Selecting, Evaluating, and Using Sharps Disposal Containers

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FOREWORD

he Occupational Safety and Health Act of 1970 created the National Institute for Occupational Safety and Health (NIOSH). NIOSH is charged with identifying the causes of work-related diseases and injuries, evaluating the hazards of new technologies and work practices, creating ways to control hazards, and recommending occupational safety and health standards.

Occupational exposure to bloodborne pathogens (including the hepatitis B and C viruses [HBV and HCV] and the human immunodeficiency virus [HIV]) poses a significant risk to workers in the health care industry and related occupations. The primary route of exposure to bloodborne pathogens is accidental percutaneous injury caused by needlesticks (puncturing of the skin by a needle or similar sharp object). In the United States, approximately 800,000 needlestick injuries occur in hospitals annually—an average of one injury every 10 seconds. Studies have shown that many of these injuries occur after a sharp (needle or other sharp object) is used; as many as one-third of all sharps injuries have been reported to have occurred during disposal activities.

This document presents a comprehensive framework for selecting sharps disposal containers and evaluating their efficacy as part of an overall needlestick injury prevention plan. The correct and consistent use of rigid sharps disposal containers in the health care environment has been demonstrated to reduce needlestick injuries. This document reviews the Occupational Safety and Health Administration (OSHA) bloodborne pathogens standard and recommends containers on the basis of a site-specific hazard analysis. The document also establishes criteria and provides tools for evaluating the performance of sharps disposal containers.

No single container type meets the disposal containment needs for every facility, but this document establishes a basis for selecting sharps disposal containers that will decrease the risk of percutaneous sharps injury. Each day, thousands of dedicated men and women in health care and related industries risk their well-being to protect and improve the health of others. We must work together to ensure that their jobs are performed in a safe and healthful environment. This document is a valuable tool and an important part of a comprehensive strategy to reduce injury and illness in health care workers.

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ABSTRACT

ccupational transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) has been well documented. The risk of infection with HIV following one needlestick exposure is approximately 0.3% and ranges from 6% to 30% for HBV and from 5% to 10% for HCV. The passage of the Occupational Safety and Health Administration's (OSHA's) bloodborne pathogens standard (29 CFR 1910.1030) has increased compliance and awareness of prevention strategies. No single sharps disposal container design meets all the disposal containment needs for all health care settings or for an entire hospital. Container selection should be based on a comprehensive site-specific hazard analysis.

The safety performance criteria for sharps disposal containers are divided into four areas. First, containers should remain functional during their entire use. They should be durable, leak resistant, and puncture resistant under all normal environmental conditions. Second, containers must be accessible to workers who use, maintain, or dispose of sharp devices. This criterion includes sufficient number, sufficient container volume, and safe access to the disposal opening on individual containers. Other important factors include convenient placement and (if necessary) portability of containers within the workplace. Third, containers should be visible to the workers who must use them. Container fill status and warning labels are also important visibility criteria. Fourth, container designs should accommodate the user, the facility, and the environment. Although engineering controls such as needleless IV systems and "safety" needles will reduce injuries, proper selection and use of sharps disposal containers are still important. Prevention strategies include implementing engineering controls, using personal protective equipment, training employees, and involving occupational health professionals and workers.

Code of Federal Regulations

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PUBLIC HEALTH SUMMARY

What are the hazards?

Workers in the health care industry and related occupations are at risk of occupational exposure to bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other potentially infectious agents.

How do these hazards occur?

The primary route of occupational exposure to bloodborne pathogens is accidental percutaneous (through the skin) injury. Health care workers handle sharp devices and equipment such as hypodermic and suture needles, intravenous blood collection devices, phlebotomy devices, and scalpels. Of the 800,000 needlestick injuries (NSIs) estimated to occur in the hospital setting annually, the greatest number occur to health care workers with the most involvement in direct patient care. Nursing staff and phlebotomists sustain the highest percentage of reported NSIs.

Hospital NSI studies have shown that many of these injuries occur after the device is used and during disposal activities. As many as one-third of all sharps injuries have been reported to be related to the disposal process. The factors most often related to sharps injuries include the following:

- Inadequate design or inappropriate placement of the sharps disposal container
- · Overfilling of sharps disposal containers
- Inappropriate sharps disposal practices by the user during patient care

How can these hazards be avoided?

The use of safer needle-bearing products, worker education and training, other measures for preventing sharps injuries, and compliance with standard precautions for preventing exposure to bloodborne pathogens should be part of an overall strategy for preventing NSIs.

Important elements of an overall prevention strategy include the following:

- Engineering controls (an example is the use of safer needle-bearing products)
- Organizational controls (examples are the elimination of unnecessary sharps and training in the use of sharps disposal containers)
- Surveillance of NSIs to assess their frequency and circumstances

The routine use of rigid sharps disposal containers in the health care environment has been demonstrated to reduce NSIs. This document presents a framework for selecting disposable and reusable sharps disposal containers and evaluating their efficacy as part of an NSI prevention plan.

Section I (A) of this document addresses four major criteria for evaluating the performance of sharps disposal containers.

- Functionality: Containers should remain functional during their entire usage (i.e., they should be durable, closable, leak resistant on their sides and bottom, and puncture resistant until final disposal).
- Accessibility: Containers should be accessible to workers who use, maintain, or dispose of sharp devices. Convenient placement should also be considered, along with portability of containers within the workplace, if necessary.
- Visibility: The following should be plainly visible to the workers who use the containers: the container, the degree to which it is full, the proper warning labels, and the color coding of the container.
- 4. Accommodation: Containers should be accommodating or convenient for the user and the facility and should be environmentally sound (e.g., free of heavy metals and composed of recycled materials). Accommodation also includes ease of storage, assembly, and operation.

