
Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report



This document provides guidance for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel.

An NCCLS report for national application.



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Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report

Abstract

NCCLS document X3-R—*Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report* was written for use by laboratory managers and is intended to provide a systematic approach for implementing the requirements of the *Revised OSHA Bloodborne Pathogen Standard*, a U.S. federal regulation. Written in an expanded checklist format, it outlines the important steps laboratory professionals must take in identifying devices that have the potential for causing injury, selecting safer medical devices for evaluation, evaluating the selected devices, adopting the new device for routine use, and implementing a continuous quality improvement process. While this document will serve as a useful resource for a wider audience, it is based on U.S. regulations, and is intended for use primarily in the United States.

NCCLS. *Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report*. NCCLS document X3-R (ISBN 1-56238-460-0). NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

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Foreword

This document, developed as a report, was initiated in direct response to a need expressed by NCCLS constituencies. As defined in the Administrative Procedures, a report is a document that does not undergo consensus review and is published upon approval by the Board of Directors. It allows for an expedited review, with the purpose of getting the needed information out as quickly as possible, while not sacrificing quality or important review. Because healthcare institutions are required to implement the provisions of the *Revised OSHA Bloodborne Pathogen Standard* in a short period of time, an expedited process was desirable.

Implementing a sharps prevention program is the responsibility of the institution whose workers may be at risk for exposure to blood or other potentially infectious materials. But it is clear that the laboratory has specific needs relative to identifying, evaluating, and adopting safer medical devices. The working group's goal was to outline a process that goes beyond general recommendations for the healthcare institution and specifically addresses the needs of the professionals performing specimen collection and clinical laboratory procedures.

Use this report as a checklist, checking off each box as you have addressed the issue.

The working group welcomes comments on the utility of *Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory*.

Standard Precautions

Because it is often impossible to know what might be infectious, all human blood specimens are to be treated as infectious and handled according to "standard precautions." Standard precautions are new guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of any pathogen and thus are more comprehensive than universal precautions which are intended to apply only to transmission of bloodborne pathogens. Standard precaution and universal precaution guidelines are available from the U.S. Centers for Disease Control and Prevention (*Guideline for Isolation Precautions in Hospitals*. Infection Control and Hospital Epidemiology. CDC. 1996;Vol 17;1:53-80), (MMWR 1987;36[suppl 2S]2S-18S), and (MMWR 1988;37:377-382, 387-388). For specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials and for recommendations for the management of blood-borne exposure, refer to the most current edition of NCCLS document [M29](#)—*Protection of Laboratory Workers from Occupationally Acquired Infections*.

Key Words

Evaluation, needlestick, safer medical devices, sharps

I. Introduction

In 1991, the Occupational Safety and Health Administration (OSHA) published the *Bloodborne Pathogens Standard* (29 CFR 1930.1030) to reduce the health risk to workers whose duties involve exposure to blood or other potentially infectious materials. The provisions of the standard were based on OSHA's determination that a combination of engineering and work practice controls, personal protective equipment, training medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission. To address the provisions of the standard, each institution was required to develop and implement an *Exposure Control Plan*. Such plans have guided compliant institutions for the last ten years.

Since the publication of the standard, a wide variety of medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. In late 2000, Congress passed the *Federal Needlestick Safety and Prevention Act* (Public Law 104-439) that authorized OSHA to revise the *Bloodborne Pathogens Standard* to strengthen the identification, evaluation, documentation, and use of safety engineered sharp devices. (Luebbert, *advance/LABORATORY*, March 2001) Healthcare facilities whose workers are subject to potential exposure to bloodborne pathogens are covered under the *Bloodborne Pathogen Standard* and subject to this final rule. There are several requirements outlined in the rule, including:

- Modifying definitions related to engineering controls;
- Updating the *Exposure Control Plan* to include specified requirements;
- Soliciting employee input for the purpose of identifying safer medical devices and evaluating their effectiveness; and
- Maintaining a detailed log and database of exposures to bloodborne pathogens related to needlestick and other sharps injuries.

