay permanent or whether other solutions for the MSDS problem in the dental field are at hand.

I appreciate your help and response in this matter.

Thank you.

Sincerely,

Linda M. Chatwin, Esq.
General Counsel

_____
January 7, 1997

Thomas F. Fise, Esq.
Special Council, Regulatory Affairs for the American Dental Trade Association
4900 B South 31ST Street
Arlington, Virginia 22206

Dear Mr. Fise:

Thank you for your letter of November 21, addressed to Ms. Ruth McCully of my staff and sent as a follow up to the October 11 meeting between yourself, representatives of the Occupational Safety and Health Administration (OSHA), Office of Solicitor (SOL), and the Food and Drug Administration (FDA). This letter provides a recapitulation of the Hazard Communication Standard (HCS) issues that have been under discussion with the ADTA, the Agency's conclusions, and brief explanations for those conclusions.

FDA and OSHA Jurisdiction

One of the ADTA's issues concerned the perceived overlap between FDA and OSHA in the regulation of dental devices. Throughout this process, we have worked closely with FDA to ensure that the integrity of jurisdictional boundaries was respected and maintained, and we hope that, with the assistance of the FDA representatives, we were able to provide you with a better understanding of our respective jurisdictional boundaries regarding dental devices. OSHA's jurisdiction is limited to employees' exposure due to handling or use of hazardous chemicals in the workplace. FDA is concerned with product efficacy and patient safety. Given these different statutory and regulatory mandates, OSHA and FDA were unable to identify any clear areas of regulatory overlap. One issue of specific concern to the ADTA was labeling. We informed you that dental devices which require labeling under FDA regulations are exempt from OSHA's HCS labeling requirements (29 CFR 1910.1200(b)(5)).

In your December 12 correspondence, we note your position that Material Safety Data Sheets (MSDSs) fall within FDA's definition of labeling. As we have discussed in earlier meetings, this is unfounded. As the FDA has neither prescribed nor enforced regulations requiring manufacturers to transmit information on the hazards of chemicals to downstream users by means of MSDS's, FDA's labeling provision for Dental Devices is not duplicative and would not meet the criteria of a (4)(b)(1) pre-emption of the OSH Act. 29 USC Section 653(b)(1). This is further discussed in the preamble to the HCS final rule. 59 Federal Register 6126, 6149-50 (Feb. 9, 1994) (package inserts accompanying FDA regulated dental devices cannot be considered to be material safety data sheets (MSDS)).

Dental Devices Covered by HCS

Another issue concerned the identification of dental devices that are covered by the HCS. In our communication of August 22, 1995, from Assistant Secretary Joseph A. Dear, we made a commitment to "provide further compliance assistance to the ADTA to ensure that the industry is fully applying all the existing HCS exemptions." OSHA worked closely with FDA in this effort. We conducted a broad hazard determination of the FDA's defined classes of dental devices, beginning with a review of FDA regulation, 21 CFR 872, Dental Devices. Next, we excluded devices that failed to meet the HCS definition of a hazardous chemical. We also excluded those devices that met the "article" and "consumer product" exemptions under the HCS (29 CFR 1910.1200(b)(6)).

In this regard, articles are exempt under the HCS if they are "a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees." If a dental device does not potentially release hazardous chemicals during normal use, it would be considered an article, e.g., an endosseous implant, a dental chair, a dental handpiece, an x-ray unit, all would be considered articles and would

be exempt from the HCS. If hazardous chemicals are released during normal use, the manufacturer is required to create an MSDS.

Likewise, consumer products are exempt, "where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended." The standard requires the employer to ascertain whether the workplace use is more frequent or of longer duration than would be expected in normal consumer use. Exposures in workplace situations can be greater than a consumer would experience, and thus, the need increases for additional information for employee protection.

In order for the exemption to be applied, the consumer product must have the same chemical composition, intended use, and potential for exposure as a specific dental device. In this regard, let me stress that to qualify for the consumer product exemption, the Standard provides two criteria which must be met. These are that the dental device, 1) must be used by the consumer and dental professional in the manner intended by the manufacturer, and 2) is a consumer product as that term is defined in the Consumer Product Safety Act, 15 U.S.C. 2051 et seq. In your November 21 correspondence, we note that although consumer products were identified which contain chemicals also found in dental devices, the items fail to meet criteria for a consumer product under the HCS. For example, stove-gasket cement and joint crack sealant have a different intended use by a consumer than the use of porcelain powder by a dentist or a dental technician.

Our hazard determination effort generated two tables of dental devices referenced by class (enclosed). The first table identifies "Dental Devices Which Require Manufacturer's Determination for Presence of Hazardous Chemicals and, if Present, Would Then Require a MSDS." The second table identifies "Dental Devices Not Covered by the Hazard Communication Standard." Please bear in mind that these lists represent a preliminary hazard determination performed on a broad category of dental devices. The device manufacturer or importer maintains the responsibility and right to perform a more specific hazard determination to decide whether or not a particular device may be considered a hazardous chemical(s) under the HCS. The HCS requires that a MSDS be generated only if the device contains a hazardous chemical as shown by the manufacturer's or importer's hazard determination.