Appendix D contains a questionnaire designed to

evaluate container performance based on these four performance criteria. This questionnaire should help product evaluation committees, facility management, and health care workers select and evaluate sharps disposal containers.

Section II (B) of this document presents requirements of the Occupational Safety and Health Administration (OSHA) and recommendations of the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), concerning sharps disposal container selection and implementation. OSHA's bloodborne pathogens standard is reviewed to establish minimum design performance elements. Recommendations are made for reprocessing reusable sharps disposal containers.

NIOSH recommends selecting a container or combination of containers that are based on a site-specific hazard analysis and have the following components:

- Assessment of workplace hazards (biological, physical, chemical, and radiological containment needs)
- Assessment of size and types of sharps to be disposed of
- Assessment of the volume of sharps to be disposed of at each point of use
- Assessment of frequency of sharps disposal container emptying and mounting bracket servicing by maintenance staff
- Compliance with Federal, State, and local regulations
- · Security requirements
- · Container transport or mobility needs

- Clinician and procedural variability and movement
- Laboratory equipment variability and movement
- Environmental and disposal constraints
- Cost considerations
- Continued evaluation of medical device technology, including ongoing changes in equipment design and barrier materials

Appendix C presents a decision logic outlining appropriate criteria and priorities for selecting a sharps disposal container. This decision logic can be used alone or in conjunction with the performance evaluation questionnaire (Appendix D) to frame the selection process.

Sharps disposal containers that are functional, accessible, secure from patient and visitor tampering (if necessary), visible, and convenient to use will decrease the risk of percutaneous sharps injury. There is no single container type that meets the disposal containment needs for an entire facility. The diversity of health care settings and procedures makes selecting a single container impossible.

Where can I get more information?

The references and related reading list at the end of this document provide a useful inventory of published reports and literature. If you have any questions about obtaining equipment described here, contact your local biohazard safety/waste equipment supplier or call NIOSH.

> 1-800-35-NIOSH (800-356-4674)

SELECTING, EVALUATING, AND USING SHARPS DISPOSAL CONTAINERS

IINTRODUCTION

he Occupational Safety and Health Administration (OSHA) estimates that more than 5.6 million workers in health care and related occupations are at risk of occupational exposure to bloodborne pathogens, including human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), and other potentially infectious agents. Occupational transmission of bloodborne pathogens (including HBV, HCV, and HIV) has been well documented. Ongoing surveillance of needlestick injuries (NSIs) and other sharps-related injuries indicate that occupational bloodborne pathogen exposure remains an important public health concern.

The primary route of occupational exposure to bloodborne pathogens is percutaneous injury (i.e., NSI). Health care workers (HCWs) handle sharp devices and equipment such as hypodermic and suture needles, intravenous blood collection devices, phlebotomy devices, and scalpels.

As many as 800,000 NSIs are estimated to occur in the hospital setting annually. 12,13 However, the true incidence of sharps injuries is unknown because many injuries go unreported in both health care and public safety settings. Centers for Disease Control and Prevention (CDC) studies have estimated that the rate of seroconversion following occupational parenteral exposure to infected blood approximately 6% to 30% for HBV exposures, 5% to 10% for HCV exposures, 3-5 and 0.3% for HIV exposures. 9,14 Other CDC surveillance data on NSIs indicate that 86% of reported occupational HIV exposures result from hollow-bore needles.14

NSIs occur most often to HCWs with the greatest involvement in direct patient care. Nursing staff and phlebotomists sustain the highest percentage of reported injuries. ¹⁵⁻²⁰ Other HCWs are at risk of injury from specific types of sharps—for example, surgeons (scalpels and suture needles), dental workers (dental burs), and housekeepers and laundry workers (discarded or lost needles in waste and laundry). The use of safer needle-bearing products and other measures

for preventing sharps injuries should be part of an overall strategy to prevent NSIs.^{21,22} Compliance with standard precautions for prevention of exposure to bloodborne pathogens should be part of this overall strategy.²³ Moreover, surveillance of NSIs is an integral part of sharps injury prevention and control. Accurate assessment of the frequency and circumstances of these injuries is necessary to direct prevention efforts.

Hospital NSI studies have shown that many of these injuries occur after the device is used and during disposal activities. ^{15,16,24} As many as one-third of all sharps injuries have been estimated to be related to the disposal process. These injuries have most often been related to a number of factors, including inappropriate sharps disposal practices by the user, inadequate sharps disposal container design, inappropriate sharps disposal container placement,* and overfilling of sharps disposal containers.

The correct and consistent use of rigid sharps disposal containers in the health care environment has been demonstrated to reduce the number of NSIs.²⁵ Studies indicate that placement of disposal boxes in all patient and treatment rooms decreases the frequency of sharps injury.^{15,16,18,25} Investigators have concluded that appropriately placed sharps disposal containers reduce NSIs related to recapping of sharps by as much as 80%. ¹⁸ Cost-benefit studies show that when the increased costs of materials management are compared with the decrease in injury compensation costs, sharps disposal containers are cost effective—even when both direct and indirect costs (medical evaluation and followup, treatment costs, and lost workdays) of injury reduction are considered.²⁴

In addition to engineering controls such as the use of rigid sharps disposal containers, organizational controls are a vital part of an overall prevention strategy. These include the elimination of unnecessary sharps, changes in device-handling procedures, worker education and training, and placement of sharps disposal containers where sharps are used.