The intent of the *Revised OSHA Bloodborne Pathogen Standard* is to minimize the risk of exposure to bloodborne pathogens by implementing safer medical devices that reduce or eliminate sharps injuries to healthcare workers.

This guide will aid institutions in implementing the requirements and analyzing and improving practices, with the goal of providing a safer work environment. The clinical laboratory plays an important role in a sharps injury prevention program. Though some steps may be the responsibility of the institution, it is vital that the clinical laboratory actively participates and leads the organization in implementing the steps relative to assessing the clinical laboratory's devices and procedures.

II. Scope

This guide provides direction for implementing the requirements of the *Revised OSHA Bloodborne Pathogen Standard*. It is limited to devices related to specimen collection and clinical laboratory testing. It will provide guidance for medical centers and hospitals, as well as for reference and physician office laboratories.



While it is well understood that sharps such as needles are responsible for many injuries, it is very important to understand that, in the clinical laboratory, there are other devices that have the potential of causing injury. Though not an inclusive list, devices that have the potential for causing injury include:

- phlebotomy needles
- syringe needles used in the laboratory and used for drawing blood
- winged blood collection sets
- glass capillary tubes
- glass blood collection tubes
- glass test tubes
- glass pipettes
- glass slides
- instrument probes
- scalpels used in the laboratory
- lancets
- microtome blades.

III. *Glossary*^a

Active safety device, *n* - A device requiring a user to take action to actively engage the safety feature to ensure its proper function.

Bloodborne pathogens, *n* - Pathogenic microorganisms that are present in human blood and can cause disease in humans; **NOTE:** These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Contaminated, *adj* - The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated sharps, *n* - Any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Engineering controls, *n* - Controls that isolate, minimize, or remove the bloodborne pathogens hazard from the workplace; **NOTE:** That is, safer medical devices, such as sharps with engineered sharps injury protection and needleless systems as well as other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Examples include blunt suture needles and plastic or mylar-wrapped glass capillary tubes, as well as controls that are not medical devices, such as sharps disposal containers and biosafety cabinets.

^a Some of these definitions are found in NCCLS document NRSL8—*Terminology and Definitions for Use in NCCLS Documents*. For complete definitions and detailed source information, please refer to the most current edition of that document.

Exposure control plan (ECP), *n* - A written plan required by OSHA that identifies those tasks and procedures in which occupational exposure may occur and that identifies the positions whose duties include those tasks and procedures identified as having occupational exposure; **NOTE:** The ECP requires the employer to identify the individuals who will receive the training, protective equipment, vaccination, and other protections of the standard. The plan must be reviewed and updated at least annually.

Exposure incident, *n* - A specific eye, mouth, other mucous membrane, nonintact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Laboratory, *n* - A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body.

Needleless system, *n* - A device that does not use needles for: i) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; ii) the administration of medication or fluids; or iii) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational exposure, *n* - 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. **NOTE:** "Reasonably anticipated" includes the potential for accidental exposure.

Passive safety device, *n* - A device that incorporates a safety mechanism that does not rely on the worker to activate it and is in effect throughout the use of the device.

Sharps with engineered sharps injury protection, *n* - A nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Work practice controls, *n* - Controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

IV. *Updating the Exposure Control Plan*

Since 1991, every institution whose workers are subject to potential exposure to bloodborne pathogens is required to have an *Exposure Control Plan*. (For more information regarding this *Exposure Control Plan*, see the *Compliance Directive for the Bloodborne Pathogens Standard* (29 CFR 1930.1030). **While the responsibility for updating the plan may rest with someone outside of the clinical laboratory (e.g., institutional safety officer), it is**

important to understand the requirements relative to the plan and how it impacts on establishing a sharps injury prevention program in the laboratory.

