

**DIVISION OF OCCUPATIONAL SAFETY AND HEALTH  
POLICY AND PROCEDURES MANUAL**

<b>ENFORCEMENT OF <u>8 CCR SECTION 5193</u></b>	P&P C-14  Issue Date: 5/1/00  Revised: 1/1/03
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**AUTHORITY:** California [Labor Code Section 144.7](#) and Title 8, California Code of Regulations (CCR), [5193](#).

**POLICY:** It is the policy of the Division of Occupational Safety and Health to conduct all programmed and unprogrammed inspections involving enforcement of [8 CCR 5193](#) in a manner that is consistent with the provisions of [8 CCR 5193](#).

**PROCEDURES:**

**A. ENFORCEMENT ASSISTANCE**

1. "[Frequently Asked Questions About Bloodborne Pathogens Standard](#)"

a. For enforcement assistance, compliance personnel shall utilize the information contained in "[Frequently Asked Questions About the Bloodborne Pathogens Standard](#)," as an adjunct to P&P C-14.

b. Access to this document can be obtained through the Division's Internet Home Page as follows: [www.dir.ca.gov/DOSH](http://www.dir.ca.gov/DOSH)

c. The FAQs are structured so that each issue is addressed according to the specific subsection of [8 CCR 5193](#) that gives rise to that issue.

2. District Manager and Regional Senior Industrial Hygienist

Where reference to the "[Frequently Asked Questions About the Bloodborne Pathogens Standard](#)" is not sufficient to resolve a specific enforcement issue, compliance personnel shall consult with their District Manager and/or their Regional Senior Industrial Hygienist.

3. Research and Standards Unit Industrial Hygienists

If additional guidance is needed, the Senior Industrial Hygienists in the Division's Research and Standards Unit are also available to provide consultative assistance.

#### 4. Medical Unit

Throughout the course of an investigation or inspection, compliance personnel are encouraged to contact the Medical Unit for assistance in collecting evidence to sustain alleged violations of [8 CCR 5193](#), especially violations of [8 CCR 5193\(f\)](#), pertaining to Hepatitis B Vaccination and Post-Exposure and Follow-Up.

EXAMPLE: There are several ways that the Medical Unit can assist compliance personnel when they conduct an investigation involving [8 CCR 5193](#), e.g., assistance through telephonic contact, review of medical records, on-site assistance (when appropriate) to conduct interviews with evaluating healthcare professionals.

### B. SCOPE AND APPLICATION

#### 1. General Scope

a. The scope and application of the Bloodborne Pathogens Standard is purposefully broad. [8 CCR 5193](#) applies to "all occupational exposure to blood or other potentially infectious materials (OPIM)." See [8 CCR 5193\(a\)](#).

b. Occupational exposure means "reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or OPIM that may result from the performance of an employee's duties." See [8 CCR 5193\(b\)](#).

c. Compliance personnel shall apply [8 CCR 5193](#) to all covered industries when there is evidence that reasonably anticipated occupational exposure may occur or has occurred.

#### 2. Exemptions

Construction (Standard Industrial Classification (SIC) Codes 152-179) is specifically exempted from coverage pursuant to [8 CCR 5193\(a\)](#). See Section A.4.

#### 3. General Approaches to Determining the Applicability of [8 CCR 5193](#)

Compliance personnel can utilize a "facility" approach or an "operation or employee category" approach to determine if [8 CCR 5193](#) applies to a particular enforcement situation.

#### a. Facility Approach

The facility approach can take one of two forms:

##### (1) Intrinsic Nature of the Facility

The easiest facilities to identify as subject to [8 CCR 5193](#) are those in which the intrinsic nature of the facility, e.g., a hospital, medical outpatient facility, physician or dentist office or coroner's office, identifies it as one in which at least one employee has occupational exposure.

##### (2) Specific Circumstances of the Facility

Facilities that do not intrinsically involve occupational exposure may still, because of their specific circumstances or operations, pose an exposure hazard.

**EXAMPLE:** Commercial laundry facilities that process laundry from hospitals are likely to involve occupational exposure by virtue of the occasional contamination of the laundry with used, improperly discarded sharps.

#### b. Operation or Employee Category Approach

In some cases, it is more appropriate to approach occupational exposure by considering a specific employee category, or a specific operation performed by an employee. These are usually cases in which there is one particular employee category that raises a question about coverage for an employer to whom [8 CCR 5193](#) may not otherwise appear to apply.