See Appendix F for an OSHA hazard information bulletin regarding sharps disposal containers with needle removal features.

The purpose of this document is to provide a framework for selecting sharps disposal containers and evaluating their efficacy as part of an overall NSI prevention plan. Both disposable and reusable sharps disposal containers are included. The plan is intended for use by infection control practitioners, purchasers, and others who are responsible for the selection process.

II—SHARPS DISPOSAL CONTAINERS

A. Performance Criteria

ocus group studies (Appendix A) suggest that there are four major criteria for sharps disposal container safety performance: functionality, accessibility, visibility, and accommodation. More detailed descriptions of these criteria follow:

- Functionality: Containers should remain functional during their entire usage. They should be durable, closable, leak resistant on their sides and bottoms, and puncture resistant until final disposal. A sufficient number of sharps disposal containers should be provided. Individual containers should have adequate volume and safe access to the disposal opening (inlet).
- Accessibility: Containers should be accessible to workers who use, maintain, or dispose of sharp devices. Containers should be conveniently placed and (if necessary) portable within the workplace.
- Visibility: Containers should be plainly visible to the workers who use them. Workers should be able to see the degree to which the container is full, proper warning labels, and color coding.
- Accommodation: Container designs should be accommodating or convenient for the user and the facility, and they should be environmentally sound (e.g., free of heavy metals and composed of recycled materials). Accommodation also includes ease of storage and assembly and simplicity of operation.

1. Functional criteria

Sharps disposal containers should be of sufficient

thickness or construction design to be durable, leak resistant, and puncture resistant under normal use and stresses imposed during storage, handling, installation, use, closure, and transport within the user facility before final disposal.*

Durability and puncture resistance should remain unaffected by moderate variation in temperatures during storage and use. † Brackets and locking mechanisms used for installation should also be durable.

Barrier material performance. Sharps disposal container material should be resistant to chemical or liquid permeation or degradation, punctures, tearing, abrasion, and laceration.

Closure mechanisms. Closure mechanisms should be designed to minimize exposure to contents and injury to the hand during engagement of the closure mechanism or during transport within the user facility before final disposal. Once activated, the final closure mechanism of a sharps disposal container should be resistant to manual opening.

Stability. Containers (including those designed to be kicked or wheeled) should be stable when placed on a horizontal surface and when used as described in the product labeling. Some manufacturers provide trays, holders, or enclosures to stabilize their containers in certain applications. The use of these items should also be detailed in the labeling.

Size and shape. Where workers handle sharp devices, a sufficient quantity of sharps disposal containers should be available in the appropriate size and shape. Sharps disposal containers should be of sufficient size to accommodate the largest sharp used at the workstation it serves. Containers should also be shaped to accommodate the partic-

No requirements exist for sharps disposal containers to meet Department of Transportation (DOT) certification for shipping containers. Sharps disposal containers are generally placed within DOTcertified containers before shipping to a final disposal site.

[†] Caution must be exercised when handling sharps disposal containers at extremes of temperature—such as those encountered by home health care providers when transporting sharps disposal containers in their cars. Sharps disposal containers are not typically designed for high- and low-temperature conditions.

ular type of sharp that requires disposal. At a minimum, one sharps disposal container should be provided at each worksite where sharps are predictably generated or located.

Sharps disposal containers should also be of sufficient size to accommodate the volume of sharps typically generated at the site between maintenance operations. Providing sharps disposal containers of sufficient size will minimize the possibility of overfilling the container, which would compromise its safe operation.

Mounting brackets. Mounting brackets for sharps disposal containers should be rugged and provide for ease of servicing and decontamination.

2. Accessibility criteria

Disposal opening or access mechanism. Sharps disposal containers should be designed to permit safe disposal of sharps. They should be simple and easy to operate. The disposal opening should prevent spills of the contents (objects or liquid) while in use in the intended upright position, during the closure and sealing process, and during transportation within the user facility before final disposal. The design should also minimize any catching or snagging of sharps during insertion into the sharps disposal container. The disposal opening should be identifiable and accessible by the user and should facilitate one-handed disposal.

Security may be a concern in some areas of facilities using sharps disposal containers. For instance, to prevent children and others from putting their hands into the containers, the facility should consider selecting containers with guards that prevent hands or fingers from entering the containers. Where safety features are added to restrict child access, these features should not interfere with the worker's vision of the inlet opening. Injury to visitors may also be a problem. Sharps disposal container options that accommodate these concerns should be available within the facility.

Handles. For some designs, handles may facili-

tate safe handling of the sharps disposal container. If present, they should be sufficiently sturdy to avoid breaking when the sharps disposal container is in use or during transportation before final disposal. If handles are present, they should be placed so that the user's hands are not close to the disposal opening when the handles are used, and they should be positioned above the full-fill level.

General location and placement. Proper sharps disposal container location and placement should ensure that containers are readily visible and within easy horizontal reach of the user. Placement of containers should be in compliance with any existing State or local regulations or site-specific certification or accreditation licensing requirements. Where containers are fixed to walls or other permanent sites, the vertical height should allow the worker to view the opening or access of the container.