To meet the requirements of the *Needlestick and Other Sharps Injuries; Final Rule*, the *Exposure Control Plan* must incorporate the following revisions (check them off as you complete them):

- Two new definitions:
 - Needleless System: *a device that does not use needles for: (a) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (b) the administration of medication or fluids; or (c) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.*
 - Sharps with Engineered Sharps Injury Protections: *a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.*
- An expanded definition for:
 - Engineering Controls: *Controls that isolate or remove the bloodborne pathogens hazard from the workplace (i.e., safer medical devices, such as sharps with engineered sharps injury protections and needleless systems as well as other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Examples include blunt suture needles and plastic or mylar-wrapped glass capillary tubes, as well as controls that are not medical devices, such as sharps disposal containers and biosafety cabinets.)*
- Identification of the ways in which employers implement new requirements that reflect changes in technology to eliminate or reduce exposure to bloodborne pathogens.
- A process for soliciting input from nonmanagerial employees (who potentially are exposed to injuries from contaminated sharps) responsible for direct patient care in the identification, evaluation, and selection of effective engineering and work practice controls, as well as a process for documenting this input.

Employee input can include:

- involvement in informal problem-solving groups;
- participation in safety audits, worksite inspections, or exposure incident investigations;
- participation in analysis of exposure incident data or in job or process hazard analysis;
- participation in the evaluation of devices through pilot testing; and

- involvement in a safety and health committee properly constituted and operated in conformance with the National Labor Relations Act.
- Documentation of ongoing consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure by:
 - describing safer devices identified as candidates for adoption;
 - the method or methods used to evaluate devices and the results of evaluation; and
 - justification for selection decisions.
- Establishment and maintenance of a sharps injury log for recording percutaneous injuries from contaminated sharps.* The information recorded must protect the confidentiality of the injured employee and contain, at a minimum:
 - type and brand of device involved in the incident;
 - department or work area where the exposure incident occurred; and
 - explanation of how the exposure incident occurred.

*The Exposure Prevention Information Network (EPINet) was developed by Janine Jagger, M.P.H., Ph.D., and colleagues to provide standardized methods for recording percutaneous injuries and blood and body fluid contacts, in order to assist hospitals in complying with the OSHA recordkeeping requirements of the 2001 revised *Bloodborne Pathogens Standard*. Hospitals can use the EPINet system to compare and share information and identify successful prevention measures. The EPINet system includes a Uniform Needlestick and Sharp Object Injury Report and a Uniform Blood and Body Fluid Exposure Report, as well as software for entering, accessing, and analyzing the data from the forms. EPINet provides specific identification of the devices and products associated with exposures and the mechanisms by which the exposures occurred. This information allows hospitals to target high-risk devices and products and to evaluate the efficacy of new technology designed to prevent needlesticks and other exposures. Since its introduction in 1992, more than 1,500 hospitals in the U.S. have acquired it for use; it has also been adopted in other countries, including Canada, Italy, Australia, Spain, Japan, and Brazil. For further information about EPINet, call (434) 982-0702.

V. *Implementing a Sharps Injury Prevention Program*

The laboratory needs to be very proactive to ensure the needs of the clinical laboratory personnel are being met in the implementation of the sharps injury prevention program. This is especially important in large institutions, where the devices that cause the most injuries are associated with patient care.

The following outlines the steps for implementing a Sharps Injury Prevention Program. Be sure to document the actions taken to implement each step.

A. *Establish a Multidisciplinary Team*

An institution's success in implementing a coordinated sharps injury prevention program is dependent upon involving all of the affected parties and ensuring their input in the process. It is recommended that a multidisciplinary team should be formed to serve as a



sharps injury prevention task force. The objective of the team is to develop and implement a plan to strengthen the identification, evaluation, documentation, and use of safety engineered sharps devices. Generally, the team is composed of representatives from all departments, such as:

- Employee or occupational health management
- Housekeeping
- Infection control
- Laboratory
- Nursing
- Pharmacy
- Purchasing
- Quality management
- Respiratory therapy
- Risk management
- Waste management