**EXAMPLE:** Short-term or long-term lodging establishments where housekeepers' risk of contact with items such as contaminated hypodermic syringes in bed sheets or in trash receptacles is high enough to be "reasonably anticipated."

#### 4. Construction

Where an issue arises regarding exposure of construction employees to bloodborne pathogens, e.g., where construction employees are designated to provide first aid, compliance personnel shall determine the extent to which

appropriate precautions against exposure are required pursuant to [8 CCR 3203](#) (IIP Program).

#### 5. Less than "Reasonably Anticipated" Occupational Exposure

Even in those situations where the risk to employees of contact with blood or OPIM is not so high as to be "reasonably anticipated," the specific 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.

EXAMPLE: There may be situations in which compliance personnel determine that evidence exists that workers (such as sanitation workers) are at risk of receiving cuts, abrasions, and punctures in the course of their work. In these cases, compliance personnel shall determine if the employer's IIP Program is "effective," as required by [8 CCR Section 3203\(a\)](#), in preventing exposure incidents by utilization of procedures for handling possibly contaminated materials safely (e.g., in the case of sanitation workers, use of gloves and protective clothing).

### C. GENERAL PRECAUTIONARY MEASURES DURING AN INSPECTION

#### 1. Contaminated Evidence

a. Compliance personnel shall take all necessary precautions to minimize the likelihood of their own exposure to blood and OPIM, as defined by [8 CCR 5193\(b\)](#), when conducting any inspection or investigation.

b. Compliance personnel shall avoid situations during an inspection or investigation that may increase the risk of an exposure incident.

c. If a concern arises at any time about how to gather necessary evidence without risking an exposure incident, compliance personnel shall consult with their District Manager and/or Regional Senior Industrial Hygienist before proceeding to gather the evidence.

#### 2. Photographic Documentation

Compliance personnel shall avoid obtaining digital, photographic or video images of patients during an inspection or investigation of a healthcare establishment, unless it is determined to be absolutely necessary to support the existence of a violative condition. If it is absolutely necessary to photograph a patient, this should be done in a way that minimizes the

potential for the identity of the patient to be ascertainable by looking at the photograph.

## D. GENERAL INSPECTION PROCEDURES

### 1. Inspection Scope

#### a. Unprogrammed Inspection

##### (1) SIC Major Group 80 (Health care establishments)

In FY 2002 DOSH established the Bloodborne Safety and Health Inspection Program (BSHIP). This program has been continued for FY 2003 as a local emphasis program. All bloodborne pathogens complaints or accidents within SIC Codes 8011 through 8099 shall be assigned to a BSHIP-trained industrial hygienist, in accordance with the attached BSHIP Protocol. Industrial hygienists will evaluate the facility's compliance with 5193, and, in addition to any other compliance activity, will complete the Outcome Measures Report that is part of the attached protocol.

When an accident or complaint that does not include bloodborne pathogens issues is received relative to a facility in SIC codes 8011 through 8099, the district manager shall determine whether to investigate compliance with 5193 in the course of the inspection. If a 5193 investigation is to be conducted, the district manager shall assign a BSHIP-trained industrial hygienist to conduct that portion of the investigation, and to complete the required Outcome Measures Report.

The district manager shall notify the BSHIP coordinator when a BSHIP inspection has been assigned.

##### (2) Bloodborne Pathogen Complaint -- other than SIC codes 8011-8099

When conducting an inspection in response to a bloodborne pathogens complaint or accident, compliance personnel shall, in addition to addressing the complaint item or accident circumstances, also conduct a documentation review to determine if the employer's compliance with §

CCR 5193 needs to be further evaluated. See Section D.2. below.

(a) If a Documentation Review does not reveal exposure incidents, then compliance personnel may limit the scope of the complaint inspection or accident investigation at their discretion.

(b) If the Documentation Review reveals exposure incidents, then compliance personnel shall conduct a thorough review of the employer's compliance with 8 CCR 5193.

(3) Non-Bloodborne Pathogen Complaint or Accident -- other than SIC codes 8011-8099

Whenever compliance personnel conduct a complaint inspection or accident investigation of a facility that is not in SIC codes 8011-8099 and where employees may have occupational exposure, compliance personnel shall, in addition to inspecting the complaint item(s) or investigating the cause(s) of the accident, also review the employer's compliance with 8 CCR 5193 by conducting a Documentation Review. See Section C.2. below.

