

2011 Edition

Needlestick Safety and Prevention Law

How to Achieve Compliance

Written by Jan Harris, M.P.H.
Edited by Elise Handelman, MEd

Earn nursing CE credits at NO charge

ABOUT THE AUTHOR



Jan Harris is Director of Environmental, Health & Safety for Sharps Compliance, Inc. She has provided OSHA consulting services and educational seminars to healthcare employers and employees alike for over 24 years. Harris holds a Masters degree in Public Health in Occupational Health and Safety Management from Tulane University. She is a certified instructor in OSHA's Voluntary Compliance in Safety & Health Program, and is a recognized expert on compliance with the Bloodborne Pathogens Standard and individual state medical waste regulations.

Professional affiliations include the Organization for Safety and Asepsis Procedures (OSAP) and Association for Professionals in Infection Control and Epidemiology (APIC). Jan designed this special education booklet as a guide to help facilities achieve compliance with the Needlestick Safety and Prevention Law.

Jan has designed the original version of this education booklet as a guide to help facilities achieve compliance with the Needlestick Safety and Prevention Act.



Elise Handelman is an Occupational and Environmental Health Consultant. She holds a Masters degree in Adult Education and is a Certified Occupational Health Nurse Specialist. She and is considered a national expert on the Bloodborne Pathogens Standard. Ms. Handelman served in the Occupational Safety and Health Administration (OSHA) for nearly 20 years before her retirement in 2010. Prior to coming to OSHA, Ms. Handelman worked in acute care, public health, occupational health and infection control. She is affiliated with Johns Hopkins University, the University of Virginia and the University of North Carolina, Chapel Hill.

Ms. Handelman has published peer reviewed articles and other materials in a number of venues. To date, she has revised the most recent version of this educational booklet.

ABOUT THIS PUBLICATION

The Needlestick Safety and Prevention Law set forth new requirements for healthcare facilities on the use of safety-engineered devices, employee solicitation, record keeping and employee training. These regulations apply to all healthcare employers, including those in physician offices, surgery centers, outpatient clinics, home care and nursing homes. The purpose of this book is to provide clear and concise information on what is really required. This publication uses a question and answer format to address the most common questions about the Needlestick Safety and Prevention Law.

We have listed a number of resources in the back of this publication for those of you who would like more in-depth information.

DISCLAIMER

While the authors, providers and distributors believe that the information contained herein is accurate; they cannot be held liable for the information, contained in this document or for any omission of information nor for compliance by employers or employees with the regulations. Due to the constantly changing nature of government regulations, the information contained herein may cease to be accurate. For that reason, updating safety policies and procedures at least annually is crucial to a successful program.

The information herein is provided with the understanding that it is not legal advice and questions with respect to particular government regulations and employment issues should be addressed to the appropriate governmental authority or legal counsel.

EDUCATION CREDITS COURSE OBJECTIVES

This activity for 2.0 contact hours is provided by Becton Dickinson Clinical Resource Services Department, which is accredited as a provider of continuing education in nursing by the American Nurses Credentialing Center's Commission on Accreditation.

California Board of Registered Nursing

BD Medical Clinical Resource Services Department is accredited as a provider of continuing education in nursing by the California Board of Registered Nursing provider.

Course Description

This program is intended to educate healthcare workers on the Needlestick Safety and Prevention Law.

Course Objectives

Upon completion of this workshop, the participant should be able to:

1. Describe the Needlestick Safety and Prevention Act that was signed into law.
2. Discuss the requirements for compliance to the legislation.
3. List four types of safety devices available in the market today.
4. Discuss the process recommended for selecting safety devices.
5. Describe acceptable sharps disposal collectors and procedures.
6. Describe the components of an Exposure Control Plan.
7. Discuss the procedure to follow if a needlestick occurs.

Course Requirements

The participant will be awarded 2.0 contact hours for continuing nursing education after meeting the following requirements:

1. Completion of the offering.
2. Completion of the Registration/Evaluation form available on the last page of this booklet.
3. Return the Registration/Evaluation form to:

BD Medical
Clinical Resource Services
9450 South State St.
Sandy, UT 84070

OR

Fax the Registration/Evaluation Form to:
801-565-2378

TABLE OF CONTENTS

INTRODUCTION	Page 7
MOST COMMON QUESTIONS and ANSWERS	
1. What is the Needlestick Safety and Prevention Act?	Page 7
2. How does the Needlestick Act apply to OSHA's Bloodborne Pathogens Standard? What must we now do differently?	Page 8
3. Why did the government feel the need to get involved with the needlestick safety issue and enact new regulations?	Page 11
4. My facility is in a state with its own occupational safety and health program. Does this federal law apply to us?	Page 11
5. By what date must we implement safer medical devices and the other requirements?	Page 11
6. Doesn't this law really just apply to hospitals and other high-risk facilities? Needlesticks are not a problem in our small practice, and I heard that practices with fewer than 10 employees are exempt. Is this true?	Page 12
7. What if none of our employees has ever reported a needlestick? Do we still need to use safety devices?	Page 13
8. How much of a risk do needlestick injuries really represent?	Page 13
9. We feel safety-engineered devices cost too much. Is it acceptable if we delay converting to safety products because of economic reasons?	Page 15
10. Does OSHA have a list of recommended safety medical devices?	Page 16
11. What is considered a safety medical device?	Page 16
12. How should we determine which safety medical device is best for our practice?	Page 20
13. What if a safety device option is not available for the medical device that I use?	Page 21
14. Do I have to keep a confidential Sharps Injury Log?	Page 22

15. We already use sharps collectors, and we place our collector right next to the patient so that we immediately dispose of the used devices. Isn't this enough?	Page 23
16. Sometimes our sharps collectors cause us problems, like when the used device doesn't fit inside the collector. What can be done to improve the sharps disposal process?	Page 23
17. We have placed a box of safety products on the shelf to use for select "high-risk" patients. We feel that doing so will suffice to protect our workers. Does this make us compliant with the safety legislation?	Page 25
18. We have made safety devices available to our staff, and we leave it up to them to decide whether they should use a safety device or not. Is this enough?	Page 26
19. Does the safety legislation still apply when the physician is both the employer and the employee?	Page 26
20. Isn't it true that OSHA will only enforce the safety legislation with hospitals, since they don't have time to inspect smaller facilities?	Page 26
21. What should we do if an employee does get a needlestick?	Page 27
22. What else can we do to help prevent needlesticks from occurring?	Page 28
REFERENCES	Page 30
RESOURCES	Page 31
EDUCATION CREDIT REGISTRATION/EVALUATION	Page 32-33

INTRODUCTION

The 1980s brought the fear of AIDS as well as an increased incidence of hepatitis B infection. Centers for Disease Control and Prevention (CDC) guidelines for safe practices, intended to prevent the spread of these diseases within the healthcare environment, failed to bring desired changes. In 1992, the Occupational Safety and Health Administration (OSHA), using the CDC Guidelines, began its regulation of employers by finalizing the Bloodborne Pathogens Standard (the Standard). The Standard includes requirements such as engineering controls, hepatitis B vaccination, and personal protective equipment.

Centers for Disease Control and Prevention (CDC)

“Occupational exposure to bloodborne pathogens from needlesticks and other sharps injuries is a serious problem, resulting in approximately 385,000 needlesticks and other sharps-related injuries to hospital-based healthcare personnel each year. Similar injuries occur in other healthcare settings, such as nursing homes, clinics, emergency care services, and private homes. Sharps injuries are primarily associated with occupational transmission of hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), but they have been implicated in the transmission of more than 20 other pathogens.”
(<http://www.cdc.gov/sharpsafety/>)

This educational course is designed to aid both employers and employees of non-hospital healthcare facilities with regulatory compliance and sharps injury prevention.

ANSWERS TO HEALTHCARE’S MOST COMMONLY ASKED QUESTIONS ABOUT THE NEEDLESTICK SAFETY AND PREVENTION LAW

1. What is the Needlestick Safety and Prevention Act?

On November 6, 2000, after a unanimous vote by the United States Congress, President Clinton signed into law the Needlestick Safety and Prevention Act (Pub. L. 106-430). The Needlestick Safety and Prevention Act (the Law) was fully enacted July 17, 2001.

This Law **requires employers to identify, evaluate and implement safer medical devices**. It also mandates additional requirements for maintaining a Sharps Injury Log, and for the involvement of non-managerial healthcare workers in evaluating and choosing devices.

**As Reported by the American Medical Association,
Report 1 of the Council on Scientific Affairs (A-00):**

“Scientific data now appear to indicate that the appropriate use of needlestick prevention devices, especially in comprehensive prevention programs, significantly reduces the incidence of needlestick injuries. Additionally, cost analyses are beginning to indicate that in the long term, the use of needlestick prevention devices will be cost-effective and most importantly, save healthcare workers the emotional and physical trauma associated with needlestick injuries.”