Small Quantity Use

ADTA was also concerned regarding the HCS coverage for dental devices that are often used in relatively small quantities. As proposed by Assistant Secretary Joseph A. Dear in his letter of November 22, 1995, this issue was referred to the National Advisory Committee on Occupational Safety and Health (NACOSH) Hazard Communication Workgroup. This Workgroup was established in response to The President's Report, "The New OSHA," issued in May, 1995, and was

composed of professionals with expertise in hazard communication representing small and large businesses, unions, state governments, and consulting firms (see pages 13 and 14 of the enclosed report for a listing of Workgroup members.) The mission of the Workgroup was to provide OSHA with recommendations to simplify MSDSs, reduce the amount of required paperwork, improve the effectiveness of worker training, and revise enforcement policies so that they focus on the most serious hazards. In all our meetings and correspondence we invited and urged ADTA's participation in this process. In your absence, we presented to the NACOSH Hazard Communication Workgroup the "small quantity issues" on ADTA's behalf. The NACOSH Workgroup issued its report on September 12, with their findings and recommendations. The "small quantity issue" is discussed on pages 84 through 86 of the report. The Workgroup's conclusion on this issue follows:

"...that a small quantity exemption that could be uniformly applied in all workplaces could not be identified. In addition, workgroup members agreed that all workers deserve equal protection, and they could not quantify any small quantity exception at this time that would balance the above factors appropriately. Therefore, the workgroup does not agree that an across-the-board small quantity exemption should be developed, and further believes that such an exemption could actually increase the compliance burdens associated with the standard."

Please remember, that the HCS is an information transmittal standard triggered whenever a substance is covered as a hazardous chemical. The fact that a chemical poses a potential hazard is different from the concept of risk. The risk that a chemical presents is dependent upon the concentration, frequency, and duration of exposure. The standard requires the development of MSDSs based on the intrinsic properties (i.e., corrosivity, irritation, sensitization, etc.) of a hazardous chemical, not on predictions about the level of risk experienced by particular employees.

Transmission of MSDSs

Another concern discussed was the transmission of MSDSs for dental devices by manufacturers, importers, or distributors. In our October 11 meeting, we discussed options that would reduce compliance costs. The HCS requires MSDSs to be sent with the initial shipment of a hazardous chemical and when the MSDS is updated. An alternative method of sending MSDSs to downstream users is by electronic transmission. For example, MSDSs may be transmitted by available technology such as telefaxes, electronic bulletin boards, Internet, and CD-ROM/floppy disks to eliminate the need to send paper copies. Both the MSDS sender and receiver must be equipped and agreeable to the electronic transmission. We have been informed that there are a number of manufacturers in a variety of industries that are successfully using electronic transmission of MSDSs.

Conclusions

In summary, based upon our discussions, the information provided by FDA and ADTA and our extensive review of the issues, the Agency has concluded the following:

(1) HCS-covered dental devices are exempt from HCS labeling requirements (but not exempt from MSDS requirements) whenever there is an existing FDA labeling requirement for that device.

(2) Dental devices meeting the definition of a hazardous chemical are covered by the HCS. The enclosed tables represent a broad hazard determination for classes of dental devices rather than for specific items in each class. Manufacturers or importers of HCS-covered dental devices have the responsibility and right to conduct a specific hazard determination for specific dental devices.

(3) Employees who handle dental devices covered under the HCS are entitled to the protections provided under the Standard. The HCS requires that these employees have access to information regarding the hazards of the chemicals to which they are exposed, independent of the risk or quantity of the chemical present.

(4) Electronic transmission of MSDSs can reduce compliance costs and is an accepted alternative to sending paper copies.

Finally, as you know, the Agency issued a temporary enforcement stay on May 16. This allowed OSHA the opportunity to conduct a broad hazard determination for the FDA classes of dental devices. During this interval, NACOSH proceeded with its task of reviewing pertinent HCS issues and published its final report. In addition, the stay permitted OSHA to carefully consider all other issues raised by ADTA. We believe that with the assistance of the FDA, ADTA, and NACOSH, the Agency has conducted a thorough evaluation of these issues within the parameters of the HCS and the OSH Act. As a result, OSHA ended its temporary enforcement stay on dental devices effective December 16.
We appreciate your cooperation throughout our discussions and the industry perspective you presented. We valued your participation in the process and your interest in worker safety and health.

Sincerely,

John Miles, Jr., Director
Directorate of Compliance Programs

Enclosures
Table No. 1.
Dental Devices Which Required Manufacturer's Determination for Presence of Hazardous Chemicals, and if Present, Would Then Require a MSDS

FDA Class No.	Device Class Name
872.3050	Amalgam alloy
872.3060	Gold based alloys and precious metal alloys for clinical use

872.3300 Hydrophillic resin coating for dentures
872.3310 Coating material for resin fillings
872.3690 Tooth shade resin material
872.3200 Resin tooth bonding agent
872.3260 Cavity Varnish
872.3600 Partially fabricated denture kit
872.3700 Dental mercury
872.3710 Base metal alloy
872.3660 Impression material
872.3645 Subperiosteal implant material
872.6200 Base plate shellac
872.6660 Porcelain powder for clinical use
872.3750 Bracket adhesive resin and tooth conditioner
872.3760 Denture relining, repairing, or rebasing resin
872.3765 Pit and fissure sealant and conditioner
872.3770 Temporary crown and bridge resin
872.3250 Calcium Hydroxide cavity liner
872.3820 Root canal filling resin
872.3930 Tricalciun phosphate granules for dental bone repair