The laboratory should form its own task group to identify sharps-injury issues and provide feedback to the multidisciplinary team through the laboratory's representatives. (This is especially important for free-standing laboratory facilities). The task group could include:

- **Chief pathologists (anatomical and clinical)**
- **Laboratory manager**
- **Section manager(s)**
- **Staff technologist(s)**
- **Infection control director**
- **Phlebotomy supervisor**
- **Phlebotomist(s)**
- **Respiratory services manager**
- **Respiratory therapist(s)**

Major responsibilities of the team are to:

- Develop an implementation plan for soliciting employee input, defining criteria for device evaluation, conducting evaluations, adopting new devices and work practice controls, and continuous improvement;
- Perform an internal review to identify devices or practices that have the potential for sharps injury;
- Establish task groups as appropriate to implement the sharps-injury prevention plan; and
- Review and revise the *Exposure Control Plan* at least annually.

B. Perform an Internal Review

The purpose of the internal review is to determine if there are areas that require immediate action to reduce the potential for sharps injury. There are two major components to the internal review:

- Log/database that is the official record of all injuries/exposures:

The intent of the review of the log of injuries/exposures is to identify any patterns that point to a specific device or practice that bears further review and evaluation. Devices that consistently have contributed to injury should be considered a priority for device evaluation.

- Devices that have the potential for causing injury ([see Section II](#)):

The intent of the review of devices that have the potential for causing injury is a prophylactic measure, i.e., to review potential hazards and prevent injury before it happens. *Input must be solicited from nonmanagerial (front-line) healthcare workers.* The front-line healthcare workers are in the best position to provide practical information.

The following steps should be taken in conducting the internal assessment. Check them off as you complete them.

- Review/analyze the injury/exposure database:

This review assumes that the institution has been logging injury/exposure incidents. It should be conducted by the multidisciplinary team and nonmanagerial employees.

- Solicit input from employees responsible for obtaining specimens and/or performing clinical laboratory test procedures.

Input may be solicited via:

- written surveys
- personal interviews
- focus groups
- informal problem-solving groups
- hospital committee reports.

The following questions could be asked to help solicit input relative to laboratory devices:

What are the hazards for sharps injury in pathology, hematology, microbiology, etc.?

How do the injuries occur?

What prevention strategies are currently being used?



- Assess the availability and use of safer medical devices in the facility.
- Prioritize devices and/or processes that should be changed to reduce the potential for sharps injury.

Prioritization is based on analysis of the institution's history of sharps injuries (i.e., through review of the database), employee input, and risk assessment.

Risk is based on:

- frequency of use (i.e., number of procedures performed on a daily basis using a device);
 - potential for transmission (e.g., a large-bore needle that contains blood has a high potential);
 - device-specific injury rate (based on review of injury database); and
 - occupation-specific injury rate.
- Develop an implementation plan and timeline for the identified devices and/or work practices.

An implementation plan should specify whether the intent is to select a new device or to change work practices.

C. Select Devices for Evaluation

The laboratory representatives should be very proactive in identifying the need for safer medical devices and requesting evaluation of devices that may address the need. Because much emphasis is placed on engineered devices, devices such as cut-resistant gloves, which are especially important for autopsy and pathology, may be overlooked.

Because of the resources required to evaluate devices, careful consideration should be given to identifying options and selecting candidate devices. The following process steps should be used in device selection. Check them off as you complete them.

- Develop device criteria that will aid in selecting devices for evaluation. The criteria should be based on:
 - the primary use of the device;
 - clinical needs;
 - the desired safety goals (i.e., eliminate the hazard or reduce the risk);
 - desired safety design features (i.e., active safety device; passive safety device); and

- previously developed criteria (e.g., as included in the OSHA document, *Safer Needle Devices: Protecting Health Care Workers*).
- Research options via:
 - review of current literature;
 - website search;
 - networking with colleagues; and
 - review of vendor products.
- Screen identified devices to determine priority for hands-on evaluation.