Sharps disposal containers should be placed with no furniture or other obstacles between the site of use and the container. Injuries may result if sharps disposal containers are located in awkward, unsafe locations. These unsafe locations may force workers to make unnecessary movements while holding a sharp and accessing the container. Placement of the sharps disposal container outside the patient room also increases the possibility of injury. Examples of inappropriate installation include placement in the corners of rooms; on the backs of room doors; under cabinets; on the insides of cabinet doors; under sinks; in areas where people might sit or lie beneath the container; near light switches, room environmental controls, or utility system access ways; near mail boxes; or where the container is subject to impact and dislodgement by pedestrian traffic, moving equipment, gurneys, wheelchairs, or swinging doors. Standard operating procedures and practices should be developed to allow the worker to dispose of the device as soon as possible after use-preferably without needing to put the device down and pick it up again.

Special situations may require innovative sharps disposal container placement and security approaches. Examples of these special situations include pediatric and geriatric wards and mental health or correctional facilities. If necessary, in areas with high patient or visitor traffic, sharps disposal containers should be mounted in a lockable fixture. In the emergency room, sharps disposal containers may need to be mounted on wheels to facilitate the movement of gurneys and monitoring equipment. In some situations, it may be appropriate to mount sharps disposal containers directly on gurneys to facilitate their use. Although some pediatric facilities mount sharps disposal containers high on walls to prevent access by children, such placement should not be so high that it impairs safe access by workers.

Installation height. Installation of a container at an appropriate height for the user may reduce sharps-related injuries. Sharps disposal containers should be placed within arm's reach and below eye level at their point of use. For certain types of permanently fixed, wall-mounted containers, an ergonomically acceptable range of installation height can be calculated (Appendix B). Standard anthropometric tables should be used determine the normal range of human physical variation. Fixture heights are commonly designed to accommodate 95% of the adult population. The following criteria should be used to determine the optimal range for fixed installation height: (1) users should have a clear, unobstructed view of the container inlet opening, (2) the container should be located within arm's reach, and (3) the fixture height should be below the eye level of 95% of adult female workers. These requirements yield an optimal installation range of 56 to 52 inches at a standing workstation, and 42 to 38 inches for a seated workstation. The upper and lower ranges for the installation height are calculated by allowing for the reach behavior of workers. For a complete explanation of installation height, calculating optimal see Appendix B.

Other ergonomic alternatives include (1) using an extension arm on a fixed-height installation at a seated workstation to bring the sharps disposal container closer to the work surface, (2) providing height-adjustable chairs that allow the worker to view the entire top surface of a

container at a seated workstation, and (3) using bracketing and mounting systems designed to allow user adjustment of the container (Appendix B).

3. Visibility criteria

To reduce the chance of percutaneous injury, sharps disposal containers should be visible and recognizable. Safe disposal of sharps requires clear vision of both the sharp device and the container. The disposal opening or access mechanism and current fill status should be visible to the user before sharps are placed in the container.

Sharps disposal containers should carry a hazard warning labeling. Such labels and device colors should imply danger. Either the device color or a warning label should be visible to the user to warn of a potential hazard before sharps are placed in the container. The current fill status of the container should be easily observable by the user before sharps are placed in the container. Sufficient illumination is needed at the container to determine whether any sharp object is protruding from the container or whether the container is grossly soiled at holding points or on opening mechanisms. Container fill status should be obvious under lighting conditions at the installation location. Safety features, security measures, and aesthetics should not distort recognition of the container, fill status, warning labels, or the disposal opening or access.

OSHA's bloodborne pathogens standard [29 CFR 1910.1030, section (g)(1)(I)(C)] contains very specific requirements about the labeling of containers for contaminated sharps: "These labels shall be fluorescent orange or orange-red or predominantly so, with lettering or symbols in a contrasting color." The standard also requires that the biohazard symbol and the word *Biohazard* be displayed; note, however, that "[R]ed bags or red containers may be substituted for labels" in section (g)(1)(I)(E).

4. Accommodation criteria

Sharps disposal container designs should be accommodating to the user, the facility, and the

environment. Accommodation is a measurement. of ease of storage and assembly, minimal worker training requirements, ease of operation, and flexibility in design. Container design should promote one-handed disposal. Design and product finish should minimize sharp surfaces or hazards. Special aesthetic. cross-infection operational, or safety features should not hide or impede free access to the device, the inlet, or the closure process. Users should be able to assemble containers easily, if required. Mounting systems should be safe, durable, stable, cleanable, and (where appropriate) lockable. Placement in and removal from mounting systems should be simple and uncomplicated and should not compromise safety and security. To ensure proper fit and functioning of the container mounting system. mounting systems should be used only for the sharps disposal containers for which they were designed. Modifying mounting systems to accommodate containers for which they were not designed is not a safe or effective practice.

Containers should be designed so that they are simple to use. Manufacturers of sharps disposal containers should provide recommended user training information, which could include the following:

- 1. Assembly instructions
- 2. Safety considerations
- 3. Maintenance criteria for reusable containers
- 4. Optimum storage conditions
- 5. Warranty information
- Decontamination recommendations (for reusable containers and their holders)
- Container retirement considerations (for re-usable containers and their holders)
- 8. Bilingual or multilingual material, where needed
- Sharps disposal container disposal considerations
- Information for periodic in-service retraining, if required

B. Existing Standards

Existing Federal standards for sharps disposal containers are outlined here. Published sources for other standards are listed in Appendix E.