Table No. 2 Dental Devices Not Covered by the Hazard Communication Standard

FDA Class No. Device Class Name

872.3275 Denture Cement
872.3640 Endosseous implant
872.3400 Karaya and sodium borate with or without acacia denture adhesive
872.3410 Ethylene oxide homopolymer and/or carboxymethyl-cellulose sodium denture adhesive
872.3420 Carboxymethylcellulose sodium and cationic polyacrylamide polymer denture adhesive
872.3450 Ethylene oxide homopolymer and/or karaya denture adhesive
872.3480 Polyacrylamide polymer (modified cationic) denture adhesive
872.3500 Polyvinylmethylether maleic anhydride (PVM-MA), acid copolymer, and carboxy methlcellulose (NACMC) denture adhesive
872.3490 Carbomethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive

6/11/1991 - The Hazard Communications Standard as it applies to employees who prepare and administer drugs/medications

Dear Mr. Ray

This is in response to your letter of November 27, 1990 to Mr. John E. Plummer, Director, Office of Federal Agency Programs, concerning the Occupational Safety and Health Administration (OSHA) standard, 29 CFR 1910.1200, the Hazard Communication Standard (HCS) and its application to employees who prepare and administer drugs/medications. Please accept our apology for the delay in response.

1. Question - "In what ways does the HCS apply to hospital employees who mix and/or repackage drugs/medications, for dispensing to patients? For example, Tylenol may be dissolved or crushed by one employee for administration by another. Paragraph (b)(6)(viii) of the HCS does not define "final form;" it is therefore unclear whether or not the paragraph applies to tablets or pills which have been dissolved or crushed."

Response - Tablets or pills which are designed to be dissolved or crushed by employees prior to administration to a patient are not in "final form", and are covered by the HCS. There may be situations (such as the Tylenol example) where a tablet or pill is dissolved or crushed for purposes of administration when that is not generally the way it is dispensed. The final form exemption would apply in this situation.

2. Question - "Similarly, to what extent does the HCS apply to drugs and medicines in liquid form (e.g., alcohol, Betadine) which are diluted and/or repackaged before administration or application?"

Response - Liquid drugs which are hazardous chemicals would be covered if there is a potential for employee exposure to them.

3. Question - "What are the requirements to obtain Material Safety Data Sheets from manufacturers on drugs/medications and other products which are not received by a hospital in final form?"

Response - Manufacturers and distributors of hazardous chemicals (including drugs/medications that are not otherwise exempted from the rule) are required to provide a Material Safety Data Sheet (MSDS) with the first shipment to downstream employers (including hospitals), and with the first shipment after the MSDS is updated. Employers must have MSDSs for each hazardous chemical in the workplace to which employees are exposed. If one is not received with the shipment, the employer must obtain one.

4. Question - "To what extent are employees who administer a unit dose of a drug/medication, prepared by an in-house pharmacy, covered by the HCS?"

Response - The frequency of exposure to the drugs has no impact on coverage.

5. Question - "To what extent does the frequency with which ointments, alcohol, or other similar items are used by an employee on patients impact on how that employee is covered under the HCS?"

Response - The frequency of exposure does not effect the application of the HCS. Coverage under the HCS for ointments, alcohol and other similar items is not determined by the frequency of employee exposure. The employer is required to comply with the MSDS and training requirements in the HCS for any ointment, alcohol, or similar medication in liquid form that the manufacturer has found to be hazardous (as defined in the HCS).

05/15/1997 - Clarification of the definition of a hazardous chemical and the requirements for Material Safety Data Sheets.

Dear Ms. _____:

Thank you for your March 6, letter to Ruth McCully, former Director of the Office of Health Compliance Assistance, requesting clarification of the definition of a hazardous chemical and the requirements for Material Safety Data Sheets (MSDS) in a physician's office.

A hazardous chemical, as defined by the Hazard Communication Standard (HCS), is any chemical which can cause a physical or a health hazard. This determination is made by the chemical manufacturer, as described in 29 CFR 1910.1200(d). Attached is a copy of this section of this standard. Drugs are potentially hazardous chemicals, as defined by the HCS, therefore, manufacturers of pharmaceuticals must conduct a hazard evaluation for their products. If the pharmaceutical company determines that their product is a hazardous chemical, the downstream users, including physicians' offices, are required to maintain the MSDS. However medications which are in solid, final form for direct administration to the patient (tablets, capsules) are exempt from this requirement.

Chemical manufacturers are not required to provide MSDSs for chemicals not covered under the HCS. OSHA realizes that manufacturers often provide MSDSs for reasons other than those of meeting the requirements of the HCS and that this can cause confusion to downstream users. OSHA has recommended, and continues to do so, that if a chemical is not covered by the rule, manufacturers provide a statement to that effect on the MSDS. In the absence of such a statement, employers should contact the manufacturer when they question the hazard status of a chemical.

While the Physicians' Desk Reference (PDR) is an excellent resource, its intent is to describe the drug's effect on a patient and not to convey hazard information to employees. The HCS requires that employees have access to information regarding appropriate personal protective equipment, physical characteristics of the chemical, storage requirements, and other information as found in 29 CFR 1910.1200(g)(2). Not all of this is found in the PDR. Additionally, the HCS requires the manufacturer to address exposure to the hazardous chemical during foreseeable emergencies, such as leakage or spill from an injectable syringe.

04/17/2007 - Emergency action plan procedures when employees discover an unknown biohazard.