Once you have identified options and collected information, the next step is to subject potential devices to a screening process designed to identify the top priorities for hands-on evaluation.

The following questions may be used in screening:

- If the device is an active safety device, does the safety mechanism have to be employed to use the device?
 - Is the device reasonably easy to use?
 - Is there information from the manufacturer on the device's effect on test results?
 - Is there a full array of products (e.g., sizes) available?
 - Is the vendor willing to train all staff on all shifts assigned to evaluate the device?
 - Will the vendor be available for all shifts during the evaluation?
 - Does the device meet the identified clinical goals and performance goals without compromising patient safety?
- Select devices for hands-on evaluation.

The multidisciplinary team should recommend which devices should undergo a full evaluation. It is important that there is team buy-in, because the evaluation will likely affect several departments and work processes.

D. Evaluating Selected Devices

Evaluation must be viewed from the dual perspective of patient care and healthcare-worker safety. The evaluation should involve nonmanagerial front-line workers who routinely perform the procedure using the device. The evaluation may be relatively informal, such as front-line workers getting together to evaluate a selected device, or the



evaluation may follow a more formalized process. In either case, documentation of devices reviewed, persons involved in the review, and the reason the selection was made is required.

When possible, a formalized process should be followed. The following process is recommended (check them off as you complete them):

- Determine length of time the device(s) will be evaluated.

The length of time required will be based on the complexity of the device, the similarity to the product being replaced, and frequency of use. If the learning curve is long, sufficient time must be allowed to overcome any learning bias.

- Determine which services, areas/departments will be affected, directly or indirectly, by the use of a new device(s).
- Identify staff to evaluate the device(s).

Staff from each department which may adopt the device should be included. It is very important to choose staff that routinely perform the procedure to evaluate the device. Staff should be selected based on the frequency that they perform the procedure. Be sure to communicate to the staff your support and appreciation for the evaluation.

- Train staff on device(s) to be evaluated.

Staff should understand both the purpose of the clinical evaluation system and each step of the process. Without adequate training for staff performing the evaluation, the process is likely to fail. The vendor must be fundamentally involved in the training and be on call when problems arise. Remember to provide training for staff across all shifts.

- Conduct the evaluation according to defined protocol and collect data.

Whenever possible, remove the old device and replace it with the device to be tested. This avoids having “choice” as a variable that can influence the evaluation outcome.

This step should be undertaken using well-developed forms or models. Use a form designed to measure staff opinion about a device. [See *The Training for Development of Innovative Control Technologies Project* website (www.tdict.org) for sample forms.] A well-constructed evaluation tool should avoid bias, be easy to complete and score, and should reflect the performance criteria established for each device. A numeric scoring system allows quantitative analysis of data and comparisons among subsets of the users, which may reveal issues that were not previously identified. The tool should include questions regarding:

- ease of use;
- activation and reliability of the safety feature (if applicable);

- impact on technique or procedure;
 - duration of the learning curve;
 - compatibility with other equipment/instrumentation; and
 - observed impact on patient care.
- Objectively assess the data.

Final selection factors include assessment of:

- the impact the device has on patients;
- confirmed compliance of use of the device (e.g., through observation, survey of users);
- acceptance by clinical staff;
- potential for reduction of risk of sharps injury, as well as for meeting safety goals; and
- cost effectiveness when compared to other prevention options.

A review of the data should elicit information regarding impact on patients, hazard reduction, and acceptance by staff. In determining the cost effectiveness of a safety device, the incremental cost of implementing the new device and the cost savings achieved by reducing injuries must be taken into account.

Important considerations relative to clinical laboratory testing include:

- **Are the results of laboratory tests altered?**
- **Are there manufacturer data available regarding the effects on performance or results?**
- **Is the device under consideration compatible with current instrumentation?**

It is up to the multidisciplinary team to determine if an evaluated device is appropriate and effective. According to the *Bloodborne Pathogens Standard*:

- An **appropriate** safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated;
- An **effective** safer medical device is a device that, based on reasonable judgment, will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used.