#### b. Programmed Inspections

When conducting a programmed inspection of a facility where employees may have occupational exposure to blood or OPIM, compliance personnel shall conduct a comprehensive review of the employer's compliance with 8 CCR 5193. If the facility is in SIC codes 8011-8099, a BSHIP-trained industrial hygienist shall conduct the investigation in accordance with the BSHIP protocol in Attachment 1 and complete the required Outcome Measures Report. The district manager shall notify the BSHIP coordinator when a BSHIP inspection has been assigned.

### 2. Inspection Starting Point -- Documentation Review

#### a. Log 300, Injury & Illness Prevention Program and Exposure Control Plan

(1) All inspections in which compliance with 8 CCR 5193 is investigated shall include at the outset a detailed review of the employer's Log 300, Injury and

Illness Prevention (IIP) Program, Exposure Control Plan (ECP) and [Sharps Injury Log](#) (SIL).

(2) Unless unusual circumstances indicate a need to begin elsewhere, this documentation review shall generally be the starting point of the investigation once the Opening Conference has been completed.

(3) Review of these documentation items is performed to:

(a) Determine whether the employer is in compliance with these documentation requirements;

(b) Identify problem areas that should be addressed by the inspection; and

(c) Gain an understanding of the employer's procedures for addressing compliance issues, which will facilitate conducting an effective inspection and determining the extent to which the employer's procedures have been implemented and are actually being followed by employees.

b. Review of [Log 300](#)

Compliance personnel shall review the employer's [Log 300](#) to determine if there are entries for "exposure incidents," i.e., specific eye, mouth or other mucous membrane, non-intact skin or parenteral contact with blood or OPIM that results from the performance of an employee's duties, that have been recorded.

NOTE: Compliance personnel shall not rely solely on the absence of [Log 300](#) entries of exposure incidents to determine the scope of any investigation, but also shall interview a representative number of frontline healthcare workers--those employees directly exposed to the hazard of blood or OPIM--from the establishment to determine whether exposure incidents have occurred.

c. Injury & Illness Prevention Program

Compliance personnel shall evaluate every employer's IIP Program, but especially when the risk to an employer's employees of contact with blood or OPIM is not so high as to be "reasonably anticipated." See Section B.5.

EXAMPLE.

d. Exposure Control Plan

(1) Every employer having employees with occupational exposure is required to establish, implement and maintain an effective Exposure Control Plan. [8 CCR 5193\(c\)\(1\)\(A\)](#).

(2) Compliance personnel shall evaluate the effectiveness of the employer Exposure Control Plan by determining the effectiveness of each of the eight procedural elements of the Exposure Control Plan. [8 CCR 5193\(c\)\(1\)\(B\)1](#).through 8.

(3) Evaluation of the elements of the employer's Exposure Control Plan requires that compliance personnel conduct interviews not only with the employer and the employer's representatives but also with frontline healthcare workers.

EXAMPLE: Every employer is required to establish, implement and maintain an effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed by employees in their respective work areas or departments. To be effective, then, the employer's procedures for complying with this requirement must include mechanisms to involve, and receive feedback from, all employees in each unit of the employer's establishment.

e. [Sharps Injury Log](#)

(1) Careful review of the information contained in the employer's [Sharps Injury Log](#) is crucial in any bloodborne pathogens investigation and serves to focus the investigation on the employer's Exposure Control Plan, the employer's compliance with engineering control requirements, training requirements and post-exposure follow-up requirements.

(2) If compliance personnel have any difficulty in gaining information from the employer about the identity of a specific employee whose exposure incident is recorded on the [Sharps Injury Log](#) and with whom an interview needs to be conducted, compliance personnel shall inform the employer that the name of the employee is not confidential and that legal means will be pursued by the Division to obtain the identity of the employee so that an interview can be conducted.