Dear Mr. _____:

Thank you for your letter of February 25, 2007, to Ms. Ruth McCully of the Occupational Safety and Health Administration (OSHA). Your letter was forwarded to our office for a response. Your letter presents your concerns about the fire evacuation procedures contained in the Post Office's emergency action plan — specifically with respect to a scenario in which clerks discover an unknown powder/biohazard. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any situation not delineated within your original correspondences.

Several OSHA standards (e.g., Hazardous Waste Operations and Emergency Response — 29 CFR 1910.120, Ethylene Oxide — 29 CFR 1910.1047) require the employer to develop an emergency action plan that contains the elements set forth in 29 CFR 1910.38, Emergency Action Plans. Even if an employer is not specifically required by OSHA to establish a 1910.38-compliant emergency action plan, doing so is a good way to protect workers during an emergency.

Under 1910.38, a written emergency action plan must contain the following elements:

1. Procedures for reporting a fire or other emergency;
2. Procedures for emergency evacuation, including type of evacuation and exit route assignments;
3. Procedures to be followed by employees who remain to operate critical plant operations before they evacuate;
4. Procedures to account for all employees after evacuation;
5. Procedures to be followed by employees performing rescue or medical duties; and
6. The name or job title of every employee who may be contacted by employees who need more information about the plan or an explanation of their duties under the plan.

In addition, 1910.38 requires the employer to have and maintain a distinctive alarm system to notify employees of an emergency and to designate and train employees to assist in a safe and orderly evacuation of other employees. Under 1910.38, the employer must also ensure that the emergency action plan is available to employees for review and must review the plan with each employee covered by the plan (1) when the plan is developed or the employee is first assigned to a job; (2) when the employee's responsibilities under the plan change; and (3) when the plan changes.

Please note that the specific evacuation procedures that are appropriate for a given workplace depend upon factors such as the type of incidents (e.g., fire, weather-related, damaged packages) that workers are likely to encounter and the type of building being evacuated. As part of the plan, an employer may choose to require a total evacuation of the building or section of a building, or

possibly to shelter-in-place. It is important to hold practice evacuation or shelter-in-place drills as often as necessary to keep employees prepared. An employer may also provide additional safety and health information for the protection of employees based on their assessment of the types of incidents anticipated in the workplace.

09/16/2008 - OSHA's position on employer performing additional air monitoring that exceeds OSHA requirements.

Dear Mr. _____:

Thank you for your July 29, 2008 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP). This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any scenarios or questions not delineated within your original inquiry. Your question is restated below followed by OSHA's responses.

Scenario: Ethylene oxide (EtO) monitoring is a key service which your company offers for sterile processing departments (SPDs) in hospitals. In addition to the use of EtO sterilizers, healthcare facilities often use the STERRAD 100 commercial sterilization process which uses hydrogen peroxide and low-temperature plasma. One of your competitors offers hydrogen-peroxide monitoring services and is currently marketing this service to hospitals as a measure that should be taken to protect employees. Your company feels that hydrogen peroxide monitoring is unnecessary and will dilute needed compliance activities.

Question: Can OSHA weigh in on a company's errant recommendations to perform hydrogen peroxide air monitoring?

Reply: OSHA's mission is to assure safe and healthful working conditions for working men and women. As you may know, 29 CFR 1910.1000 sets a permissible exposure limit (PEL) of 1 part per million (ppm) as an 8-hr Time Weighted Average (TWA) for hydrogen peroxide. Employers having employees exposed to hydrogen peroxide must ensure that this level is not exceeded. Monitoring to assess the workplace is one way of achieving this objective. An employer is at liberty to perform additional monitoring as a safeguard in case existing engineering and other control measures fail to perform as expected, even after initial workplace evaluation determines that the OSHA PEL was not being exceeded.

Please be aware that each state is entitled to adopt its own OSHA-approved occupational safety and health plan that must be at least as effective as that of Federal OSHA.

Virginia has adopted such a program. As one of the states with its own OSHA-approved occupational safety and health plan, the Virginia Department of Labor and Industry's Occupational Safety and Health Program (VOSH) must adopt standards identical to, or at least as effective as, the federal standards. As such, VOSH could adopt a more stringent interpretation than that of Federal OSHA. You may contact VOSH at the following address:

Virginia Occupational Safety and Health
Attn.: Glenn Cox, Director
13 South 13th Street
Richmond, VA 23219
(804) 786-7776

December 10, 1992

Mr. John R. Schuller
845 Connecticut Avenue
McDonald, Ohio 44437

Dear Mr. Schuller:

This is in response to your letter of October 12, inquiring whether there are Occupational Safety and Health Administration (OSHA) standards which address violent employee behavior in the workplace. We apologize for the delay in this response.

Although currently there are no specific Federal OSHA standards to address these problems, the Federal Occupational Safety and Health Act (OSH Act), in Section 5(a)(1), provides that "each employer shall furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." In a workplace where the risk of violence and serious personal injury are significant enough to be "recognized hazards," the general duty clause would require the employer to take feasible steps to minimize those risks. Failure of an employer to implement feasible means of abatement of these hazards could result in the finding of an OSH Act violation.

On the other hand, the occurrence of acts of violence which are not "recognized" as characteristic of employment and represent random antisocial acts which may occur anywhere would not subject the employer to a citation for a violation of the OSH Act.

Whether or not an employer can be cited for a violation of Section 5(a)(1) is entirely dependent upon the specific facts, which will be unique in each situation. The recognizability and foreseeability of the hazard, and the feasibility of the means of abatement are some of the critical factors to be considered.

