FREQUENTLY ASKED QUESTIONS ABOUT THE BLOODBORNE PATHOGENS STANDARD TITLE 8 CALIFORNIA CODE OF REGULATIONS

5193(a) -- Scope & Application

1. Are there any industries exempt from 5193 coverage?

Yes. The construction industry (Standard Industrial Classification Codes [SIC] 152-179) is specifically exempted from coverage under 5193, as stated in the Exception to 5193(a). However, construction industry employers still have a regulatory responsibility to protect their employees from bloodborne pathogens.

2. What responsibilities do employers in the construction industry have under Title 8 standards other than 5193 to protect employees from exposure to bloodborne pathogens?

Employees in the construction industry are not necessarily free of potential hazards related to bloodborne pathogens. For example, employees assigned to first aid duties may encounter such hazards. Employers in the construction industry are subject to the Injury and Illness Prevention (IIP) Program requirements of 8 CCR 3203, and to the requirement to provide hygiene facilities and personal protective equipment pursuant to Title 8 sections other than 5193. Pursuant to these other regulatory requirements, construction employers are required to provide appropriate protective measures to employees who may be subject to the hazard of exposure to bloodborne pathogens.

3. How is coverage under 5193 determined?

5193 applies to all occupational exposure to blood or other potentially infectious materials (OPIM) as defined in 5193(b). In 5193(b), the standard 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."

Some facilities and operations are considered by Cal/OSHA to involve "occupational exposure," as defined in 5193, because the intrinsic nature of the facility or operation is such that contact with blood or OPIM is reasonably anticipated for at least some of the employees involved with the facility or operation.

Employers of these facilities or operations have the responsibility to conduct an exposure determination to determine which tasks and procedures involve occupational exposure as a part of complying with the written Exposure Control

Plan requirements of 5193(c)(l). Employers whose employees work in facilities other than those that intrinsically involve occupational exposure are still subject to 5193 if the individual circumstances of the facility or operation are such that the employee's activities or tasks place them in contact with blood or OPIM.

4. What types of facilities and operations are subject to 5193?

The facilities and operations subject to 5193 fall into two general categories. Category One consists of those facilities and operations that involve occupational exposure by virtue of the intrinsic nature of the work at the facility or operation. Lack of a history of actual exposure incidents at these facilities and operations does not preclude coverage under 5193.

Some examples of facilities and operations or services in Category One are: hospitals, hemodialysis centers, blood banks, plasma donation centers, laundries that serve healthcare or public safety facilities, correctional facilities (jails, prisons, juvenile detention centers), ambulance, emergency or public safety operations, emergency first aid operations, emergency rooms and other medical operations, fire services, lifeguard rescue services, paramedic services, police services, facilities for the developmentally disabled, funeral services, medical equipment service and repair operations, regulated waste operations, tissue bank operations, general dentistry offices and clinics, orthodontics and oral surgery offices, dental hygienists, dental laboratory technicians, dental chairside assistants, hospice facilities, home healthcare services, skilled and long-term nursing care facilities, medical laboratories, nurse practitioner's and physician assistant offices, physicians' offices, outpatient medical clinics, school-based health clinics, and other healthcare facilities where healthcare is provided by employees or independent contractors, or where medications are regularly self-administered with sharps (e.g., residential care facilities and adult day care facilities).

Category Two facilities and operations consist of those that involve occupational exposure only because of the specific exposure circumstances in the facility or operation. These specific features are such that employee tasks and activities can reasonably result in anticipated contact with blood or OPIM, although such facilities and operations are not usually thought of as covered by 5193, e.g., laundry facilities and lodging establishments.

5. Under what circumstances does 5193 cover employers with employees such as housekeepers, laundry attendants, janitorial workers, sanitation workers, plumbers, and other workers not generally thought of as being at risk for exposure to bloodborne pathogens?

5193 applies wherever occupational exposure exists, i.e., where skin, eye, mucous membrane, or parenteral contact with blood or OPIM is reasonably anticipated. In facilities that intrinsically involve occupational exposure, e.g., hospitals, it is obvious that healthcare workers will be covered by 5193.

However, operations not commonly understood to involve occupational exposure may involve such exposure if carried out in such a facility. For example, laundry

operations are not usually thought of as involving occupational exposure, but laundry workers in hospitals have such exposure because they work with bedding and other laundry and are likely to encounter contaminated sharps from time to time that have been inadvertently discarded or other wise found their way into the laundry.

Similarly, if plumbers are required to work on plumbing or sewage systems inside, or directly coming from hospitals or other healthcare facilities, it is "reasonably anticipated" that they would have contact with blood or other potentially infectious material. Therefore, they have occupational exposure are also be covered by 5193.

Occupational exposure does not depend only on the nature of the facility in which the operation is conducted. Taking again the example of laundry services, if laundry workers work at a commercial laundry facility rather than a hospital, they will still have occupational exposure if they work with laundry that has come from a hospital or other facility that may contain contaminated sharps.

The same may be true of housekeepers or laundry workers who work in short-term or long-term lodging establishments where contact with items such as contaminated hypodermic syringes in bed sheets or in trash receptacles is reasonably anticipated.

Even in those situations where the risk of contact with blood or OPIM is not so high as to be "reasonably anticipated," the nature of the work may still require basic protective measures under the provisions of 8 CCR 3203 (IIP Program) to prevent events that could lead to an exposure incident.

For example, municipal sanitation workers are at risk of receiving cuts, abrasions, and punctures in the course of their work unless precautions such as using gloves, protective clothing, and specific procedures for handling garbage and refuse are taken. A skin puncture from a contaminated hypodermic syringe could, on occasion, be among these injuries. Therefore, the protections and training that sanitation workers must receive, even if they are not covered by the bloodborne pathogens standard, must be calculated to eliminate exposure to bloodborne pathogens that could arise in the course of their work, if the employer's IIP Program is to be considered "effective" as required by 3203(a).

6. Are sewage plant and wastewater treatment workers covered by the 5193?

These workers are not ordinarily considered to have occupational exposure, since the material they contact is not visibly contaminated with blood. There is no evidence to suggest that sewage plant or wastewater workers are at increased risk for hepatitis B infection. HBV and HIV may be present in wastewater, but only in a non-viable state and in very dilute concentrations which would not be expected to pose a risk to waste water workers or sewage plant workers.

7. Are workers who use tagging guns in the garment industry and other associated industries covered by 5193?

Workers who use tagging guns may be covered by 5193 depending on the individual circumstances of the work. The use of tagging guns can result in workers sustaining a needlestick with a contaminated needle. This happens when one worker accidentally punctures his or her skin with the needle of a tagging gun, and another worker using the same gun later on with the same needle sustains the same type of injury. Under these circumstances, the risk of an exposure incident occurring can be sufficient to invoke coverage of 5193, because parenteral contact with blood is reasonably anticipated.

For this reason, Cal/OSHA believes that garment production or processing facilities, where the use of tagging guns is regular, sustained, and very frequent, are covered by 5193. In other facilities that use tagging guns, e.g., retail clothing stores, whether the standard applies will depend on the individual circumstances of the facility. However, if employers at these facilities take simple measures under their IIP Program (8 CCR 3203), they can ensure that contact with blood is not reasonably anticipated. One such measure consists of assigning employees their own tagging guns, implementing and enforcing a policy that forbids employees from using any tagging gun other than the one assigned to them, and training employees on this policy and the potential health consequences of violating the policy.

8. If I have employees who are designated to render first aid, am I covered by 5193?

Yes. Employers with employees who are designated to provide first aid or medical assistance as part of their job duties are subject to 5193. The job classification of these employees must be identified as involving occupational exposure by the employer's exposure control plan pursuant to 5193(c)(3), and the employees in this classification must be protected as required by the applicable subsections of 5193.

However, as allowed by the Exception at 5193(f)(1)(a), employees who administer first aid only as a duty that is collateral to their routine work assignments are not required to be offered the hepatitis B vaccination until they are subjected to an exposure incident. If under this exception, an employer chooses not to vaccinate as a precautionary measure and instead elects to vaccinate only in the event of an exposure incident, the employee must be provided with a hepatitis B vaccination as soon as possible, but not more than 24 hours, after occurrence of the exposure incident. The Exception to 5193(f)(1)(A) should be consulted for additional conditions and requirements.