Sharps disposal containers are regulated as class II medical devices by the Food and Drug Administration (FDA) [21 CFR 860.3].* OSHA's bloodborne pathogens standard establishes minimum design performance elements for sharps disposal containers [29 CFR 1910.1030(d)(4)(iii)(A)]. The standard requires that contaminated sharps "be discarded immediately or as soon as feasible in containers that are:

- (i) Closable:
- (ii) Puncture resistant;
- (iii) Leakproof on sides and bottom; and
- (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of the standard."

Paragraph (g)(1)(i)(A) of the standard requires that warning labels "be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport, or ship blood or other potentially infectious materials. . . ."

Paragraph (d)(4)(iii)(A)(2) further states that "during use, containers for contaminated sharps shall be:

- (i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
- (ii) Maintained upright throughout use; and
- (iii) Replaced routinely and not be allowed to overfill."

When containers of contaminated sharps are being

^{*} FDA identifies three classes of medical devices. Class I devices (e.g., tongue depressors) are subject only to general regulatory controls and receive little Agency oversight. Class II devices (e.g., infant incubators) are subject to special controls, such as performance standards, to ensure their safe and effective use. Class III devices (e.g., implantable pacemakers) are generally life-sustaining or life-supporting and are implanted in the body; they present an unreasonable risk of illness or injury.

moved from the area of use, paragraph (d)(4)(iii)(A) (3) requires that they be:

- "(i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping:
- (ii) Placed in a secondary container if leakage is possible. The second container shall be:
 - (A) Closable;
 - (B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping. . . ."

Finally, the standard states in paragraph (d)(4)(iii)(A) (4) that "[R]eusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury."

Since most sharps disposal containers are designed to be autoclavable, steam ports and air spaces between nestable parts are located on the upper portion of containers. Steam ports allow steam to penetrate to the contents of the container during sterilization procedures. These openings may allow fluid leakage or needle-tip protrusion to occur if the container is placed on its side or overturned. The OSHA standard addresses this concern by further requiring that during handling, storage, and shipment, containers be maintained upright throughout their use, routinely replaced, and not overfilled [29 CFR 1910.1030 (d)-(4)(iii)(A)(2)].

C. Recommended Strategy for Selecting and Using Sharps Disposal Containers

The following strategy for selecting and using sharps disposal containers should be implemented as part of an overall NSI prevention plan.

Selection of a container or combination of containers should be based on a site-specific hazard analysis. Components of a site-specific hazard analysis should include the following:

· Assessment of workplace hazards (biological,

- physical, chemical, and radiological hazard containment needs)
- Assessment of size and type of sharps to be disposed of
- Assessment of the volume of sharps to be disposed of at each point of use
- Assessment of the frequency of sharps disposal container emptying and mounting bracket servicing by maintenance staff
- Compliance with Federal, State, and local regulations
- Security requirements
- Container transport or mobility needs
- Clinician and procedural variability and movement
- Laboratory equipment variability and movement
- Environmental and disposal constraints
- Economic considerations
- Continued evaluation of medical device technology, including ongoing changes in equipment design and barrier materials

An individual or a group should be assigned the responsibility for regular monitoring and maintenance of sharps disposal containers. The designee(s) should frequently and routinely monitor fill levels of containers and be responsible for changing containers before they are overfilled.

Each time a reusable sharps disposal container is returned to service after reprocessing, the user facility should confirm that it meets its original performance elements. In addition, reusable sharps disposal containers should be rendered free of infectious organisms and infectious material each time they are reprocessed and before they are returned to service.

A flow chart describing a decision logic for selecting a sharps disposal container is presented in Appendix C (Figure 2).

This decision logic can be used alone or in conjunction with the performance evaluation questionnaire in Appendix D. Based on the four performance criteria, the questionnaire is designed to assign appropriate criteria and priorities to each step and can be used to frame the selection process. The questionnaire should assist product evaluation committees, facility management, and individual

HCWs with proactive sharps disposal container selection and evaluation. Although it is not possible to provide precise guidelines for evaluating questionnaire scores, the lower the score, the better the sharps disposal container (i.e., the highest score would be 44 points and the lowest would be 220 points). A priority or value must be assigned to a criterion on a case-by-case basis. It may be useful to compare the model of sharps disposal container currently in use with the replacement models under consideration by using the questionnaire scoring system.

Before a new sharps disposal container is introduced, worker training should be conducted to address the proper use of sharps disposal containers. All workers who might come into contact with sharps should be included in this training (e.g., maintenance and laundry service staff). Where appropriate, multilingual educational materials should be developed.

For optimal protective value, the sharps disposal container must be readily available, of sufficient size and capacity, replaced when full, and used by workers. No single container type meets the disposal containment needs for an entire facility. The diversity of health care settings and procedures makes selecting a single container impossible.

III—CONCLUDING REMARKS

harps disposal containers that are functional, accessible, secure from patient or visitor tampering (if necessary), visible, and convenient to use will decrease the risk of percutaneous sharps injury. For optimal protective value, the container must be readily available and of sufficient size and capacity. Sharps disposal container use should be part of an institutional process that

- supports surveillance of sharps injury,
- eliminates unnecessary sharps,
- promotes worker education and training in the proper use of sharps disposal containers and safety devices,
- immunizes HCWs at risk of exposure to HBV,
- advocates compliance with standard precautions.

Products that meet all of the performance criteria identified in this document may not exist. To develop and disseminate products that meet these criteria, manufacturers and end users should work together to design and modify containers.