This overall issue of violence in the workplace is under review. At this time, we feel that the situation you described is best handled through your company's employee relations activities.

We hope this information is responsive to your concerns.

Sincerely,

Roger A. Clark, Director
[Directorate of Enforcement Programs]

February 9, 2009

Mr. Joe Winkelman
Regional Contractors Alliance, LLC
BP Whiting Business Unit
2815 Indianapolis Boulevard Mail Code 002
Whiting, IN 46394

Dear Mr. Winkelman:

Thank you for your December 2, 2008, letter to the Occupational Safety and Health Administration (OSHA) regarding the Recordkeeping regulation found at 29 CFR Part 1904. Specifically, you requested guidance from OSHA on a case regarding "horseplay."

Scenario: In your letter, you describe an instance where two of your supervisors had completed their work for the day and had entered the change trailer to change clothes and proceed home. There was some bantering back and forth concerning how to beat the traffic at shift's end. The discussion escalated into a physical confrontation where one supervisor allegedly pulled a knife and struck the other in the right bicep, causing a laceration that required sutures to close.

Issue: You have asked OSHA to endorse your contention that, because the work environment did not contribute to the "horseplay gone badly," as you described the situation, the injury was not work-related and thus was non-recordable under OSHA regulations.

Response: Under 29 CFR Subpart C, "Recordkeeping Forms and Recording Criteria," an injury must be recorded if it is work-related, is a new case, and meets one or more of the general recording criteria (such as requiring medical treatment beyond first aid). See 29 CFR §1904.4(a). An injury is presumed to be work-related if it results from an event occurring in the work environment, unless an enumerated exception to this geographic presumption applies. See 29 CFR §1904.5(a). The work environment includes any location where one or more employees are working or are present as a condition of their employment. See 29 CFR §1904.5(b)(1). We assume that the supervisors were in the change trailer as a part of their work or as a condition of their employment. If our assumption is correct, the injury resulted from an event (the altercation between the two supervisors) occurring in

the work environment and was thus work-related. When a work-related injury requires treatment beyond first aid, it is recordable unless it falls within one of the §1904.5(b)(2) exceptions to the geographic presumption.

Violence in the workplace does not generally qualify as an exception. OSHA's Frequently Asked Question 5-2 (found at http://osha.gov/recordkeeping/detailedfaq.html#1904.4) provides guidance on this issue:

Question 5-2: Are cases of workplace violence considered work-related under the new Recordkeeping rule?

The Recordkeeping rule contains no general exception, for purposes of determining work-relationship, for cases involving acts of violence in the work environment. However, some cases involving violent acts might be included within one of the exceptions listed in section 1904.5(b)(2). For example, if an employee arrives at work early to use a company conference room for a civic club meeting and is injured by some violent act, the case would not be work-related under the exception in section 1904.5(b)(2)(v).

Furthermore, the geographic presumption (that is, an injury is work-related if it occurs in the work environment) covers cases in which an injury or illness results from activities that occur at work but that are not directly productive, such as horseplay. See the preamble to the final rule (66 *Fed. Reg.* 5916, 5929 (Jan. 19, 2001)).

Applying these principles to your situation, it is OSHA's position that the injury was work-related and required medical treatment beyond first aid. This is so whether the incident leading to the injury is characterized as horseplay or as workplace violence, neither of which is covered by any exception to the geographic presumption. Therefore, the injury is recordable.

Both the Note to Subpart A of the regulation (29 CFR §1904.0) and the Overview to OSHA Form 300 (http://osha.gov/recordkeeping/new-osha300form1-1-04.pdf) expressly state that recording a case does not indicate that an employer or employee was at fault or that an OSHA standard was violated. In addition, OSHA recognizes that injury and illness rates do not necessarily indicate an employer's lack of interest in safety and health. Recording a case indicates only three things: (1) that an injury or illness has occurred; (2) that the employer has determined that the case is work-related (using OSHA's definition of that term); and (3) that the case is non-minor, i.e., that it meets one or more of the OSHA injury and illness recording criteria. See 66 *Fed. Reg.* at 5933.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters

explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. In addition, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at http://www.osha.gov.

Staff to resident ratio in your nursing home - August 14, 2006

Dear Ms. Meeker:

Thank you for your January 8, 2006 letter to the U.S. Department of Labor, Occupational Safety and Health Administration (OSHA). Your letter was submitted to OSHA's Directorate of Enforcement Programs for an answer to your specific question regarding the staff to resident ratio in your nursing home. This letter constitutes OSHA's interpretation only of the requirements herein, and may not be applicable to any question(s)/scenario not delineated within your original correspondence. We apologize for the delay in responding to your request.

Scenario: In the nursing home where I work, the Alzheimer's Unit is a locked and controlled unit with 21 residents. These residents are considered physically violent or are considered a fall risk. Management has indicated that only one staff member is required at night. I feel that this is going to generate an unsafe environment, both for the worker and for the residents.