9. Are employers of emergency response teams covered by 5193?

Emergency response teams usually have members who are designated to provide first aid and these members are considered to have occupational exposure under 5193. On this basis, their employers are subject to the standard and must identify the job classification of these employees as one involving occupational exposure pursuant to the exposure control plan requirements of 5193(c)(3).

However, if an emergency response team member is not designated to provide first aid as either a primary or collateral duty, the member is not considered to have occupational exposure. If the employer has an emergency response team with no members designated to provide first aid as either a primary or collateral duty, the employer is not subject to 5193, at least to the extent that having an emergency response team may invoke the application of 5193. Examples might include a hazardous materials team or a refinery fire brigade, provided that no members are responsible for administering first aid as either a primary or collateral duty.

10. Are lifeguards covered by the standard?

Yes. Lifeguards are covered by 5193 because they are considered to be primary first aid providers.

11. Are volunteers covered by 5193?

No. 5193, like other Title 8 occupational safety and health standards, applies only to employers and employees. A volunteer is not considered to be an employee. However, to be a volunteer, the individual must not receive compensation of a monetary nature for his or her services. One common example of a volunteer is a student who receives academic credit for his or her services but no remuneration. However, an individual who is not paid, but is allowed to work off a debt, e.g., a monetary fine, is considered to be an employee and not a volunteer.

12. Are physicians who are not employees of the hospital in which they work subject to 5193?

Cal/OSHA has jurisdiction to enforce occupational safety and health standards only with respect to employers and employees. In some cases, physicians are neither employers nor employees. For example, they may be sole proprietors or members of a partnership. However, a sole proprietor or partnership that hires someone to work as an employee becomes an employer subject to Cal/OSHA's jurisdiction.

Similarly, if a physician has created an entity such as a corporation or limited liability company, and the entity has identified one or more individuals as employees, the entity is subject to Cal/OSHA's jurisdiction and must comply with 5193 as well as all other standards applicable to the work situation of those employed by the entity. Sometimes, articles of incorporation designate an owner as an employee of the corporation. If a physician is in this position, the corporation will be considered an employer even if the physician is the sole employee of the corporation.

13. Are there any circumstances under which Cal/OSHA can issue a citation to physicians or other health care professionals who are not considered to be employers?

Yes. Existing case law recognizes the concept of the "special employer." A special employer is any entity or person who is not generally considered an employer, but is deemed by law to become an employer by engaging in the

supervision of other people who are employed as the employees of someone else. For example, a physician who is not an employer, but works at a hospital, performs a surgical procedure, and supervises those who assist with the procedure can be cited as a "special employer" for violations that occur within the context of that supervision.

14. Can a hospital be cited by Cal/OSHA if a physician, who is not employed by the hospital and is not subject to Cal/OSHA's enforcement jurisdiction, refuses to comply with the requirements of 5193 and/or other occupational safety and health standards?

Yes. The hospital is responsible for the protection of its employees from workplace hazards. If the practices of any person present in the hospital, whether or not he or she is an employee of the hospital, create conditions that expose hospital employees to a hazard, the hospital may be cited for allowing such exposure to occur. It is therefore important that hospitals have in place procedures that ensure to the extent reasonably possible that all individuals working in the hospital follow hospital health and safety rules and comply with applicable occupational safety and health standards.

15. If my company is a temporary help agency that supplies employees to health care facilities, what are my responsibilities under 5193?

Cal/OSHA terms this a "dual employer" situation. This type of situation is discussed in detail in Cal/OSHA's Enforcement Policy & Procedure C-1D. Since your company maintains a continuing employment relationship with its employees, but another employer (your client) directs and supervises these employees, there is a shared responsibility for assuring that your employees are protected from workplace hazards.

Your client is considered to be the "secondary employer," and you are considered to be the "primary employer." The secondary employer usually has the most direct responsibility for such protection while the employee is at the secondary employer's worksite, but the primary employer also has responsibility for assuring occupational safety and health protection for its employees as to those issues reasonably under its control. The primary and secondary employer must work together to ensure that the employees receive all protection required by applicable occupational safety and health standards. If the employees are exposed to violations at the secondary employer's worksite, both employers may be cited by Cal/OSHA for failure to protect employees.

Primary employers are required to ensure that their employees are provided with all of the required training, personal protective equipment, and medical evaluations, and vaccinations required by the standard. In addition, they are required to do what is reasonably necessary to protect their employees from hazards under their control. Primary employers in the healthcare industry usually discharge this responsibility by providing some of these items directly, and by assuring that the remaining items are covered by the secondary employer. For example, the primary employer typically is the direct provider of general training to employees, who are given site-specific training by the secondary employer when placed at the site of the secondary employer. The secondary employer, of

course, may specify what qualifications are required for supplied personnel, including vaccination status.

It is clearly in the primary employer's interest to actively ensure that all steps required under 5193 have been taken and continue to be taken by your client, the secondary employer, to ensure safe and healthful work for the employees you have sent to work at your client's worksite.

16. Are "other potentially infectious materials" or OPIM regulated by 5193 limited to those of human origin?

No. While "blood" is defined in 5193(b) as including only "human blood, human blood components, and products made from human blood," the definition of "other potentially infectious material" includes "any of the following, if known or reasonably likely to contain or be infected with HIV, HBV or HCV: (A) cell, tissue or organ cultures from human or experimental animals; (B) blood, organs, or other tissues from experimental animals; or (C) culture medium or other solutions."

5193(b) -- Definitions

17. Does 5193 define all items that are contaminated with blood or OPIM as "regulated waste," so that they must be disposed of according to the regulated waste requirements of 5193(d)(3)(G)?

No. There are some categories of contaminated items that are not considered regulated waste.

5193 uses the term "regulated waste," to refer to the following categories of waste which require, at a minimum, special handling: (1) liquid or semi-liquid blood or other potentially infectious material (OPIM); (2) items contaminated with blood, or OPIM, and which would release these substances in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood, or OPIM, and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood, or OPIM.

In 5193(b), the definition of "regulated waste" makes it clear that some contaminated items may become contaminated with blood or OPIM during the course of their use, but are not within the scope of regulated waste and the disposal provisions of 5193. These include minimally contaminated absorbent items, such as dental drapes, gauze, band-aids, and sanitary napkins, that will dry out and be free of dried blood in quantities that could be considered "caked."

5193(c) -- Exposure Control

5193(c)(1)(A)

18. Why must the Exposure Control Plan be consistent with 8 CCR 3203, and what is the significance of the new language in 5193, borrowed from

3203, that requires employers to "implement and maintain" an "effective" Exposure Control Plan?

The reference to 8 CCR 3203, and the new language, were added to 5193 to emphasize that the requirement for an Exposure Control Plan, like that for the IIP Program in general, is intended not just to result in preparation of a written document, but rather in implementation of an effective program that puts exposure control concepts into actual practice in the employer's facility, and subjects the employer's IIP Program to periodic evaluation and adjustment based on the implementation experience.

19. In what language must the Exposure Control Plan be written?

The Exposure Control Plan need only be in English. However, the materials used to communicate the plan and provide other required training to employees (pursuant to 5193(g)(2)(F)), must be in language that the employer's employees will readily understand, including a language other than English if that is what is necessary for the employer to communicate effectively with his or her employees.

5193(c)(1)(C)

20. Must an employer provide employees with a copy of the Exposure Control Plan upon request?

Yes. A paper copy of the Exposure Control Plan must be accessible to employees within fifteen (15) working days of the employee's request, in accordance with 8 CCR 3204**.**

5193(c)(1)(E)

21. To whom besides employees must the Exposure Control Plan be available?

The Exposure Control Plan must be made available, upon request, for examination and copying, to the Chief of the Division of Occupational Safety and Health, and to the Director of the National Institute for Occupational Safety and Health (NIOSH), or their respective designees.

5193(c)(2)

22. What is a Sharps Injury Log and why is it required by 5193?

A Sharps Injury Log is a record of each exposure incident involving a sharp, and is required by 5193. The purpose of the Sharps Injury Log is to generate a record of exposure incidents in the employer's facility that will include enough information about the cause of the incidents to allow the employer to analyze them and take preventive action.

The Sharps Injury Log record is different from the OSHA Log 200 and requires the following specific information:

(1) The date and time of the sharps-related exposure incident;

(2) The type and brand of the sharp involved in the incident; and

(3) A description of the incident including:

a) The job classification of the exposed employee;

b) The department or work area where the incident occurred;

c) The procedure being performed;

d) How the incident occurred;

e) The body part injured;

f) For sharps with engineered sharps injury protection or ESIP, if the safety mechanism was activated; and

g) If the incident occurred before action, during activation or after activation of the mechanism; for sharps without ESIP, the employee's opinion if ESIP could have prevented the injury.