2. How does the "Needlestick Act" apply to OSHA's Bloodborne Pathogens Standard? What must we now do differently?

OSHA was mandated to enforce the Law by updating the Bloodborne Pathogens (BBP) Standard to strengthen the requirements related to the use of what OSHA terms “sharps with engineered sharps injury protections” (safety medical devices). The Standard, which must be available at the worksite, can be accessed at: www.osha.gov/SLTC/bloodbornepathogens/index.html.

The updates to the Standard are listed below.

Change 1: Update the Exposure Control Plan (ECP)

A written Exposure Control Plan (ECP) must be established in order to explain how employers intend to eliminate or reduce employee exposure to blood and other potentially infectious materials (OPIM). OSHA requires an ECP for all facilities where one or more employees (incorporated physicians are considered employees) engage in tasks that could expose them to blood or OPIM. Since the establishment of the standard in 1991, employers have been required to annually review and update their Exposure Control Plans. Even if no changes have occurred, the date of the review needs to be entered into the ECP. Any need for process, policy, procedural, administrative or technological change must be addressed.

Under the 2001 revisions to the Standard, safety medical devices must be addressed as well.² In addition to previous requirements, plans must include documentation of annual consideration and implementation of safety medical devices including the solicitation of input from non-managerial staff.

Documentation in the ECP should include a description of:

- Safety devices used or considered for use
- Methods used to assess their safety, suitability and appropriateness for clinical use
- Rationale for the decision to use or not use a specific device

The following checklist includes ECP requirements:

- ☐ Exposure determination
- ☐ Practice of Universal or Standard Precautions
- ☐ Schedule and method of implementing engineering and work practice controls, and personal protective equipment (gowns, gloves, masks, eye protection)
- ☐ Housekeeping, including medical waste and contaminated laundry handling
- ☐ HBV vaccination and post exposure procedures
- ☐ Communication of hazards including labeling and training
- ☐ Record keeping
- ☐ Procedure for evaluating circumstances surrounding an exposure incident
- ☐ Where and how the ECP is made accessible to employees
- ☐ Annual documentation of consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure
- ☐ Evaluation of new technologies that reduce exposure
- ☐ Documentation of employee input regarding new and effective engineering and work practice controls

Help establishing or updating your Exposure Control Plan can be found by contacting private consultants, contacting your local OSHA Office (<http://www.osha.gov/html/oshdir.html>) or using OSHA's model exposure control plan at: http://www.osha.gov/OshDoc/Directive_pdf/CPL_2-2_69_APPD.pdf.

Change 2: Involve Employees

Employers must receive input on the selection of effective engineering controls, including safety devices, from non-managerial employees responsible for direct patient care. These employees must represent all job classifications within the workplace with exposure to the sharps being evaluated.²

The reason for this requirement is to reduce the potential of employers choosing devices based solely on economics. A representative number of non-managerial employees with direct patient care from each affected job classification are required for the evaluation "team". Once devices are implemented, ALL employees required to handle, utilize and dispose of sharps are required to utilize the selected devices.

Documentation of employee involvement can be accomplished by:

- Listing the involved employees and describing how input was solicited
- Presenting minutes, evaluation forms, employee interviews

Involve as many employees as possible in the safety device evaluation process in order to encourage employees to become part of the solution and to enlist their support of change.

Change 3: Identify, Evaluate and Implement Safety Devices

Employers must implement the safer medical devices that are “appropriate, commercially available and effective.” For clarification, OSHA has revised the definition of *Engineering Controls*, and added two new definitions: *Needleless System* and *Sharps Injury Protections (SESIPs)*.

1. *Engineering Controls* – The definition of required engineering controls was clarified by including definitions for safety medical devices such as sharps with engineered sharps injury protections (SESIPs) and needleless systems designed to isolate or remove the bloodborne pathogens hazard from the workplace.
2. *Sharps with Engineered Sharps Injury Protections (SESIPs)* – Safety medical devices with built-in safety features or mechanisms that effectively reduce the risk of exposure incidents. These devices include, but are not limited to, safety scalpels, safety needles/syringes, shielded or retracting IV catheters and blunt suture needles. These are commonly referred to as safety-engineered medical devices or safety (or safer) medical products.
3. *Needleless System* – A device that does not use a needle for collection of body fluids, administration of medication/fluids, or any other procedure with potential percutaneous exposure to a contaminated sharp.