Question: Does OSHA have a "...staff-to-Alzheimer resident ratio" requirement?
Reply: No. OSHA does not have any requirements that specifically address a "staff-to-Alzheimer resident ratio." However, OSHA has provided general guidance on the issue of violence inflicted by patients or clients against staff employee its publication #3148-11R, *Guidelines for Preventing Workplace Violence for Health Care & Social Service Workers* (copy enclosed). These guidelines are not a new standard or regulation. They are advisory in nature, informational in content and intended to help employers to establish an effective workplace violence prevention programs adapted to their specific worksites. These guidelines do not address issues related to patient care. They are performance-oriented, and how employers implement them will vary based on the hazards identified.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also,

from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at www.osha.gov. if you have any further questions, please feel free to contact the Office of General Industry

Hazard Communication Standard - Pesticide Labeling May 8, 1991

This is in response to your memorandum of January 28, and follow up of April 16, requesting an interpretation of the labeling requirements of the Hazard Communication Standard (HCS) with regard to containers of pesticides. In your memo you question whether OSHA can cite an employer when an unlabeled container of a pesticide is found in the workplace. Your conclusion appears to be that OSHA cannot cite since the pesticide is "subject" to EPA pesticide labeling requirements, whether the label is present or not.

If OSHA is certain that the chemical is a pesticide -- and that the lack of a label is therefore a violation of EPA's requirements and not OSHA's -- no citation would be issued, but a referral would be made to EPA. However, the CSHO cannot objectively ascertain that the container holds a covered pesticide unless an appropriate pesticide label -- with an EPA registration number -- is produced by the employer. Existence of such a label needs to be established for OSHA to be certain that the chemical is an EPA-regulated pesticide. This is particularly important since many pesticides are used for other purposes (e.g., carbon tetrachloride and ethylene dibromide).

Thus, from a practical perspective, if the CSHO finds an unlabeled container of chemicals in the workplace, the employer should be cited for violating the labeling provisions of the HCS unless: 1) it is exempted under the portable container provisions; 2) the employer can demonstrate that the chemical is not hazardous, and therefore not subject to the HCS; or 3) the employer can demonstrate that the chemical is subject to labeling requirements of EPA (or other Federal agency) by producing the appropriate label.

If the appropriate pesticide label is produced after the citation is issued, we will withdraw it upon proof that the chemical is covered under EPA regulations.

Hazard Communication Standard - Pesticide Labeling January 28, 1991

Questions have arisen concerning the need to label pesticides according to the Hazard Communication Standard (HCS).

The standard states in section (b)(5) that pesticides, as defined in FIFRA, are not required to be labeled under the HCS when "subject to the labeling requirements" of FIFRA. This clearly states that HCS labeling requirements cannot be cited for containers of pesticides, even if the pesticide containers are not labeled in accordance with FIFRA since the pesticides are still subject to the FIFRA labeling requirements. Statements have been made that OSHA should cite under the HCS if pesticide containers are not labeled in accordance with FIFRA. It does not appear that these statements would be able to be supported. Confusion has apparently arisen due to an erroneous reading of (b)(5) as stating that the exception applies when labeled in accordance with FIFRA. Since section (b)(5) clearly does not state this, the labeling exemption under the HCS would not be affected by the failure to label in accordance with FIFRA.

Preliminary discussion on this issue has been held with Orlando Pannochia of the Solicitor's office. It is requested that a legal opinion be rendered.

Medical Services and First Aid April 18, 2002

Dear Mr. Mateus:

Thank you for your November 21, 2001 letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Compliance Programs. You requested clarification of OSHA standard 29 CFR 1910.151 (Medical Services and First Aid). This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any questions not delineated within your original correspondence. Your questions have been restated below for clarity. We apologize for the delay in your response.

Question 1: How does the ANSI standard Z308.1-1998 relate to 29 CFR 1910.151(b)? In a non-industrial workplace (for example, a corporate office) where employees perform administrative duties and there are no specific employment-related injuries anticipated, would a kit matching the ANSI standard be sufficient for compliance with 29 CFR 1910.151(b)?

Reply: Paragraph (b) of 29 CFR 1910.151 requires that in the absence of an infirmary, clinic, or hospital near the workplace, a person or persons must be adequately trained to render first aid. Adequate first aid supplies must be readily available.

ANSI standards become mandatory OSHA standards only when, and if, they are adopted by OSHA; ANSI Z308.1, ***Minimum Requirements for Workplace First Aid Kits***, was not adopted by OSHA. However, ANSI Z308.1 provides detailed information regarding the requirements for first aid kits; OSHA has often referred employers to ANSI Z308.1 as a source of guidance for the minimum requirements for first aid kits.

The contents of the first aid kit listed in ANSI Z308.1 should be adequate for a small worksite, like the one you describe in your letter. However, larger or multiple operations should consider the need for additional first aid kits, additional types of first aid equipment, and first aid supplies in larger quantities. You may wish to consult your local fire and rescue department, an appropriate medical professional, your local OSHA area office, or a first aid supplier for assistance in putting together a first aid kit which suits the needs of your workplace. You should also periodically assess your kit and increase your supplies as needed.

Question 2: Are there any specific interpretations for the term "readily available"?

Reply: The term "readily available" is not defined in the standard. However, responding in a timely manner can mean the difference between life and death. Therefore, the person who has been trained

to render first aid must be able to quickly access the first aid supplies in order to effectively provide injured or ill employees with first aid attention. The first aid supplies should be located in an easily accessible area, and the first aid provider generally should not have to travel through several doorways, hallways and/or stairways to access first aid supplies.

Question 3: Can an employer use the interpretation for "near proximity" (the 3-4 minute and 15 minute standards) for determining the quantity and location for first aid supplies?

[For the response to this question, please see the 01/16/2007 Letter to Mr. Brogan for OSHA's current policy on "near proximity."]

Question 4: Is there a standard for placing first aid kits and/or cabinets based on employee numbers, density, or geography?