The Sharps Injury Log must be maintained for five (5) years from the date of the occurrence of the exposure incident and must be made available to employees and their representative, to the Chief of the Division of Occupational Safety and Health, to the California Department of Health Services, and to the Director of the National Institute for Occupational Safety and Health (NIOSH).

23. Is there a particular format or form that is required for the Sharps Injury Log?

The Sharps Injury Log requirements in 5193 focus on content, not format. The Sharps Injury Log must contain all of the eight (8) items specified in 5193(c)(2). These items may be presented in any format, provided the format chosen encourages provision of full information for each item.

For example, some of the required items may require several sentences for full responses. Space for providing such full responses must be made available in the Sharps Injury Log form used by the employer, or the logging system must allow for attachment of additional pages.

Because the Sharps Injury Log is intended to provide employers with data to be used as a workplace surveillance tool for sharps injury prevention, the employer's system for making and maintaining these records should allow and encourage use of the aggregate data that they contain.

24. Should employees involved in exposure incidents recorded in the Sharps Injury Log be identified in the Log?

No. No personal employee identifiers should be used in the Sharps Injury Log. The Sharps Injury Log is intended to serve as a tool for control of future incidents, not as a record of which employees have been injured.

5193(d) -- Methods of Compliance

5193(d)(1)

25. What are "Universal Precautions"?

The concept of "Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human bodily fluids are treated as if known to be infectious for HIV, HBV or HCV and other bloodborne pathogens. Under circumstances in which differentiation between body fluids is difficult or impossible, all body fluids shall be considered potentially infectious materials. See 5193(d)(1).

26. Can Body Substance Isolation (BSI) be used in place of Universal Precautions?

Yes. Body Substances Isolation (BSI) is an infection control approach that defines all body fluids and substances as being infectious. BSI is an acceptable alternative to Universal Precautions, provided facilities utilizing BSI adhere to all other provisions of 5193.

5193(d)(2)

27. What responsibilities does an employer have under 5193(d)(2), given that other parts of 5193 set forth specific requirements?

5193(d)(2) contains general requirements related to the use of engineering and work practice controls to eliminate or minimize employee exposure. The purpose of 5193(d)(2) is to put employers on notice that, since not every safety precaution can be specifically identified and listed in 5193, employers must utilize the general principles of engineering and work practice controls to protect employees, wherever appropriate, in addition to meeting the specific requirements of 5193.

5193(d)(3)(A)

28. What is meant by "engineered sharps injury protection" or ESIP?

ESIP is defined in 5193(b) of the regulation. To qualify as "engineered sharps injury protection" the anti-stick safety feature of the sharp must: (1) be "built into" the device; and (2) "effectively" reduces the risk of an exposure incident.

"Built into." Cal/OSHA interprets "built into" to mean that no assembly of the safety features of the device is required by the user and that the safety features are integral to the design and function of the device.

"Effectively Reduces the Risk of an Exposure Incident." Whether a device "effectively" reduces the risk of an exposure incident depends on factors that include, but are not limited to, the design of the device, its ability to perform as intended by the design, the appropriateness of the device for the use to which it is put and how well employees have been trained in the proper use of the device.

29. Is there a list of needleless systems and sharps devices with "engineered sharps injury protection," or ESIP?

Yes. The California Department of Health Services (DHS) maintains a list of devices and basic information about them that has been reported to DHS by the device manufacturers. This list is available at www.ohb.org/sharps.htm. This list is maintained and provided for informational purposes only. The list provides information about devices that are on the market and potentially available for purchase, but it does not offer any information on the effectiveness of the devices or their appropriateness for particular applications. The fact that a device is on the list does not necessarily mean that its use will constitute compliance with 5193(d)(3)(A).

30. Does Cal/OSHA have a procedure for approving needleless systems and sharps with ESIP?

No. Cal/OSHA does not approve, certify, or provide evaluations of needleless systems or sharps with ESIP, nor does the California Department of Health Services. However, in the course of individual enforcement actions, Cal/OSHA will evaluate the safety features of sharps devices used by employers to determine if they meet the definition of "engineered sharps injury protection."

31. Must an employer use the most effective available device with ESIP, or is any device with ESIP allowed?

5193 does not, per se, require use of the most effective device with ESIP available. However, Cal/OSHA's evaluation of what is considered to be "effective," as per the definition of "sharps with engineered sharps injury protection," must necessarily be guided by the state of the technology available at the time of an enforcement inspection. When a technological advance increases the level of effectiveness of sharps injury prevention that can reasonably be expected to be attained, this will necessarily affect Cal/OSHA's evaluation of whether any particular sharp with ESIP meets the effectiveness requirement set by the definition of this term.

32. Some manufacturers sell "add-on" anti-stick mechanisms that can be installed onto a traditional sharp. Does a sharp with such a mechanism installed qualify as sharp with "engineered sharps injury protection or ESIP" under 5193(d)(3)(A)?

The definition of sharps with ESIP requires the anti-stick protection to be "effective" and "built into" the device. Some add-on safety features may meet these two criteria depending on the effectiveness of the device with the add-on anti-stick mechanism added, and the nature and timing of the process of "adding on" the anti-stick mechanism.

Cal/OSHA will generally evaluate these devices on a case-by-case basis to determine whether they comply with 5193(d)(3)(A). However, Cal/OSHA does not believe that a sharp with a safety mechanism added can qualify as a sharp with ESIP if the mechanism is installed by the user, or if the mechanism is not as resistant to removal, defeat, or tampering as a factory-manufactured sharp with ESIP.

33. How will Cal/OSHA determine whether any of the four Exceptions applies in any given case?

The four exceptions define specific circumstances in which the requirements of 5193(d)(3)(A) will not apply. Under each of these exceptions, it is the employer's burden to demonstrate the applicability of the exception to the employer's specific circumstances. Cal/OSHA will generally decide on a case-by-case basis when it conducts an enforcement inspection whether an employer who claims that a particular exception applies has adequately demonstrated the exception's applicability.

34. If a vendor is temporarily unable to supply the needleless system, or sharps device with ESIP, we have selected for a particular procedure, what course of action should we follow?

5193(d)(3)(A)(i), which provides the first exception to the requirement for use of needleless systems and sharps with ESIP, allows an employer to forego using a required engineering control if it is not available in the marketplace. The fact that a particular vendor is unable to supply the device selected by the employer does not constitute market unavailability, if other vendors can supply the device. If no other vendor can supply the device, the employer must make reasonable efforts to look for other engineering controls that qualify under 5193(d)(3)(A). Just as with all equipment critical to patient care and employee safety, alternative devices and suppliers should be evaluated, selected, and maintained as a back-up resource.

35. If there have been very few or no sharps-related exposure incidents among employees in my health care facility, do I still need to comply with the requirements for use of needleless systems and sharps with ESIP?

California Labor Code Section 144.7, which mandated revision of the California Bloodborne Pathogens Standard to include these new requirements, was enacted into law in 1998 in recognition of the fact that the risk of sharps-related exposure incidents remains unacceptably high among healthcare workers. While there may be times when the number of such incidents known and recorded in particular facilities is below the industry average, or even zero, the intent of Section 144.7 was not to focus on the number of incidents known to have occurred in the past, but to reduce the overall risk of such incidents occurring in the future.

5193(d)(3)(A)(iii), the third exception to the requirement for use of needleless systems and sharps with ESIP, allows an employer to forego using an engineering control required by 5193(d)(3)(A) if the employer can demonstrate by

means of objective product evaluation criteria that the engineering control is no more effective in preventing exposure incidents than the alternative used by the employer. Cal/OSHA believes that, to meet this exception, an employer must demonstrate that the risk of exposure incidents likely to occur in the employer's workplace if required engineering controls are used is equal to or higher than the risk of exposure incidents likely to occur if the employer's alternative is used. This cannot be done by merely pointing to an absence or low incidence of recorded exposure incidents in the employer's workplace, since a record of what has happened in the past does not, by itself, address what is likely to occur in the future.

36. Are catheter securement devices and devices that replace or minimize the use of needle access to intravenous catheters considered to be needleless systems?

Devices that replace needles capable of causing an exposure incident are considered by Cal/OSHA to be needleless systems. For example, techniques or systems that eliminate the need to secure intravenous catheters with sutures are a "needleless system."