Change 4: Sharps Injury Log and Evaluation of Circumstances Surrounding a Sharps Injury

In order to assess if the employer’s bloodborne pathogens exposure prevention policies and procedures are effective, documentation and evaluation of all employee sharps injuries is required. The updated Standard provides for this by requiring the maintenance of a Sharps Injury Log by any employer required to keep OSHA Injury and Illness Records. The evaluation of circumstances surrounding bloodborne pathogens incidents is also required. (*See Question #14 for more information on Sharps Injury Logs.*)

Change 5: Train on Hepatitis C

The Standard requires that the employer train employees on the epidemiology, symptoms and modes of transmission of Hepatitis C as well as HIV and HBV. It is important to stress to employees that there are as many as 20 different pathogens that can be carried in the human blood. Opportunities for training on HCV can be found at:
<http://www.cdc.gov/ncidod/diseases/hepatitis/c/faq.htm>.

3. Why did the government feel the need to get involved with the needlestick safety issue and enact new regulations?

After years of development, research and clinical data collection, it was determined that using safety medical devices could substantially reduce the risk of needlestick injuries. Many states passed their own legislation requiring the use of such devices prior to the federal legislation. Due to the perceived importance of this issue and the need for a consistent approach across state lines, the federal government stepped in to ensure that these regulations were enacted in all 50 states.

“Numerous studies have demonstrated that the use of safer medical devices, such as sharps with engineered sharps injury protections, when a part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.”
- The Needlestick Safety and Prevention Act

4. My Facility is in a state with its own occupational safety and health program. Does this federal law apply to us?

In the OSHA Act of 1970, states may set up their own occupational safety and health programs, but they must set job safety and health standards that are “at least as effective as” federal standards. Most states adopt standards identical to those of federal OSHA, but states with programs that are frequently more restrictive than federal OSHA include:

- California
- Hawaii
- Michigan
- Oregon
- Washington

Employers in states with their own state OSHA programs should check with their specific state OSHA offices for possible additional requirements. State OSHA offices can be contacted by phone, mail and the Internet. A directory is provided at: <http://www.osha.gov/fso/osp/index.html>.

5. By what date must we implement safer medical devices and the other new requirements?

The revised Standard took effect on April 18, 2001. Enforcement of the Standard began on July 17, 2001. If you have not yet started the selection process for safety devices, the time to start is now!

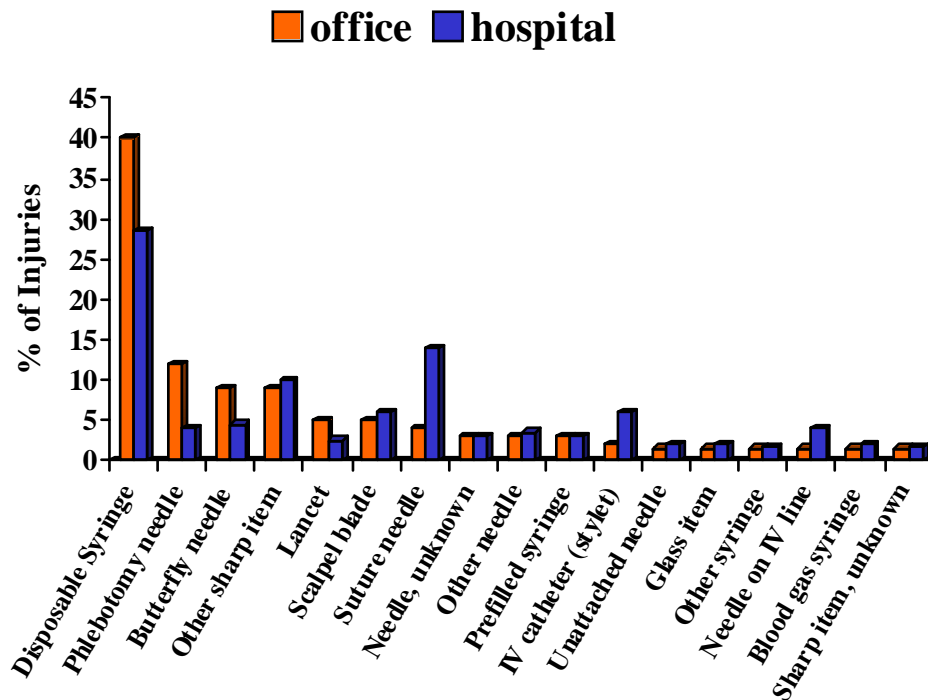
6. Doesn't this law really just apply to hospitals and other such higher risk facilities? Needlesticks are not a problem in our small practice, and I heard that practices with fewer than 10 employees are exempt. Is this true?

As has been the case since 1991, OSHA's Bloodborne Pathogens Standard applies to all employers with employees who have occupational exposures regardless of how many workers are employed (incorporated physicians are considered employees). Since the updated Bloodborne Pathogens Standard incorporates the components of the Law, if employees are exposed to contaminated sharps, they are covered by the Standard.