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APPENDIX A-FOCUS GROUP INPUT

IOSH initiated several cooperative agreements to conduct research on sharps disposal containers with the Educational Resource Centers (ERCs) during fiscal years 1992–94. These research agreements provided the environments necessary to study interrelated ergonomic, behavioral, and selection/evaluation variables associated with sharps disposal containers in a variety of health care settings.

Input from focus groups was used to develop this document. Experts or users were recruited to supply information to estimate the likelihood of a situation or event based on their experience. Focus groups were used to obtain user input about sharps disposal container design, safety, and management. Studies conducted by NIOSH ERCs selected health care workers considered at risk of exposure to HIV in a variety of health care settings. The evaluation criteria (identified in the performance evaluation questionnaire of this document) were developed, in part, using focus groups. The use of focus groups provided a rapid and relatively inexpensive measurement tool to identify worker perceptions, beliefs, and attitudes regarding the performance of sharps disposal containers.

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APPENDIX B—DETERMINING SHARPS DISPOSAL CONTAINER INSTALLATION HEIGHT USING STANDARD ERGONOMICS MEASUREMENTS

rchitects, ergonomists, and interior designers use standard anthropometric tables to determine the normal range of human physical variation. Fixture heights (i.e., the distance from the floor to the opening of the sharps disposal container) are commonly designed to accommodate 95% of the adult population. An ergonomically acceptable range for fixed installations (i.e., containers located in permanent, wall-mounted holding brackets) can be calculated to facilitate the reduction of sharps-related injuries and standardize the container height location within the health care facility. HCWs should be able to comfortably view the entire inlet opening of the disposal container, and containers should be located within arm's reach. Neck and eye fatigue is most effectively reduced when objects to be viewed are slightly below eye level (i.e., 0 to 15 degrees below eye level).

Installation heights vary, depending on whether the installation is designed to be a standing workstation or seated workstation. Maximum and minimum heights for both design situations can be calculated by establishing the eyelevel height for each design (standing or sitting), the maximum thumb tip reach (MTTR)* of the target adult female population and the drop in inches based on an angle of 15 degrees. The basic formula is as follows:

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fixture height = (eye-level height) - (tangent 15°)(MTTR)
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However, in observations of workers using fixed, wall-mounted containers, nearly all workers bent their elbows and wrists when approaching sharps disposal containers to dispose of used sharps and actually stood closer to the container rather than extending their arms to their maximum reach. On the basis of these data, the calculation can be enhanced to accommodate actual behavior. The upper and lower ranges for the installation height can be modified by allowing for the reach behavior of workers. Thus the middle 50% distance of the MTTR was used to adjust for human behavior and provide for a more functional installation height range.

If eye level equals 57 inches and the modified MTTR is used,

fixture height = 57 inches – (.2679)(18.7 inches) and fixture height = 57 inches – (.2679)(3.7 inches)

Therefore,

fixture height = 57 inches - 5 inches = 52 inches and fixture height = 57 inches - 1 inch = 56 inches

The optimal installation heights for fixed, wall-mounted sharps disposal containers are

Standing workstation: +,‡

52 to 56 inches above the standing surface of the user (Figure 1)

Seated workstation:5

38 to 42 inches above the floor on which the chair rests

^{*} MTTR, the distance from the tip of the thumb to the shoulder.

All standard measurements were taken from tables contained in J. Panero and M. Zelnick's Human Dimension and Interior Space, 1979, pages 98 and 102.

Standing eye level includes a 1-inch shoe heel thickness and a 56.3-inch eye height.

Seated eye level includes a 0.25-inch clothing thickness, 1-inch chair seat thickness, 14.9-inch popliteal height, and 27.4-inch erect sitting eye height.

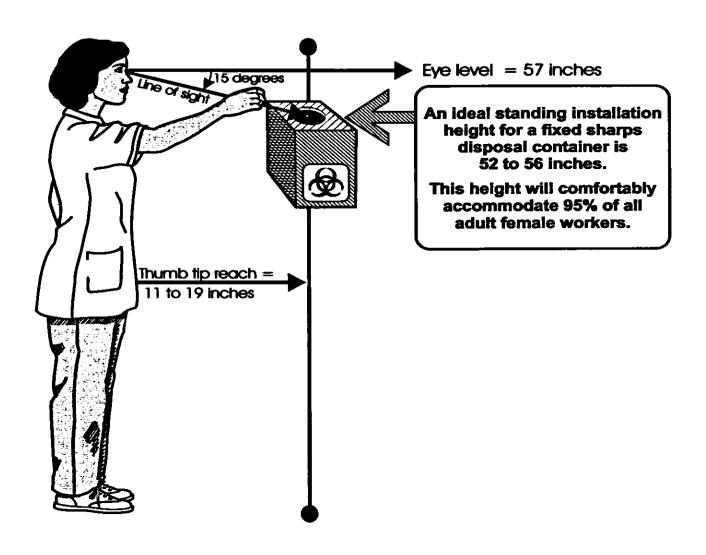


Figure 1. Ergonomic installation height for a wall-mounted work station.

APPENDIX C—DECISION LOGIC FOR SELECTING SHARPS DISPOSAL CONTAINERS

IOSH has developed a decision logic to present appropriate criteria and priorities for selecting a sharps disposal container (Figure 2). This decision logic can be used to frame the selection process.