Reply: 29 CFR 1910.151(b) does not specifically address the placement of first aid kits and/or cabinets based on employee numbers, density, or geography. Therefore, it is the employer's responsibility to assess the particular needs of the workplace and tailor first aid kits and their placement to the specific needs of the workplace.

Question 5: What "measuring stick" would an OSHA compliance officer use to determine acceptable first aid supplies for compliance with 29 CFR 1910.151(b)?

Reply: OSHA compliance officers take into consideration a variety of factors when assessing compliance with 29 CFR 1910.151(b). The factors that you mention above are some of the things that a compliance officer evaluates when assessing a first aid kit. We cannot provide a list of "exact requirements" which will apply for every workplace; each workplace must be evaluated on a case-by-case basis, taking into account the types of injuries and illnesses that are likely to occur at that workplace.

Question 6: Other than inspection of a site for specific hazards, are there quantitative measurements such as employee-to-kit ratios, time frames within which employees should be able to access supplies, etc.?

Reply: Please see our response to Question 4.

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also,

from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at http://www.osha.gov. If you have any further questions, please feel free to contact the Office of General Industry [Enforcement] at (202) 693-1850.

Medical Services and First Aid Kit -2/2/2007

February 2, 2007

Dear Ms. Cress:

Your November 23, 2006 letter to the Occupational Safety and Health Administration (OSHA) has been referred to the Directorate of Enforcement Programs for response. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question or scenario not delineated within your original correspondence. You asked if it was mandatory for all workplaces to provide a first aid kit.

Title 29 CFR 1910.151(b) states: "In the absence of an infirmary, clinic, or hospital in near proximity to the workplace which is used for treatment of all injured employees, a person or persons shall be adequately trained to render first aid. Adequate first aid supplies shall be readily available."

Employers may elect not to provide first aid services if all such services will be provided by a hospital, infirmary, or clinic in near proximity to the workplace. If the employer has persons who are trained in first aid, then adequate first aid supplies must be readily available for use. Therefore, employers are required to provide first aid supplies that are most appropriate to respond to incidents at their workplaces. OSHA allows employers to provide first aid supplies specific to the needs of their workplace.

Although we have provided our interpretation of the federal standard, twenty-six states, including California, operate their own OSHA-approved occupational safety and health programs. These State-plan States adopt and enforce their own standards, which may have different requirements from the federal standards regarding medical services and supplies. The California Department of Industrial Relations (Cal-OSHA) administers the state plan program. Cal-OSHA standards are accessible on the state's website —http://www.dir.ca.gov/occupational_safety.html. If you would like more information about California workplace safety and health regulations, the address is as follows:
John Rea, Acting Director
California Department of Industrial Relations
1515 Clay Street, Suite 1901
Oakland, California 94612

(415) 703-5050
FAX (415) 703-5058

Thank you for your interest in occupational safety and health. We hope you find this information helpful. Please be aware that OSHA's enforcement guidance is subject to periodic review and clarification, amplification, or correction. Such guidance could also be affected by subsequent rulemaking. In the future, should you wish to verify that the guidance provided herein remains current, you may consult OSHA's website at http://www.osha.gov. If you have any further questions, please feel free to contact the Office of General Industry Enforcement at (202) 693-1850.

Sanitation Standard – 4/18/2005

Dear Mr. Kubly:

This is in response to your letter dated April 18, 2005, which was sent to the U.S. Department of Labor and forwarded to the Occupational Safety and Health Administration (OSHA). This letter constitutes OSHA's interpretation only of the situation discussed and may not be applicable to any question or situation not delineated within your letter. You had specific questions concerning restroom usage at your place of employment. We apologize for the delay in responding.

Question 1: What are OSHA's regulations regarding bathrooms, and where can this regulation be found?

Response: OSHA's sanitation standard that addresses restrooms for general industry may be found in Title 29 of the Code of Federal Regulations, Part 1910, Section 141 (abbreviated as 29 CFR 1910.141). A copy is enclosed.

The Code of Federal Regulations (CFRs) may be found in the reference section of your local public library. You can also access the CFRs on the Internet through the Government Printing Office website at http://www.gpoaccess.gov/cfr/retrieve.html. The specific link to OSHA's sanitation standard is at http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=29&PART=1910&SECTION=141&TYPE=TEXT.

Question 2: Are there any circumstances in which an employer could regulate restroom usage? Is the restroom allowed to be locked, thus requiring an employee to ask or to sign out a key in order to use the restroom?

Response: OSHA addressed the issue of employee access to toilet facilities in a memorandum to OSHA's Regional Administrators dated April 6, 1998. This memorandum is a public document and a copy is enclosed. In addition, the Agency also addressed this issue in a letter dated April 23, 2003, to Professor Marc Linder at the University of Iowa; a copy of that letter is also enclosed.

Memoranda and letters interpreting OSHA's sanitation standard may be accessed on the Internet through OSHA's website at www.osha.gov. When on the website click on "I" in the alphabet at the top of the page, then click on "Interpretations of OSHA Standards." When the next page comes up, type "1910.141" in the Text Search box and click on the search button.

If an employer puts any restrictions on employee access to toilet facilities, such as locking the doors and requiring the employees to ask and sign out a key, the restriction must be reasonable, and may not cause extended delays. If OSHA were to receive a complaint concerning such a restriction, the Agency would evaluate the situation on a case by case basis to examine the nature of the restriction, including the length of time that employees are required to delay bathroom use, and the employer's explanation for the restriction. The enclosed memorandum and letter provide additional guidance.