Devices and procedures that reduce the number of intravenous catheter insertions by making catheters more secure and resistant to being pulled out may be required under the general engineering and work practice control requirements of 5193(d)(2), depending on their effectiveness relative to the devices and procedures already in use by the employer.

37. Are needleless systems or sharps devices with ESIP required to be used in a pharmacy?

The requirements of 5193 apply to procedures or employee duties that are reasonably anticipated to result in skin, eye, mucous membrane, or parenteral contact with blood or OPIM. Where pharmacy activities involving sharps are reasonably anticipated to result in such contact, the requirements for needleless systems and sharps devices with ESIP must be implemented. If pharmacy activities with needles and sharps do not involve manipulation of blood, unsterilized blood products, or OPIM, these activities would not be subject to 5193(d)(3)(A).

Wherever sharps are frequently used, and an employee might reasonably be expected to suffer from an occasional inadvertent stick with a clean (i.e., uncontaminated) needle, a sharps disposal container must be immediately available.

38. Are "pre-filled syringes" (i.e., syringes pre-filled by the manufacturer with specific medications) that do not have built-in ESIP exempt from the requirements of 5193(d)(3)(A)?

No. There are no specific exemptions from the requirements of 5193(d)(3)(A). The permissible use of non-qualifying devices is governed entirely by the four exceptions set forth at 5193(d)(3)(A).

Cal/OSHA has been informed by some drug manufacturers that they may be unable to deliver certain drugs in quantities sufficient to meet demand in containers such as vials and ampules, because the manufacturers have geared their supply to the preference of many users in the past for medications packaged in pre-filled syringes.

If drugs are unavailable in the market place in sufficient quantity, unless delivered by pre-filled syringes that do not have ESIP, or are unavailable to the employer, then 5193(d)(3)(A)(i), the market unavailability exception, may apply.

39. Do the requirements for use of needleless systems and sharps with ESIP apply to home healthcare providers?

In general, yes. However, where patients in the home self-inject and dispose of the sharp in the presence of, but without the participation of, the home healthcare employee, the requirements for the use of a needleless system or sharp with ESIP do not apply. The requirements do apply if the home healthcare employee physically assists the patient in the use, handling or disposal of any sharp for a medical procedure.

Some contractual arrangements may result in situations where home healthcare employees use syringes or other devices supplied by an entity other than their employer. Such third party sources can include the patient or the pharmacy supplying the patient's medication. In these situations the employer still has the responsibility to ensure that if their employees use these devices, applicable 5193 requirements associated with the use of these devices are met.

40. Is a device with ESIP that has been activated required to be disposed of as sharps waste?

Yes. Because safety features of some devices can be defeated or deactivated, and all devices are subject to breakage, sharps devices with ESIP must be disposed of in a sharps container as sharps waste.

41. Can electrical needle destruction devices (NDDs) be used to comply with 5193(d)(3)(A)?

Needle destruction devices (NDDs) are not prohibited by 5193. However, it is Cal/OSHA's understanding that NDDs are designed only for use with needle devices that do not have ESIP. Thus, their use will be an option only if one of the four exceptions applies to permit use of a needle that does not have ESIP. The following is an explanation of how NDDs may be used with traditional needles pursuant to these exceptions:

A. General conditions under which a needle-destruction device may be used.

Subject to the caveat in Item (B) below, NDDs may generally be used whenever the specific engineering control measures required by 5193 (d)(3)(A) are not required. This means that one of the four exceptions must apply. See Item (C) below for further discussion of how to determine whether an exception applies.

Where a traditional needle is being used with an NDD, the NDD serves as an alternative or a supplement to a traditional sharps container. If the NDD does not completely destroy the needle, the syringe must be placed in a sharps container immediately after destruction of the needle. If the needle is completely destroyed by the device, the syringe need not be disposed of in a sharps container, but must be disposed of as regulated waste. These devices must always be used in accordance with instructions.

B. Caveat regarding use of needle-destruction devices.

While NDDs may be used as stated in Item (A) above, the manner in which the device is used must not add a hazard that would not be present if the syringe were to be discarded directly into a sharps container. For example, use of an NDD with a two-handed technique would not be allowed. These devices must not be used in any potentially explosive environment, or where flammable liquids or gases are stored. In addition, since the NDD is serving as an intervening step between use of the syringe and disposal of the syringe into a sharps container, it must, like a sharps container, be positioned so that it is "easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used..."

C. Applicability of the exceptions to 5193(d)(3)(A).

For any of the four exceptions to (d)(3)(A) to apply, employers must be able to show that they have met the terms of the exception. For example, in the case of evaluating whether an employer must use a safety needle, the third exception to (d)(3)(A) will apply:

"if the employer can demonstrate by means of objective product evaluation criteria that [use of the safety needle] is not more effective in preventing exposure incidents than the alternative used by the employer."

D. How will Cal/OSHA evaluate use of needle-destruction devices?

To determine whether the third exception or any other exception applies such that an employer may use a traditional syringe coupled with an NDD and/or any other alternatives the employer has chosen, Cal/OSHA will evaluate such situations on a case-by-case basis.

5193(d)(3)(B)

5193(d)(3)(B)2.

42. Is the use of an electronic needle destruction device (NDD) a prohibited practice under 5193?

The use of an electronic NDD is not a prohibited practice under 5193.

43. Under what circumstances may needles and other sharps be bent, recapped, or removed from devices?

Bending, recapping, or removing contaminated needles by hand is prohibited, except under certain circumstances. In those situations where bending, removal or recapping is required by a specific medical procedure, or no alternative to bending, recapping, or removal is feasible, recapping or needle-removal is only permitted by some method other than the traditional two-handed procedure, e.g., a mechanical device or a one-hand scoop method.

An acceptable means of demonstrating that no alternative to bending, recapping, or removing contaminated needles is feasible or that such action is required by a specific medical procedure, would be a written justification included as part of the Exposure Control Plan.

This justification must state the basis for the employer's determination that no alternative is feasible, or must specify that a particular medical procedure requires deviation from the requirement of 5193, e.g., the bending of the needle and the use of forceps to accomplish this. Shearing or breaking contaminated needles is completely prohibited by 5193(d)(3)(B).

5193(d)(3)(B)9.

44. Can employees of ambulance medical rescue services eat or drink inside the cab of the ambulance?

Employees are allowed to eat and drink in an ambulance cab only if the employer has implemented procedures to permit employees to wash up and change contaminated clothing prior to entering the ambulance cab. The employer must prohibit the consumption, handling, storage, and transport of food and drink in the rear of the vehicle, and have procedures to ensure that patients and contaminated materials remain within the patient treatment portion of the vehicle preferably behind a partition separating the two areas.

5193(d)(3)(B)10.

45. Can food, cosmetics and other such consumable or edible items be stored with medication in a refrigerator or freezer?

No personal use or edible items may be stored where other items covered by 5193 are stored in the same refrigerator or freezer. Such items include blood samples or tissue samples. Refrigerators which contain medication or other substances stored for medical procedures are not subject to the restriction, e.g., challenge solutions for glucose tolerance tests.

46. Are there restrictions on refrigerators that store medical waste?

Refrigerators used to store medical waste must be secure and not used for the storage of other materials.

5193(d)(3)(C)1.

47. In 5193(d)(3)(C)1., what is meant by the terminology "effective patient-handling techniques and other methods designed to minimize the risk of a sharps injury?"

This language was added to 5193 in 1999 to emphasize that in addition to well known control measures designed to minimize the risk of sharps injury--engineering controls, work practices and the use of personal protective equipment--it is important to recognize adequate procedures to control or restrain a struggling patient as additional opportunities for minimizing the risk of sharps injury.

5193(d)(3)(C)3.a.

48. Where must sharps containers be located?

Sharps containers must be easily accessible to employees and located as close as feasible to the immediate area where sharps are used, e.g., patient care areas. Sharps containers must also be placed where sharps can be reasonably anticipated, e.g., laundries. In areas such as correctional facilities and psychiatric units where security is a concern, there may be difficulty placing sharps containers in the immediate area of use. If a mobile cart is used in these areas, an option would be to lock the sharps container in the cart.

5193(d)(3)(D)1.e.

49. Must sharps containers be labeled?

Yes. Sharps containers must be labeled with the words "sharps waste" or with the international biohazard symbol and the word "BIOHAZARD." This requirement is noted in 5193(g)(1)(A)2 and is consistent with the California Medical Waste Act (MWA).