**E. INSPECTIONS OF EMPLOYERS IN THE HEALTHCARE AND ALLIED INDUSTRIES WITH RESPECT TO PREVENTION OF CONTAMINATED SHARPS INJURIES**



## 1. General Considerations in addition to those outlined in the BSHIP Protocol

a. What primarily sets inspections in this category apart from other bloodborne pathogens inspections is that exposure to blood or OPIM are intrinsic to these facilities. Evaluation of the employer's use of medical sharps devices, compliance with the requirements to keep a [Sharps Injury Log](#) and to utilize needleless systems and sharps with engineered sharps injury protection (ESIP), is central to any investigation of these types of facilities.

b. These employers have specifically enumerated obligations related to medical sharps and their usage under the ECP requirements of [8 CCR 5193\(c\)\(1\)\(B\), \(c\)\(1\)\(D\), and \(c\)\(2\)](#), the engineering and work practice control requirements of [8 CCR 5193\(d\)\(3\)\(A\)](#) through [\(d\)\(3\)\(E\)](#), and the recordkeeping requirements of [8 CCR 5193\(h\)\(3\)](#).

c. Medical sharps usage issues must also be fully addressed by the employer's procedures for complying with more general [8 CCR 5193](#) requirements, e.g., the information and training requirements of [8 CCR 5193\(g\)](#), which may not mention sharps specifically, but necessarily require their full consideration.

## 2. Evaluation of Engineering Controls

### a. Use of Engineering Controls

Compliance personnel shall determine whether the employer has implemented the use of engineering controls under [8 CCR 5193\(d\)\(3\)\(A\)](#) according to the following criteria:

#### (1) Needleless Systems

The employer must select and use a needleless system, when one exists in the marketplace, for a given medical procedure, unless one of the Exceptions to [8 CCR 5193\(d\)\(3\)\(A\)](#) applies.

#### (2) Needle Devices and Other Sharps with ESIP

(a) Where needleless systems are not used, employers are required to select and use needle devices with ESIP.

NOTE: Employers are also generally required to use non-needle sharps with ESIP.

(b) What constitutes a qualifying sharp with ESIP is governed by the definition of ESIP, which requires that the anti-stick properties be "built into" the device, and that the device be "effective" in reducing sharps related exposure incidents arising from use of the device.

(c) If a citation is to be issued pursuant to [8 CCR 5193\(d\)\(3\)\(A\)](#), it is the Division's burden to show that the employer is not using a qualifying sharp. The non-mandatory Device Checklist in Appendix 1 can be used by the compliance officer to help determine if ESIP is required for each type sharp being used. Special care in gathering and evaluating evidence must be exercised in the following situations:

i. The employer is using a device that purports to have ESIP, but the effectiveness of the device appears to be questionable, either because other currently available devices clearly provide superior protection or because of flaws inherent in the design or physical properties of the device chosen by the employer.

ii. The employer is using a device equipped with an "add-on" anti-stick protection feature, which was installed at some time after the original manufacture of the device.

iii. The employer claims in good faith that there are no devices in existence that meet the effectiveness test of the definition.

In situations such as these, the evidentiary issues presented shall be evaluated by consultation with their District Manager and/or Regional Senior Industrial Hygienist.

#### b. Exceptions to the Use of Engineering Controls

Where an employer is not using qualifying devices under circumstances that justify issuance of a citation if the exceptions to [8 CCR 5193\(d\)\(3\)\(A\)](#) do not apply, compliance personnel shall request that the employer provide information about, and demonstrate how, at least one of the exceptions applies:

##### (1) Exception One -- Market Availability

This exception applies if a required [8 CCR 5193\(d\)\(3\)\(A\)](#) engineering control is not available for purchase by the employer in the marketplace.

NOTE ONE: Where a particular device is not available through an employer's group buying program, but is otherwise available in the market, the market availability exception does not apply.

NOTE TWO: Where the employer can demonstrate that a device is temporarily unavailable due to factors beyond the employer's control, the market availability exception will apply while the device and acceptable substitutes are not available. However, the employer must demonstrate through credible documentation that a good-faith effort has been made to obtain the device and whatever suitable substitutes are available in the market.

### (2) Exception Two -- Patient Safety

This exception applies if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgment, that use of the device with ESIP will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient.

NOTE ONE: An employer may establish criteria for classes of patients that will not be treated using a specific type of device. However, as required by [8 CCR 5193\(c\)\(1\)\(B\)7.](#), there must be documentation that application of the criteria to any particular patient is decided upon by a licensed healthcare professional directly involved in providing the patient's care.

NOTE TWO: The fact that use of a device may require modification of a medical procedure does not necessarily mean that patient care or safety will be compromised.