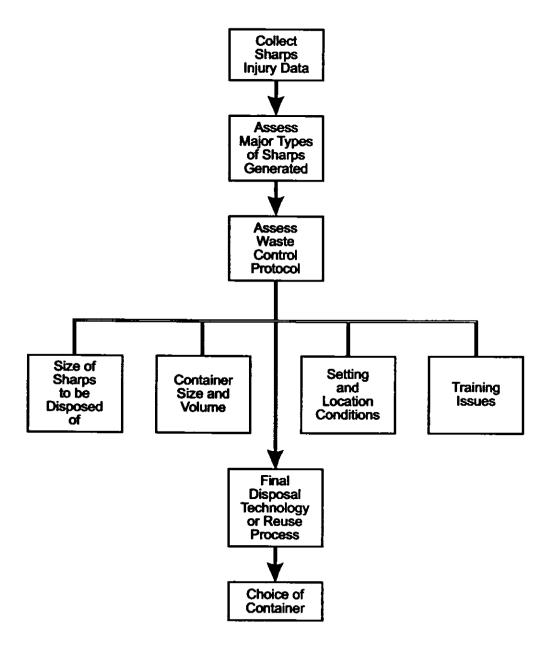


Figure 2. Decision logic for sharps disposal container selection.

APPENDIX D—QUESTIONNAIRE FOR EVALUATING SHARPS DISPOSAL CONTAINER PERFORMANCE

he decision logic may be followed by a questionnaire designed to evaluate container performance based on each of the four performance criteria (functionality, accessibility, visibility, and accommodation). The questionnaire should assist product evaluation committees, facility management, and individual HCWs in proactive sharps disposal container selection and evaluation. Users of this questionnaire should be aware that the ideal product may not exist and that this evaluation tool was constructed on the basis of common product designs available at the time.

Product evaluators should inspect and operate sharps disposal container mechanisms in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, pipettes, etc.) should be on hand in sufficient numbers to test the ease of use and the intended function of candidate products. Actual use conditions should be simulated, if possible. Before inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement of the location of intended use. Evaluation facilitators should provide product manufacturer literature and visual instructions; they should also demonstrate proper operation of each container.

The waste management system represents a considerable investment for health care operations. Sharps disposal containers should be economical to acquire, store, assemble, use, and dispose of. Low unit prices do not always result in lowest overall costs. Total cost for the employer is best measured as a function of wear life, unit cost, capacity utilization, labor cost, capital investment, employee training, installation cost, disposal cost, savings in employee injury costs, employee task confidence, and compliance with standard precautions and 29 CFR 1910.1030 (OSHA's bloodborne pathogens standard). Moreover, evaluation of cost is an ongoing process that may be a driving force in deciding when new sharps disposal containers are required or relocation of existing sharps disposal containers is more appropriate.

At this time, there is no quantitative score that indicates a container is sufficient for a particular purpose. Although it is not possible to provide precise guidelines for evaluating a particular score from the questionnaire, the lower the score from the questionnaire, the better the sharps disposal container (the highest score would be 44 points and the lowest score would be 220 points). The application of priority or value to a criterion must be done on a case-by-case basis. It may be useful to submit the currently used sharps disposal container to the questionnaire scoring system to compare it with the replacement models under consideration.

QUESTIONNAIRE FOR EVALUATING SHARPS DISPOSAL CONTAINER PERFORMANCE

he following product selection questionnaire was developed by the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health in conjunction with NIOSH Educational Resource Centers; The Johns Hopkins University, Baltimore; the University of Texas, Houston; the University of California, Berkeley; and the Mount Sinai School of Medicine, New York City.

INSTRUCTIONS:

Product evaluators should inspect and operate containers to be evaluated in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, biopsy needles, pipettes, etc.) should be used to test candidate products. Actual use conditions should be simulated, if possible. Prior to inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement. Evaluation facilitators should provide product manufacturer literature and visual instructions and should demonstrate proper operation of each of the containers. Use of this guideline requires knowledge that the ideal product may not exist and that this evaluation tool was based on common product designs available at the time.

FUNCTIONALITY

PLEASE CIRCLE YOUR RESPONSE

agree disagree					
Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures	1	2	3	4	5
Container provides for puncture, leak, and impact resistance	1	2	3	4	5
Container, labels, warning devices, and brackets are durable	1	2	3	4	5
Container is autoclavable, if necessary	1	2	3	4	5
Container is available in various sizes and capacities	1	2	3	4	5
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required	1	2	3	4	5
Closure mechanism will not allow needlestick injury	1	2	3	4	5
Closure mechanism provides secure seal	1	2	3	4	5
Design minimizes needle-tip flipback	1	2	3	4	5
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)	1	2	3	4	5

	agree disagree				
Design resists easy reopening after sealing for final disposal or autoclaving	1	2	3	4	5
Inlet design defeats waste removal when open	1	2	3	4	5
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position	1	2	3	4	5
Containers designed to be reopenable have removable lids design with tight closure that facilitates ease of removal with grip safety and comfort	1	2	3	4	5
Mounting brackets are rugged and designed for ease of service and decontamination	1	2	3	4	5

ACCESSIBILITY

	agreedisagre				gree
Container available in various opening sizes and shapes	1	2	3	4	5
Containers are supplied in sufficient quantity	1	2	3	4	5
Container has an entanglement-free opening/access way	1	2	3	4	5
Container opening/access way and current fill status visible to user prior to placing sharps into container	1	2	3	4	5
Internal design/molding of container does not impede ease of use	1	2	3	4	5
Handles, if present, located above full-fill level	1	2	3	4	5
Handles, if present, facilitate safe vertical transport and are located away from opening/access way and potentially soiled surfaces	1	2	3	4	5
Fixed locations place container within arm's reach of point of waste generation	1	2	3	4	5
Fixed locations allow for installation of the container below horizontal vision level	1	2	3	4	5
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering	1	2	3	4	5