5193(d)(3)(E)

50. Are human tissue and items contaminated with blood or OPIM, such as those that may be secured in law enforcement situations, viewed as regulated waste?

Materials that have not entered the waste stream, and are intended to be put to some use rather than to be disposed of, are not "waste." Therefore, these materials are not considered to be regulated waste under the standard.

It should be kept in mind that 5193 still requires measures to prevent exposure to these materials even though they are not classified as regulated waste. Moreover, once the item fulfills its use, disposal of the item becomes an issue and the regulated waste provisions of 5193 become applicable.

51. Are feminine hygiene products considered regulated waste?

Neither Cal/OSHA nor the California Department of Health Services generally considers discarded feminine hygiene products used to absorb menstrual flow to fall within the definition of regulated waste. The intended function of products

such as sanitary napkins is to absorb and contain blood. The absorbent material of which they are composed will, under most circumstances, prevent the release of liquid or semi-liquid blood or the flaking off of dried blood.

These items must be discarded into waste containers that are properly lined with plastic bags. Such bags should protect the employees from physical contact with the contents.

52. Do I need to autoclave waste before disposal?

There is no specific requirement to autoclave waste before disposal, except as found in 5193(e), HIV and HBV Laboratories and Production Facilities. 5193(e)(2)(B)8. requires that all regulated waste from such facilities must be either incinerated or decontaminated by a method, such as autoclaving, known to effectively destroy bloodborne pathogens. 5193(e)(3)(B) requires that research laboratories have an autoclave available for decontamination of regulated waste while 5193(e)(4)(E) requires production facilities to have an autoclave available within or as near as possible to the work area, also for the decontamination of regulated waste. 5193(e)(3)(B) and (e)(4)(E) require that treatment of medical waste, including autoclaving, meet applicable requirements in the California Health and Safety Code.

5193(d)(3)(F)

53. Do specimens of blood or OPIM have to be double-bagged?

Secondary containers or bags are only required by 5193 if the primary container is contaminated on the outside. Also, if the bagged material could puncture the primary container, a secondary puncture-resistant container is required. All specimen containers, primary and secondary, must be closed, properly labeled or color-coded (except as described above) and must prevent leakage.

5193(d)(3)(G)

54. Are employers required to decontaminate equipment prior to servicing or shipping?

5193 requires that all equipment that may be contaminated must be examined and decontaminated as necessary prior to servicing or shipping, unless the employer can show that decontamination is not feasible or will interfere with a manufacturer's ability to evaluate how a device failed. If complete decontamination is not performed, the equipment must be labeled with the required biohazard label that also specifically identifies which portions of the equipment remain contaminated. In addition, the employer must ensure that this information is conveyed to affected employees, the servicing representative, and the manufacturer as appropriate, prior to handling, servicing or shipping.

(d)(3)(H)

55. What type of disinfectants can be used to decontaminate equipment or working surfaces that have come in contact with blood or OPIM?

Under 5193(d)(3)(H), cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface from previous procedures.

Appropriate disinfectants include a diluted bleach solution, Environmental Protection Agency (EPA)-registered tuberculocides, EPA-registered sterilants, or products registered as effective against HIV or HBV. The lists of these EPA Registered Products are available from the National Antimicrobial Information Network (NAIN) at telephone number 1-800-447-6349, and at the NAIN website http://ace.orst.edu/info/nain/lists.htm.

The list of products registered against HIV and HBV includes quaternary ammonia products that EPA has approved as effective against HIV and HBV. These products can be used to comply with 5193, provided the surfaces on which they are used have not become contaminated with agent(s) or volumes or concentrations of agent(s) for which higher levels of disinfection are recommended. Disinfectant products must be used according to all label instructions, including concentration, volume to be applied on a given surface area and contact time.

5193(d)(3)(I)

56. What alternatives are acceptable if soap and running water are not available for hand washing?

Antiseptic hand cleaner in conjunction with clean cloth or paper towels or antiseptic towelettes are examples of acceptable alternatives to running water. However, when these types of alternatives are used, employees must wash their hands (or other affected areas) with soap and running water as soon as feasible. This alternative would only be acceptable at worksites where soap and running water are not generally feasible.

5193(d)(3)(J)

57. What does Cal/OSHA mean by the term "contaminated laundry?"

Contaminated laundry means laundry that has been soiled with blood, or other potentially infectious materials (OPIM), or may contain contaminated sharps. See 5193(b), Definitions.

(d)(3)(J)1.

58. What color-coding is required for laundry bags?

Laundry bags must be color-coded in accordance with 5193(g)(1)(A). Facilities which utilize Universal Precautions in the handling of all soiled laundry may use alternative labeling or color-coding provided that it permits all employees to recognize the containers as requiring handling with Universal Precautions. According to 5193(d)(3)(J)3., when contaminated laundry is shipped off-site to a facility not utilizing Universal Precautions for handling of all laundry which the

facility receives, the facility generating the contaminated laundry must place it in bags or containers labeled or color-coded in accordance with 5193(g)(1)(A).

(d)(4) -- Personal Protective Equipment (PPE)

5193(d)(4)(A)

59. Who is responsible for providing Personal Protective Equipment (PPE)?

The responsibility for repairing, replacing, cleaning, and disposing of PPE rests with the employer--the employer is required to enforce these procedures in connection with PPE as well as bear the cost of the items and services provided. If laboratory jackets or uniforms are intended to protect the employee's body or clothing from contamination, they are considered to be PPE and must be provided to the employee by the employer.

60. Are uniforms considered to be PPE under 5193?

Ordinarily, uniforms are not PPE and the maintenance of uniforms or other clothing is not addressed by 5193 unless such items are designated by the employer as personal protective equipment within the scope of the standard. When a uniform is needed, or provided for the purpose of preventing contact with blood or OPIM, it is considered to be PPE and is subject to the requirements of 5193.

61. What type of PPE should be used by employees in a dental office?

Where occupational exposure remains after use of engineering and work practice controls, 5193 requires that PPE be used that is "appropriate." PPE will be considered "appropriate" only if it does not permit blood or OPIM to pass through employees' underlying garments, or to reach the skin, eyes, mouth, or other mucous membranes under normal conditions of use. PPE must retain this capability during the entire course of its use by the employee. This allows the employer to select PPE based on the type of exposure and the quantity of blood or OPIM reasonably anticipated to be encountered during performance of a task or procedure.

5193(d)(4)(D)

62. Who is responsible for laundering PPE?

The employer is responsible for laundering PPE at the workplace or at a commercial laundry and at no cost to employees. Employees must not bring PPE home to launder. See 5193(d)(3)(J).

63. Are there guidelines to be followed when laundering personal protective equipment? What water temperature and detergent types are acceptable?

The decontamination and laundering of protective clothing should be handled by washing and drying the garments according to the clothing manufacturer's instructions.

5193(d)(4)(F)2.

64. Does protective clothing need to be removed before leaving the work area?

Yes. 5193 requires that personal protective equipment be removed prior to leaving the work area. While "work area" must be determined on a case-by-case basis, a work area is generally considered to be an area where work involving occupational exposure occurs or where the contamination of surfaces may occur.

5193(d)(4)(G)

65. Are gloves required during phlebotomy procedures?

Gloves must be worn by employees whenever any vascular access procedure is performed, including phlebotomy. However, there is an exemption for phlebotomy at volunteer blood donation centers. See 5193(d)(4)(G)4.

66. Do gloves increase the risk of needlesticks?

Gloves do not increase the risk of needlesticks. Research suggests that gloves provide significant protection against the consequences of a needlestick by reducing up to 50% the amount of blood injected during a needlestick incident.

67. Are gloves required when giving an intradermal, subcutaneous or intramuscular injection?

5193 does not require gloves to be used when giving an injection, unless contact with blood or other potentially infectious materials is reasonably anticipated.

5193(d)(4)(G)1.

68. When should gloves be changed?

Gloves must be replaced as soon as practical after they have become contaminated, or as soon as feasible if they are torn or punctured, or their ability to function as a barrier to fluids is compromised. Hands must be washed after the removal of gloves used as PPE or used during any procedure which may have contaminated them with blood or OPIM whether or not the gloves are visibly contaminated.

69. What are some alternatives when an employee is allergic to gloves provided by the employer?

5193(d)(4)(C) provides that hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives must be provided for employees who are allergic to the gloves that are normally provided.