### (3) Exception 3 -- Safety Performance

This exception applies if the employer can demonstrate by means of objective product evaluation criteria that the device with ESIP is not more effective in preventing exposure incidents than the alternative used by the employer.

NOTE ONE: The basis for the employer's determination may include, but is not limited to, studies providing data on the device's performance and evaluations made by research entities that have no economic relationship with manufacturers. Data from credible efficacy studies about needle devices are available from sources such as the U.S. Public Health Service (Centers for Disease Control) or private entities, such as Exposure Prevention Information

Network (EPINET) (contact: (804) 982-0702) or ECRI (contact: <http://www.ecri.org>).

NOTE TWO: If a study is carried out by the employer, compliance personnel should review the study and its validity with the assistance of the Division's Research and Standards Unit.

#### (4) Exception 4 -- Availability of Safety Performance Information

This exception applies if an employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining, by objective product evaluation criteria, whether use of the device will reduce the risk of exposure incidents in the employer's workplace.

NOTE: The effort required by the employer to keep abreast of new information will depend on the employer's size and sophistication. For small healthcare and dental offices, it will generally be sufficient if they rely on peer organizations, academic studies, and professional journals to track currently available information on devices. Larger, more sophisticated employers will be required to make more direct efforts to evaluate devices. The employer's approach to this issue must be reflected in the ECP pursuant to [8 CCR 5193\(c\)\(1\)\(B\)5. and 6.](#)

### 3. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-Up

a. Compliance personnel shall closely evaluate exposure incidents to determine if the employer has complied with [5193](#) requirements pertaining to post-exposure evaluation and follow-up:

(1) Did the employer make immediately available a confidential medical evaluation consisting of the required elements (see [8 CCR 5193\(f\)\(3\)\(A\) through \(E\)](#))?

(2) Did the employer provide the evaluating health professional the required information (see [8 CCR 5193\(f\)\(4\)](#))?

(3) Did the employer provide the employee with a copy of the healthcare professional's written opinion within 15 days of the completion of the evaluation (see [8 CCR 5193\(f\)\(5\)](#))?

b. When conducting an investigation of an employer's compliance with the requirements of [8 CCR 5193\(f\)\(3\) through \(6\)](#), compliance personnel should consult with the Medical Unit to determine the best approach to obtaining the necessary medical information.

## F. CITATION POLICY

### 1. Issuance

Compliance personnel shall issue a citation for each violation of section [8 CCR 5193](#) found during an investigation.

### 2. Serious Classification

a. Violations shall be classified as serious when the evidence reveals that an exposure to blood or OPIM may be reasonably anticipated, and such exposure has a substantial probability of causing death or serious physical harm. See [P&P C-1B, Attachment F](#), NOTES 6 and 10 for additional guidance.

NOTE: The Division believes that it does not have to prove (e.g., by laboratory testing) that the blood or OPIM to which an employee was exposed was actually contaminated with a specific bloodborne pathogen to prove a serious violation of [8 CCR 5193](#).

b. Serious violations generally include any substantial failure to utilize engineering controls, work practice controls, or personal protective equipment. Violations based on failure to provide training or information or failure to provide adequate training or information to employees shall be classified as general or serious depending on how directly the violation is related to the potential for serious exposure.

EXAMPLE: Failure to train an employee on the proper use of a sharp with ESIP that depends on training for its safe operation shall be classified as serious.

c. When a citation that alleges a serious violation of [8 CCR 5193](#) subsections (d)(3), (e) and (f) are contested by the employer, the district manager shall consult with the Legal Unit to determine if legal representation is necessary.

NOTE: In some cases involving citations alleging a serious violation of subsections (d)(3), Engineering and Work Practice Controls; (e), HIV, HBV and HCV Research Laboratories and Production Facilities; and (f), Hepatitis B

Vaccination and Post-Exposure Evaluation and Follow-up, Legal Unit representation is required.

### 3. Non-Serious Classification

Other violations shall generally be classified as general or regulatory, unless the specific circumstances of the violation indicate a direct linkage between the violation and a resulting serious exposure hazard.

### G. Forms Distribution for BSHIP inspections

Following the issuance of citations or form 1AX, the district manager shall ensure that copies of citations or form 1AX, and the Outcome Measures Report are sent to the BSHIP coordinator. A copy of the Outcome Measures Report shall also be sent to the Deputy Chief for Enforcement.

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