VISIBILITY

agree disagree					gree
Color or warning label implies danger	1	2	3	4	5
A warning indicator (i.e., color or warning label) is readily visible to the user prior to user placing sharps into container	1	2	3	4	5
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container	1	2	3	4	5
Sharps disposal container complies with OSHA requirements	1	2	3	4	5
Disposal opening/access way is visible prior to user placing sharps into container	1	2	3	4	5
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/access way or fill status indicator	1	2	3	4	5

ACCOMMODATION

agree disagree				gree	
No sharp edges in construction or materials	1	2	3	4	5
Safety features do not impede free access	1	2	3	4	5
Promotes patient and user satisfaction (i.e., aesthetic to extent possible)	1	2	3	4	5
Is simple to operate	1	2	3	4	5
Any emissions from final disposal comply with pollution regulations	1	2	3	4	5
Easy to assemble, if required	1	2	3	4	5
Components of containers that require assembly are easy to store prior to use	1	2	3	4	5
Use allows one-handed disposal	1	2	3	4	5
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)	1	2	3	4	5
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable	1	2	3	4	5
Mounting systems allow height adjustments	1	2	3	4	5
Design promotes task confidence	1	2	3	4	5
Cost effectiveness	1	2	3	4	5

OTHER COMMENTS

What design or performance requirements are missing from the product you evaluated that are really needed to safely or more comfortably conduct your job or sharps-related task?
Additional Evaluator Concerns and Comments:

APPENDIX E-RECOMMENDED READING

Regulation and Standards

- OSHA. Occupational exposure to bloodborne pathogens: final rule (OSHA 29 CFR 1910.1030). Federal Register 1991:56:64175–82.
- American Society for Testing and Materials (ASTM). Performance standard specification for puncture resistance of containers for discarded medical needles and other sharps. ASTM Task Force F04.65.01 (in preparation).
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Focus Group/End User Assessment Methods

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NIOSH ERC Research Publications

1. Decker JA, Deitchman S, Buchta T. Health Hazard Evaluation Report No. 91-342-2271.

APPENDIX F—OSHA HAZARD INFORMATION BULLETIN: SHARPS DISPOSAL CONTAINERS WITH NEEDLE REMOVAL FEATURES

MEMORANDUM FOR: LEO CAREY

Director

Office of Field Programs

FROM: PATRICIA K. CLARK

Director

Directorate of Technical Support

SUBJECT: Hazard Information Bulletin *—Sharps Disposal Containers with

Needle Removal Features

The purpose of this bulletin is to alert field personnel to the possible safety and health risks that may arise with the use of some sharps disposal containers that incorporate an "unwinder" mechanism to accomplish needle removal. Unwinders are used to separate needles from syringes or phlebotomy needles from blood collection (e.g., Vacutainer®) apparatus.

In general, sharps containers used for discarding contaminated needles must be closable, puncture-resistant, leakproof on the sides and bottom, and appropriately labeled or color coded (1910.1030 (d)(4)(A)(1)). Additionally, the Occupational Exposure to Bloodborne Pathogens Standard (1910.1030) prohibits needle removal unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure. Needle removal must be accomplished through the use of a mechanical device or a properly performed one-handed technique (1910.1030 (d)(2)(vii)(D)). Sharps containers which have well designed unwinders may be used.

However, it has recently come to our attention that some sharps containers do not have well designed unwinders and, therefore, do not meet the intent of the engineering and work practice controls provision of the standard. The design of some of these needle unwinders can cause needlestick injuries when the container becomes overfilled, or when the unwinder fails to properly secure the needle during the removal process.

As stated in OSHA Instruction CPL 2-2.44C, "Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens Standard," needle removal devices should not create additional hazards. The design of the sharps container and the location of the unwinder must allow the needle removal to be accomplished in a safe one-handed manner. In addition to the above mentioned safety characteristics, evaluation of such sharps containers should also consider the following safety features:

- 1. The sharps container should be designed so that it is easily and safely determined when the container needs to be emptied; this avoids overfilling and reduces the risk of injury.
- 2. The sharps container with an unwinder should be stabilized (secured to a wall, table, or tray) to prevent slipping during use.

The Directorate of Technical Support issues Hazard Information Bulletins (HIBs) in accordance with OSHA Instruction CPL 2.65 to provide relevant information regarding unrecognized or misunderstood health hazards and inadequacies of materials, devices, techniques, and safety engineering controls. HIBs are initiated on the basis of information provided by the field staff, studies, reports and concerns expressed by safety and health professionals, employers, and the public. Information is compiled on the basis of a thorough evaluation of available facts and literature and in coordination with appropriate parties.

- 3. The design of the unwinder must allow the employee to use the unwinder with a one-handed technique; that is, the employee must not be required to secure the needle with one hand while it is being unwound by the other hand
- 4. The unwinder should be designed so that the needles do not slip or slide within the unwinder during the needle removal process; the unwinder should provide a secure capture that prevents movement of the needle while it is removed.

OSHA recommends that procedures requiring needle removal be carefully evaluated to determine the feasibility of equipment redesign or changes in work practices.

Please distribute this bulletin to all Area Offices, State Plan States, Consultation Projects, and appropriate local labor and industry associations.