5193(d)(4)(H)

70. What type of eye protection do I need to wear when working with blood or OPIM?

The use of eye protection is based on the reasonable anticipation of contact to the mucous membranes of the eye. 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 OPIM may be generated and exposure to the eyes can be reasonably anticipated. It should be noted that goggles specifically designed to protect the eyes from splashes of liquids generally provide more protection of the eyes than do face shields or safety glasses.

5193(e) -- HIV, HBV and HCV Research Laboratories and

Production Facilities

71. Does 5193(e) apply to clinical or diagnostic laboratories?

As specified in the Exception to 5193(e)(1)(A), 5193(e) does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. 5193(e) only applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV, HBV and HCV.

72. Are academic research laboratories included in the definition of a research laboratory under 5193?

All laboratories under Cal/OSHA's jurisdiction, including academic laboratories, which meet the definition of "research laboratory" in 5193(b), and engage in any of the activities specified in 5193(e)(1)(A), are covered by 5193(e). Although research laboratories may not have the volume of blood found in production facilities, they routinely deal with solutions containing higher viral titers than those normally found in patients' blood.

73. Are animal components used in research, such as blood, tissues, and cultures, covered under 5193(e)?

5193(e) covers animal tissues as detailed in the definition of "other potentially infectious material" when handled in research laboratories and production facilities engaged in the culture, production, concentration, experimentation and manipulation of HIV, HBV, and HCV. Although 5193, as a whole, only applies to animal blood and other tissues if known or reasonably likely to be infected with HIV, HBV or HCV, persons handling any experimental animals or animal blood or other tissues should follow the most current recommendations of the U.S. Centers for Disease Control and Prevention.

74. Are biohazard signs required in research laboratories and production facilities?

Yes, as specified in 5193(g)(1)(B)1. Additional regulatory requirements can be found in 8 CCR 3340.

5193(f) -- Hepatitis B Vaccination and Post-exposure Follow-up Procedures

5193(f)(1)(A) and (B) and (f)(2)(A)

75. Who must be offered the hepatitis B vaccination?

The hepatitis B vaccination series shall be made available after an employee has received the training required by 5193(g)(2)(G)9. and within 10 days of the initial work assignment to duties with occupational exposure to blood or OPIM. The employer does not have to make the hepatitis B vaccination available to employees who have previously received the vaccination series, who are already immune as revealed by appropriate tests for HBV antibodies, or who are prohibited from receiving the vaccine for medical reasons.

5193(f)(1)(A)

76. What is the definition of "exposure incident?"

"Exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties." See 5193(b). Employers need to evaluate each "exposure" or first aid incident carefully to determine if the employee got blood or OPIM on their broken skin or mucous membranes during the course of the incident.

77. Are employees, who render first aid as a "Good Samaritan," but not as part of their job duties, covered by 5193?

No. Only employees, whose job duties require them to render first aid, are covered by 5193. 5193 does not preclude an employer from offering first aid training to their employees. However, when an employee voluntarily provides first aid, and subsequently is exposed to blood or OPIM, Cal/OSHA encourages employers to offer post-exposure follow-up as detailed in 5193(f), including immediate evaluation for HIV post-exposure prophylaxis, and post-exposure prophylaxis with hepatitis B immune globulin (HBIG) (passive immunization), and/or vaccine (active immunization), when indicated, and as discussed below in questions on post-exposure prophylaxis for HBV and HIV.

5193(f)(1)(B)1.

78. Who is responsible for paying for the hepatitis B vaccination?

The employer has the responsibility to make the hepatitis B vaccine and vaccination, including post-exposure evaluation and follow-up, available at no cost to the employer's employees on work time.

79. Can accepting hepatitis B vaccination be made a condition of employment?

No. Cal/OSHA believes that it is unlawful for an employer to make HBV vaccination a condition of employment.

5193(f)(1)(B)4.

80. What is the appropriate course of action by an employer when the HBV vaccination series is interrupted?

5193(f)(1)(B)3. incorporates by reference as a regulatory requirement the recommendations of the U.S. Public Health Service, including the U.S. Centers for Disease Control and Prevention (CDC), with respect to procedures for hepatitis B vaccination.

CDC recommends that if the hepatitis B vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third dose should be separated by an interval of at least two (2) months. If only the third dose is delayed, it should be administered when convenient. The CDC recommendation for post-vaccination testing for antibody status after the third dose of the three-dose vaccination series, also incorporated by reference in 5193, and discussed below, helps address any concerns with respect to effectiveness of the vaccine being compromised by interruption in its provision. See "Centers for Disease Control and Prevention. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). MMWR Recommendations and Reports. November 22, 1991. Volume 40, Number RR-13."

81. Is post-vaccination testing for hepatitis B antibody required to be provided by the employer?

Yes. 5193(f)(1)(B)3. incorporates by reference as a regulatory requirement recommendations of the U.S. Public Health Service, including the U.S. Centers for Disease Control and Prevention (CDC), with respect to procedures for hepatitis B vaccination.

CDC recommends routine post-vaccination serologic testing for health care workers with ongoing risk of sharps-related exposure incidents. See "Centers for Disease Control and Prevention. Immunization of Health Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR Recommendations and Reports. December 26, 1997. Volume 46, Number RR-18."

Cal/OSHA believes this CDC recommendation indicates that post-vaccination testing is important for the overall effectiveness of a hepatitis B vaccination program and for the protection of individual employees. Therefore, Cal/OSHA will expect not only healthcare workers, but all employees covered by 5193, to be

offered and encouraged to receive testing after hepatitis B vaccination to assure the development of protective antibodies to hepatitis B surface antigen.

Post-vaccination testing should be conducted as detailed in the latest Recommendations of the CDC. The 26 December 1997 document provides the latest recommendations as of the date of this question and states:

"One to 2 months after completion of the 3-dose vaccination series, healthcare workers who have contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needlesticks should be tested for antibody to hepatitis B surface antigen (anti-HBs). Persons who do not respond to the primary vaccine series should complete a second three-dose vaccine series or be evaluated to determine if they are HBsAg-positive. Re-vaccinated persons should be retested at the completion of the second vaccine series. Persons who prove to be HBsAg-positive should be counseled accordingly. (See refs. 1,16,121,173 in the December 26, 1997 document.) Primary non-responders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG (hepatitis B immune globulin) prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood. See Table 3 in the December 26, 1997 document. Periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended."

5193(f)(2)(B)

82. Can an employer require an employee to submit to screening for hepatitis B antibody before vaccination?

No. Cal/OSHA believes that it is unlawful for an employer to require an employee to take a prescreening serologic test. An employer may, however, decide to make pre-screening available at no cost to the employee. Employees who test positive for hepatitis B antibody are not required to be provided the hepatitis B vaccination.

5193(f)(2)(D)

83. Can employees refuse the hepatitis B vaccination?

Yes. Employees have the right to refuse the hepatitis B vaccine and any post-exposure evaluation and follow-up. It is important to note, however, that the employee needs to be properly informed of the benefits of the vaccination and post-exposure evaluation through training. If after being provided appropriate training, the employee refuses vaccination, the employer must have the employee sign a declination form with wording as found in Appendix A to 5193. The employee also has the right to decide to take the vaccination at a later date if he or she so chooses. The employer must make the vaccination available at that time.

84. If an employee declines the hepatitis B vaccination, can the employer make up a declination form?

If an employee declines the hepatitis B vaccination, the employer must ensure that the employee signs a hepatitis B vaccine declination. Any alternative declination form designed by the employer must use wording that is identical to that found in Appendix A of 5193. A photocopy of the Appendix may be used as a declination form, or the words can be typed or written onto a separate document.

5193(f)(2)(E)

85. Is a routine booster dose of hepatitis B vaccine beyond the series of three injections required?

No. The relevant source document is "Centers for Disease Control and Prevention. Immunization of Health Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR Recommendations and Reports. December 26, 1997. Volume 46, Number RR-18."

This document discourages routine booster doses of hepatitis B vaccine because immunity can be present even without measurable levels of HBV antibodies. For current information consult the most recent CDC MMWR Recommendations.

86. How do I stay current, as required by 5193, with the recommendations of the U.S. Public Health Service for the following: hepatitis B vaccination, follow-up serologic testing booster doses, post-exposure evaluation and exposure incident follow-up including prophylaxis, treatment, counseling, and collection and testing of an exposed employee's blood?