If you wish to discuss your situation or file a complaint with your local OSHA office, you may contact the following:
John Tomich, Area Director
U.S. Department of Labor
Occupational Safety and Health Administration
401 New Karner Rd, Suite 300
Albany, NY 12205-3809
Telephone: (518) 464-4338
Fax: (518) 464-4337

Thank you for your interest in occupational safety and health. We hope you find this information helpful. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at www.osha.gov. If you have any further questions, please feel free to contact the Office of General Industry Enforcement at (202) 693-1850.

Sincerely,

OSHA FAQs

Richard E. Fairfax, Director
Directorate of Enforcement Programs

Sanitation Standard – 4/23/2005

April 23, 2003

Professor Marc Linder
College of Law
University of Iowa
Iowa City, IA 52242

Dear Mr. Linder:

This is a further response to your letter to me of December 10, 2002. You asked the following questions about the impact of OSHA's April 6, 1998 memorandum to the OSHA Regional Administrators concerning the interpretation of OSHA's sanitation standard for general industry 29 CFR §1910.141(c)(1)(i) as it applies to workers' use of toilet facilities. We apologize for the delay in responding.

Question: I hear criticism from managers who say that the OSHA interpretation stating that employers have to let workers go to the bathroom when they need to go makes it impossible for management (without risking a citation) to police abuses by employees who say they have to void, but are really faking and just want to loaf. How would you respond to employers who say that OSHA has in effect deprived them of their right to discipline slackers?

Response: The interpretation was written as guidance for OSHA compliance officers in evaluating situations concerning workers' complaints about access to toilet facilities when the workers needed to use them. The interpretation should not be seen as interfering with management's right/ability to discipline workers who are violating legitimate work rules. As the April 6, 1998 interpretation states, an employer is not prohibited from having reasonable restrictions on access to toilet facilities. The interpretation requires OSHA's compliance officers to evaluate employer restrictions on a case-by-case basis, giving careful consideration to such factors as the nature of the restriction, including the length of time that workers are required to delay bathroom use, and the employer's explanation for the restriction.

Question: In retrospect would it have been simpler to have issued, instead of an interpretation prescribing a performance (reasonableness) standard, one that mandated a quantitative standard requiring employers to let workers go to the bathroom at least every x minutes or hours?

Response: No. The "reasonableness" criterion is consistent with the generally worded requirement in §1910.141(c)(1)(i). Furthermore, it would be difficult to set a specific interval for breaks, because the need to use toilet facilities varies from person to person and even with respect to the same person. Some of the variables that can affect a worker's need to urinate are: diet, stress, pregnancy, prostate health, other medical conditions, medication use, weather temperature (working in a cold environment makes people need to urinate more frequently), and the amount and type of fluid consumed.

Also, in some workplaces the nature of the work or the tasks being performed may require constant worker coverage/attention. In such situations employers need flexibility in developing procedures that will allow all of their workers access to toilet facilities as needed. A specific schedule for breaks might not allow the flexibility needed to address all types of work situations.

Question: Do you have some sense of what the effect of the interpretation has been? Has it produced greater compliance by employers? More complaints by workers? More citations issued by OSHA? Or are there other ways of determining what the effect has been?

Response: Within the first year after issuing the interpretation, articles appeared in several newspapers around the country, and OSHA's office in Washington, DC received calls from various employer and employee groups asking questions about the interpretation. We believe that the interpretation has produced a greater awareness and sensitivity about this issue among the employer community, as well as providing direction to OSHA staff in responding to complaints and questions regarding this issue.

Since we have not asked our area offices to keep track of employee complaints regarding §1910.141(c)(1)(i) and employee access to toilet facilities, we have no way of knowing if the interpretation itself has produced more complaints. But, we asked our area offices to send copies of all citations issued to employers for failure to allow employee access to toilet facilities. By the end of 2002, OSHA had issued only about twelve such citations.

In discussions with our area offices, we have found that the interpretation has helped the OSHA Area Directors and compliance officers encourage agreements between employers and workers on how to provide needed access to toilet facilities. Issuing a citation does not in itself resolve the problem. Therefore, the Area Directors and compliance officers first encourage employers and employees to work together to see how they can resolve their differences and create a system/procedure that will work in that particular workplace for that specific employer and employee(s).

Question: Is it lawful for an employer to charge employees to go to the bathroom or to make it unpaid time?

Response: Questions of pay for rest/bathroom breaks are not within OSHA's jurisdiction. The Employment Standards Administration, Division of Wage and Hour, has provided guidance at 29 CFR §785.18 (copy enclosed), but you may wish to contact that agency directly. State labor laws may also cover rest/bathroom breaks. The Wage and Hour Division office closest to you is the Des Moines District Office:
U.S. Department of Labor
Employment Standards Administration
Wage & Hour Division
Federal Building
210 Walnut Street, Room 643
Des Moines, IA 50309-2407

Telephone: (515) 284-4625
Fax: (515) 284-7171

Thank you for your interest in occupational safety and health. We hope this provides the clarification you were seeking. OSHA requirements are set by statute, standards, and regulations. Our interpretation letters/memoranda explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at http://www.osha.gov. If you have any additional questions, please contact the Directorate of Enforcement Programs at (202) 693-1850.

Sincerely,

Richard E. Fairfax, Director
Directorate of Enforcement Programs

Enclosure

End