If the team endorses adoption of the device, either institution-wide or in specific departments, a step-wise approach to implementing the new device is necessary.

If no appropriate device is found to meet your goal of reducing sharps injury related to a particular device, work practice controls that minimize risk must be instituted until a safer medical device can be found.

E. Adopt the New Device for Routine Use

Once a new device is selected using the approach in Part D, plan to implement its use. Check off the steps as you complete them.

- Develop an implementation plan and timeline for putting the new device into operation.

The plan should designate the phase-in process, such as department-by-department or simultaneously across the institution (if appropriate). If there are affiliate institutions, be sure to include implementation in the affiliates in your plan.

If the new device has the potential for affecting laboratory results, method comparison studies and verification of reference ranges may be necessary and should be included in the implementation plan (see NCCLS Resources).

- Empower a staff member with the responsibility of overseeing the implementation.
- Communicate the change “upfront” to all affected departments and staff.
- Develop and implement a training program for staff across all shifts.

To ensure compliance to the change, it is necessary to make sure staff understands that they are at risk using the old device and it is to their benefit to use the safer device, even if there is a learning curve involved.

- Develop a procedure for removing all old devices and replacing them with the new device.
- Revise all appropriate procedures, make sure the procedure manual is updated, and communicate the changes to the staff.

If the change has resulted in a new reference range for a particular clinical laboratory test(s), be sure to notify physicians of the change.

- Incorporate device performance in appropriate staff competency evaluation programs (to ensure that individual staff members are using the device appropriately).
- Update training program for engineering and work practice controls.
- Update the *Exposure Control Plan* to indicate implementation of a new engineering control.

- Congratulate staff and celebrate the success of selecting, evaluating, and adopting a new safety device.

F. Implementing a Continuous Quality Improvement Process

Continuous quality improvement involves not only resolving problems that need immediate attention, but also seeking opportunities for improvement where no problems currently exist. In the latter case, improvement will minimize cost, waste, and injury; enhance resource and process management; and facilitate patient, healthcare worker, and institutional satisfaction in a preventive, anticipatory manner. A continuous quality improvement process is essential in an ongoing sharps injury prevention program and involves a systematic, total management approach that facilitates ongoing improvement as evidenced by enhanced satisfaction. Check off each of these items as you complete them.

- Evaluate work practices on a continuous, systematic basis.
- Continually monitor the use of the newly implemented devices.
- Measure the satisfaction of patients and healthcare workers.
- Train staff on safety and the importance of sharps injury prevention, and verify the training on a regular basis.
- Establish and monitor adherence to procedures for the timely reporting and postexposure evaluation of all sharps-related injuries and postexposure prophylaxis when appropriate.
- Establish safety indicators and measure against the indicators.
- Communicate to healthcare workers the success in injury reduction achieved by adopting the new device.
- Continually research safety authorities to remain informed of safety issues.
- Foster a staff attitude that “safety is everyone’s responsibility.”

Bibliography

Chiarello LA. Selection of needlestick prevention devices: a conceptual framework for approaching product evaluation. *Am J Infect Control*. 1995;23:386-395.

Chiarello LA. Designing and implementing an evaluation program. In: Pugliese G, Salahuddin M (eds.). *Sharps injury prevention program: a step-by-step guide*. American Hospital Association; 1999.

Glass Capillary Tubes: Joint Safety Advisory About Potential Risks. National Institute for Occupational Safety and Health, Joint FDA/NIOSH/CDC/OSHA Advisory. February 22, 1999.

NIOSH publication 2001-108. NIOSH Alert: Preventing needlestick injuries in health care settings. U.S. Dept. of Health and Human Services. National Institute for Occupational Safety and Health. November, 1999:1-24. Available at: <http://www.cdc.gov/niosh/2000-108.html>.