The recommendations of the U.S. Public Health Service with respect to these subjects are published as Recommendation documents in the CDC's weekly publication called the "Morbidity and Mortality Report of the Centers for Disease Control and Prevention (MMWR)." A free e-mail subscription to the MMWR is available through the CDC Internet website at http://www.cdc.gov/subscribe.html. A free subscription will automatically provide the MMWR Recommendation documents via e-mail when they are issued. Paper subscriptions to MMWR and the Recommendations are also available through CDC for a nominal fee.

5193(f)(3)

87. Is it permissible for physicians or other health care employers to provide the required confidential medical evaluation to their own employee following an exposure incident?

Yes. However, where this is done, requirements for consent and confidentiality must still be observed and followed. Medical information is to be confined to the medical department or office, and is not to be discussed or revealed to others such as supervisors or personnel representatives, or to other health care

professionals who do not need the information to comply with the requirements of 5193.

5193(f)(3)(B)1.

88. What serological testing must be done on the blood of the source individual?

The employer must identify and document the source individual if known, unless the employer can establish that identification is not feasible or is prohibited by state or local law. The source individual's blood must be tested as soon as feasible, after consent is obtained, in order to determine HIV, HBV and HCV infectivity. The information on the source individual's HIV, HBV and HCV testing results must be provided to the evaluating health care professional. Also, the results of the testing must be provided to the exposed employee. The exposed employee must be informed of applicable laws and regulations concerning disclosure of the identity and infectivity status of the source individual.

5193(f)(3)(B)1.

89. What if consent cannot be obtained from the source individual for testing of their blood?

If consent cannot be obtained, and is required by California law, the employer must document in writing that consent cannot be obtained. When the source individual's consent is not required by California law, the source individual's blood, if available, must be tested, results documented and test results provided to the exposed employee.

5193(f)(3)(C)1.

90. When must the exposed employee's blood be tested?

After consent is obtained, the exposed employee's blood is collected and tested as soon as feasible for HIV, HBV and HCV infectivity status. If the employee consents to the follow-up evaluation after an exposure incident, but does not give consent for HIV serological testing, the blood sample must be preserved for 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested for HIV, testing must be done as soon as feasible. 5193(f)(3)(C)3. requires additional collection and testing be made available as recommended by the U.S. Public Health Service.

91. Who has to pay the testing and counseling of the exposed employee and the source patient?

The employer of the exposed employee must pay for the cost of the post-exposure evaluation and follow-up, including testing and counseling of both the exposed employee and the source patient (if applicable).

5193(f)(3)(D)

92. What post-exposure prophylaxis (PEP) measures are currently recommended by the U.S. Public Health Service for HIV and therefore incorporated by reference into 5193?

The recommendations of the U.S. Public Health Service with respect to post-exposure prophylaxis for HIV can be found in the following document: "Centers for Disease Control and Prevention. Public Health Service Guidelines for the Management of Health Care Worker Exposures to HIV and Recommendations for Post-exposure Prophylaxis. MMWR Recommendations and Reports. May 15, 1998. Volume 47, RR-7."

The latest version of the CDC MMWR Recommendations should be consulted. The May 15, 1998 Recommendations state in summary:

"Occupational exposures [to blood or OPIM] should be considered urgent medical concerns to ensure timely administration of PEP. Health-care organizations should have protocols that promote prompt reporting (of exposure incidents) and facilitate access to post-exposure care.

Recommendations for PEP have been modified to include a basic 4-week regimen of two drugs (zidovudine and lamivudine) for most HIV exposures and an expanded regimen that includes the addition of a protease inhibitor (indinavir or nelfinavir) for HIV exposures that pose an increased risk for transmission or where resistance to one or more of the antiretroviral agents recommended for PEP is known or suspected. An algorithm is provided to guide clinicians and exposed health-care workers in deciding when to consider PEP.

Health-care organizations should make available to their workers a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures that may place healthcare workers (HCWs) at risk for acquiring any bloodborne infection, including HIV. Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. Antiretroviral agents for PEP should be available for timely administration (i.e., either by providing access to PEP drugs on site or creating links with other facilities or providers to make them available offsite). Persons responsible for providing postexposure counseling should be familiar with evaluation and treatment protocols and the facility's procedures for obtaining drugs for PEP.

PEP should be initiated as soon as possible. The interval within which PEP should be started for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP within hours after an exposure. To assure timely access to PEP, an occupational exposure should be regarded as an urgent medical concern and PEP started as soon as possible after the exposure (i.e., within a few hours rather than days). If there is a question about which antiretroviral drugs to use, or whether to use two or three drugs, it is probably better to start ZDV and 3TC immediately than to delay PEP administration. Although animal studies suggest that PEP probably is not effective when started later than 24-36 hours postexposure, the interval after which there is no benefit from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since

exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., 1-2 weeks) may be considered for exposures that represent an increased risk for transmission; even if infection is not prevented, early treatment of acute HIV infection may be beneficial (Reference 69 in the CDC document). The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in HCWs (Reference 2 in CDC document), PEP probably should be administered for 4 weeks, if tolerated."

In light of the above recommendations from the U.S. Public Health Service, Cal/OSHA requires employers with employees reasonably anticipated to have contact with blood or OPIM to take all feasible measures to assure that HIV prophylactic medications and a qualified physician are available to evaluate applicability of, and initiate the HIV PEP protocol where appropriate, as soon as possible, that is within hours and not days of occurrence of the exposure.

To ensure that this level of response can be implemented, the employer may have to check frequently with their employees to verify that qualified professionals are indeed available and that they have ready access to appropriate medications at all times. In situations such as highly mobile employees, employers--to assure timely initiation of the HIV PEP protocol--may have to plan and arrange in advance to maintain their own supply of the required medications in proximity to their work force, and to arrange for immediate availability of a qualified physician for post-exposure evaluation and initiation of the HIV PEP protocol.

Physicians who wish to obtain assistance with evaluation of exposed employees, and to determine if their patient's exposure incident warrants initiation of the HIV PEP, can call the CDC hotline number for Physician Consultation at 1-800-933-3413.

CDC also maintains a telephone hotline for exposed employees to call for counseling related to HIV post-exposure prophylaxis and other post-exposure concerns. The telephone number is 1-888-448-4911.

93. What post-exposure prophylaxis measures are currently recommended by the U.S. Public Health Service for hepatitis B and therefore incorporated by reference into Section 5193?

The recommendations of the U.S. Public Health Service with respect to hepatitis B post-exposure prophylaxis can be found in the following document: "Centers for Disease Control and Prevention. Immunization of Health Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR Recommendations and Reports. December 26, 1997. Volume 46, RR-18." The latest version of the CDC MMWR Recommendations should be consulted.

The December 26, 1997 Recommendations state in summary:

"Post-exposure prophylaxis with hepatitis B immune globulin (HBIG) (passive immunization) and/or vaccine (active immunization) should be used when indicated. See Table 3 in the CDC Recommendations of December 26, 1997. Needlestick or other percutaneous exposures of unvaccinated persons should lead to initiation of the hepatitis B vaccine series. Post-exposure prophylaxis should be considered for any percutaneous, ocular, or mucous membrane exposure to blood in the workplace and is determined by the HBsAg status of the source and the vaccination and vaccine-response status of the exposed person (Table 3 and refs. 1,18 in the CDC Recommendations).

If the source of exposure is HBsAg-positive and the exposed person is unvaccinated, HBIG also should be administered as soon as possible after exposure (preferably within 24 hours) and the vaccine series started. The effectiveness of HBIG when administered greater than 7 days after percutaneous or permucosal exposures is unknown. If the exposed person had an adequate antibody response (greater than or equal to 10 mIU/mL) documented after vaccination, no testing or treatment is needed, although administration of a booster dose of vaccine can be considered."

94. Has a post-exposure prophylaxis treatment regime been recommended by the U.S. Public Health Service for HCV?

At this time, CDC does not have a recommended post-exposure prophylaxis protocol for exposure to the hepatitis C virus. Findings of experimental approaches attempted, and suggestions for care management can be found in the following document: "Centers for Disease Control and Prevention. Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. MMWR Recommendations and Reports. October 16, 1998. Volume 47, RR-19." The CDC website should be consulted for the most current Recommendations and Reports.

5193(f)(3)(E)

95. What type of counseling is required following an exposure incident?

5193 requires that post-exposure counseling be given to employees following an exposure incident. Counseling should include CDC recommendations for prevention and transmission of bloodborne infections including HIV, HBV, and HCV. Counseling must be made available regardless of the employee's decision to accept serological testing.

See "Centers for Disease Control and Prevention. Public Health Service Guidelines for the Management of Health Care Worker Exposures to HIV and Recommendations for Post-exposure Prophylaxis. MMWR Recommendations and Reports. May 15, 1998, Volume 47, RR-7."

This document contains recommendations for post-exposure counseling related to HIV. The CDC Recommendations include refraining from blood, semen, and organ donation; abstaining from sexual intercourse, or use of measures to prevent HIV transmission of potentially infectious body fluids during sexual

intercourse; and refraining from breast feeding infants during the post-exposure follow-up period.

96. Who provides counseling for personnel involved in an exposure incident?

The employer is required to provide or secure the provision of appropriate counseling by a trained counselor. 5193 does not stipulate the qualifications or license requirements of the counselor. Counseling can be done by the employee's supervisor, the doctor that administers treatment, or any other person with appropriate training.

5193(f)(5)(A)

97. What information does the health care professional provide to the employer following an exposure incident?

The health care professional's written opinion for hepatitis B is limited to whether hepatitis B vaccination is indicated and if the employee received the vaccination.

The written opinion for post-exposure evaluation must include the following information:

5193(f)(5)(B)1. That the employee has been informed of the results of the evaluation and (f)(5)(B)2. That the employee has been told about any medical conditions resulting from exposure that may require further evaluation and treatment. (f)(5)(C) All other findings or diagnoses must be kept confidential and not included in the written report.

The employer must obtain and provide to the employee a copy of the evaluating health care professional's written opinion, which contains the material cited above, within fifteen (15) days of completion of the evaluation.

5193(g) -- Communication of Hazard to Employees

5193(g)(1)(A)

98. When are labels required?

Labels are required on the following:

(1) Regulated waste (when regulated waste is red-bagged per 5193(g)(1)(A)5., the bag must be labeled);

(2) Sharps containers;

(3) Laundry bags (unless Universal Precautions are observed as required by 5193(d)(3)(J)1.b.);

(4) Refrigerators and freezers that are used to store blood or OPIM;

(5) Bags and other containers used to store, dispose of, transport, or ship blood or OPIM, e.g., specimen containers; and

(6) Contaminated equipment which is to be serviced or shipped.

99. What are the exceptions to the labeling requirement?

Labels are not required as described in the following exceptions to the requirements of the standard:

5193(d)(3)(F)1. Specimen containers, if the facility uses Universal Precautions when handling all specimens, the containers are recognizable as containing specimens, and the containers remain within the facility.

5193(d)(3)(J)1.b. Laundry bags or containers, containing contaminated laundry, may be marked with an alternative label, or color-coded, provided the facility uses Universal Precautions for handling all soiled laundry and the alternative marking permits all employees to recognize the containers as requiring compliance with Universal Precautions. If contaminated laundry is sent off site for cleaning to a facility which does not use Universal Precautions in the handling of all soiled laundry, it must be placed in a bag or container which is red in color or labeled with the biohazard label described above.

(g)(1)(A)5. For items normally requiring labeling, other than sharps containers and regulated waste, red bags or red containers may be substituted for labeling.

(g)(1)(A)6. Containers of blood, blood components, and blood products bearing a FDA-required label that have been released for transfusion or other clinical uses.

(g)(1)(A)7. Individual containers of blood or OPIM that are placed in secondary labeled containers during storage, transport, shipment, or disposal.

(g)(1)(A)9. Regulated waste that has been decontaminated.

100. Does Cal/OSHA accept US Department of Transportation's (DOT) labels for waste and specimens that will be shipped or transported?

The labeling requirements of 5193 do not preempt either the U.S. Postal Service labeling requirements (39 CFR Part 111) or the Department of Transportation's (DOT) Hazardous Materials Regulations (49 CFR Parts 171-181).

DOT labeling is required on some transport containers, i.e., those containing "known infectious substances." It is not required on all containers for which 5193 requires the biohazard label. Where there is an overlap between the Cal/OSHA mandated label and the DOT-required label, the DOT label will be considered acceptable on the outside of the transport container provided the Cal/OSHA mandated label appears on any internal containers which may be present. Containers serving as collection receptacles within a facility must bear the Cal/OSHA label since these are not covered by the DOT requirements.

5193(g)(2)

101. What qualifications are required for the individual who provides the training required by 5193 or serves as the contact person for questions about the subject matter of the training?

The employer must ensure that accurate and effective information is transmitted during the course of training. At a minimum, this must include direct access to a person who is knowledgeable in all subject matter of the training program as it relates to the workplace for which the training is provided. Since employees must be provided with site-specific information (e.g. the location of the Exposure Control Plan, procedures to be followed if an exposure incident occurs, engineering and work practice control measures in place at the worksite to prevent exposure incidents, and procedures for obtaining post-exposure evaluation and follow-up), the trainer must be qualified to answer questions with respect to all of these issues.

The direct access requirement can be met if trainees have direct access to a trainer by way of a telephone hot line. The use of an electronic mail system to answer employee questions is not considered direct access to a qualified trainer, unless the trainer is available to answer the e-mailed questions at the time the questions arise.

102. If a physician is an employee of a corporation or partnership must he or she be trained to comply with 5193?

If the physician is an independent agent or partner of a medical group, he or she is not an employee. In such a situation, Cal/OSHA does not have jurisdiction over him or her, and consequently cannot require the physician to comply with the standard. However, a hospital can, as a matter of contract, require a physician practicing in the hospital to follow the requirements of 5193. If a situation arises in which an employer permits employees to be exposed to hazards created by such a physician, Cal/OSHA may cite the employer for failing to remove his or her employees from such a situation, or for failing to require the physician to abate the hazard.

103. Which employees must be trained?

All employees with reasonably anticipated occupational exposure must receive initial and annual training. Also, additional training must be provided to any employee whose occupational exposure is affected by new engineering, administrative or work practice controls as well as by any new tasks or procedures.

104. Are collateral duty first aid personnel or other assigned emergency response personnel required to be trained?

Persons with emergency response job duties with potential occupational exposure must receive the training required by 5193.

105. Are coaches and playground personnel required to be trained?

If coaches, playground aids, and similar employees have collateral duty first aid responsibilities, they must receive the training required by 5193.

106. Are part-time and temporary employees required to be trained?

Yes. Part-time and temporary employees are covered as employees by 5193 and are also to be trained on the employer's time.

5193(h) -- Recordkeeping

5193(h)(1)(A)

107. Who is the custodian of the records required to be generated and kept by the standard?

The employer is responsible for the establishment and maintenance of all records required by 5193. Medical records may be kept off site at the location of the health care provider.

5193(h)(1)(D)

108. How long must the records required by 5193 be retained?

The Sharps Injury Log must be kept five (5) years from the date the exposure incident occurred. Records of training required by 5193 are required to be retained for three (3) years from the date of training. Medical records must be kept for the duration of employment plus thirty (30) years. 5193(h)(5), and an additional standard in Title 8, Section 3204, should be consulted for requirements related to maintenance, availability, and transfer of employee medical records.

Cal/OSHA 200 Recordkeeping Log

109. Do I record exposure incidents involving bloodborne pathogens on the Log 200 Summary of Occupational Injuries and Illnesses?

Yes, but only in limited circumstances. Exposure incidents are classified as injuries for the purpose of recording on the Log 200, because they are usually the result of an instantaneous event. However, an exposure incident only needs to be recorded on the Log 200 when it results in one of the following:

(1) Loss of consciousness, transfer to another job, or a work restriction.

(2) Administration or recommendation of medical treatment beyond first aid. For example, HIV post-exposure prophylaxis treatment, hepatitis B immune globulin, gamma globulin, or hepatitis B vaccination.

(3) The exposure incident results in a diagnosis of seroconversion.

If the exposure incident results in a diagnosis of HIV, HBV, HCV or other bloodborne pathogen seroconversion, this fact should not be recorded on the Log 200. For example, "Needlestick Injury" is a sufficient description for a recorded exposure incident, and further personal details should not be recorded.

A separate record which can contain personal identifiers should be kept of details of the exposure incident. However, if such a separate record containing personal identifiers is made, the employer must keep this separate record confidential.

110. Where can I get more information about compliance with 8 CCR Section 5193, the Bloodborne Pathogens Standard?

Cal/OSHA has a Consultation Service which can answer your questions about compliance with the Bloodborne Pathogens Standard (8 CCR 5193). For assistance from the Cal/OSHA Consultation Service, please call 1-800-963-9424.

April 1, 2000