Occupational exposure to bloodborne pathogens; final rule. OSHA (29 CFR 1910.1030). Federal Register 56:64003-182; December 6, 1991.

Pugliese G, Salahuddin M (eds.). *Sharps injury prevention program: a step-by-step guide*. American Hospital Association; 1999.

NCCLS Resources

A Quality System Model for Health Care; Approved Guideline. NCCLS document GP26-A. Wayne, PA: NCCLS; 1999.

Clinical Laboratory Safety; Approved Guideline. NCCLS document GP17-A. Wayne, PA: NCCLS; 1996.

Clinical Laboratory Technical Procedure Manuals; Approved Guideline – Fourth Edition. NCCLS document GP2-A4. Wayne, PA: NCCLS; 2002. (Publication pending.)

Continuous Quality Improvement: Essential Management Approaches; Approved Guideline. NCCLS document GP22-A. Wayne, PA: NCCLS; 1999.

Evacuated Tubes and Additives for Blood Specimen Collection – Fourth Edition; Approved Standard. NCCLS document H1-A4. Wayne, PA: NCCLS; 1996.

Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline. NCCLS document EP5-A. Wayne, PA: NCCLS; 1999.

Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline – Second Edition. NCCLS document EP6-P2. Wayne, PA: NCCLS; 2001.

How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition. NCCLS document C28-A2. Wayne, PA: NCCLS; 2000.

Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline. NCCLS document EP10-A. Wayne, PA: NCCLS; 1998.

Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard – Third Edition. NCCLS document H7-A3. Wayne, PA: NCCLS; 2000.

Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline – Second Edition. NCCLS document M29-A2. Wayne, PA: NCCLS; 2001.

Training Verification for Laboratory Personnel; Approved Guideline. NCCLS document GP21-A. Wayne, PA: NCCLS; 1995.

User Protocol for Evaluation of Qualitative Test Performance; Proposed Guideline. NCCLS document EP12-P. Wayne, PA: NCCLS; 2000.

Useful Websites

CDC/NIOSH Alert

Features information on the CDC/NIOSH Alert “Preventing Needlestick Injuries in Health Care Settings.”

<http://www.cdc.gov/niosh/2000-108.html>

ECRI

This website discusses the June 1998 issue of ECRI’s Health Devices, which evaluated 19 needlestick-prevention devices and provides information for obtaining this document. (Keep in mind that there are new devices on the market since 1998.)

http://healthcare.ecri.org/News_Frameset.htm

International Healthcare Worker Safety Center, University of Virginia

Features a list of safer medical devices with manufacturers and specific product names.

<http://www.hsc.virginia.edu/medcntr/centers/epinet/safetydevice.html>

National Institute for Occupational Safety and Health (NIOSH)

Features information on selecting, evaluating, and using sharps disposal containers.

<http://www.cdc.gov/niosh/sharps1.html>

NCCLS

Features consensus documents that are valuable resources for the medical testing community.

<http://www.nccls.org>

Occupational Safety and Health Administration (OSHA)

Describes safer alternatives to conventional glass capillary tubes.

http://www.osha-slc.gov/OshDoc/Interp_data/I19990222.html

Occupational Safety and Health Administration (OSHA) Needlestick Injuries

Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

<http://www.osha-slc.gov/SLTC/needlestick/index.html>

Sharps Injury Control Program

Established by Senate Bill 2005 to study sharps injuries in hospitals, skilled nursing facilities, and home health agencies in California. Features a Beta version of Safety Enhanced Device Database Listing by Manufacturer.

<http://www.ohb.org/sharps.htm>

Safety Sharp Device Contracts

Features safety sharp devices on contract with the U.S. Department of Veterans Affairs (VA).

<http://www.va.gov/vasafety/osh-issues/needlesafety/safetysharpcontracts.htm>

Training for Development of Innovative Control Technologies (TDICT)

Features a system for promoting safer medical devices.

<http://www.tdict.org>

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