Medical Devices Causing Injury: Physician Offices vs. Hospitals

Source: International Health Care Worker Safety Center,
University of Virginia

Based on data from 84 healthcare providers submitting EPINet™ data



7. What if none of our employees have ever reported a needlestick? Do we still need to use these new safety devices?

Just because sharps injuries have not been reported in your facility, does not mean they have not occurred. The CDC estimates that half of the needlesticks each year go unreported.³ Even if employees have never had needlesticks within your facility, OSHA standards are intended to be implemented as a means to **prevent** occupational injuries and illnesses. To quote OSHA's Bloodborne Pathogens Compliance Directive, [CPL 02-02-069](#), "*The lack of recorded injuries does not exempt the employer from this provision.*"

Allowing employees to utilize traditional sharp medical devices without safety mechanisms when there are devices available that are known to reduce such injury, is "an accident waiting to happen." With safety, it is always better to anticipate a potential danger and prevent it rather than make changes after an injury occurs. Choosing to implement safety devices is similar to the reason why most of us wear seat belts: we know that severe injury and death can be avoided by doing so. Statistics show that accidents happen even to the best drivers and to the best clinicians. We don't have to wait to have an accident to know we should use the technology designed to protect us: seat belts and safety needles.

Of course, another reason to wear seat belts is because it's the law. We know that if an enforcement officer pulls us over there will be consequences. The same is true with safety medical devices as a result of the Needlestick Safety and Prevention Law.

8. How much of a risk do needlestick injuries really represent?

The reality of treating patients with the potential to transmit bloodborne diseases to healthcare workers is certainly present within every facility. According to CDC, approximately 1.1 million persons were living with HIV infection at the end of 2009. As many as 21% of infected persons are unaware of their infection.

(http://www.cdc.gov/hepatitis/Resources/Professionals/PDFs/ABCTable_BW.pdf).

Additionally, close to 1.2 million Americans are infected with the Hepatitis B virus (HBV) and approximately 3 million Americans carry the Hepatitis C virus (HCV).⁴

Position of the American Nurses Association on Needlestick Safety:

“Every year, hundreds of thousands of healthcare workers are exposed to deadly diseases like HIV and Hepatitis C through needlestick and sharps injuries. With today’s technology, nurses no longer need to face such high risks. The ANA is dedicated to working with nurses across the country to significantly reduce needlestick and sharps injuries. Nurses should not have to risk their lives every time they use a needles or sharps device.”

THIS INFORMATION IS COPYRIGHTED 2002 AMERICAN NURSES ASSOCIATION.

Visit the ANA web site at:

<http://nursingworld.org/MainMenuCategories/WorkplaceSafety/SafeNeedles/NeedlestickPrevention.pdf>

A simple needlestick can have devastating effects. OSHA estimates that “5.6 million healthcare workers are at risk from occupational exposure to bloodborne pathogens.” Needlestick injuries are the most common cause of occupational exposure.¹

According to data gathered by the International Healthcare Worker Safety Center at the University of Virginia:

- Nurses reported the greatest number of needlesticks at over 40%
- Physicians rank second at nearly 10%
- Phlebotomist/Venipuncture/IV Team members accounted for 5%
- Housekeeper/laundry workers accounted for nearly 3%⁶

Taken from Lisa Black's Personal Story: A nurse exposed to deadly bloodborne pathogens due to an accidental needlestick.

"In October 1997, I sustained a significant needlestick. My first reaction to this was sheer panic. After all, the man from whom I sustained my needlestick was dying a gruesome death from a horrific disease. After thoroughly scrubbing the wound, I reported immediately to the emergency department and was started on a vigorous medication regimen to inhibit the HIV virus from taking hold in my body. I adhered faithfully to this regimen thinking that tolerating the side effects would assure that I would not become infected with HIV.

On July 27, 1998, nine months and nine days after my needlestick injury, I learned that I had indeed been infected with HIV. There are no words to adequately describe the horror of the moment when I learned I was HIV positive.

By October 1998, I was beginning to adjust to the fact that I was now one of the statistics --- **I was a person with "occupationally acquired HIV infection."** During some followup blood work, my liver enzymes were found to be severely elevated. Subsequent tests revealed that I was now seropositive for Hepatitis C as well.

Telling my family about my illnesses has been the hardest thing I've had to do. I was unable to fully explain my situation to my own two daughters, who were then ages five and nine. I dreaded the day when they would realize that I may not be there to share the moments when they graduate high school, get married and have children of their own. I would give anything to be there at those times in their lives when my own mother's influence was so instrumental in mine. I had to accept, however, that I must make plans for a day when I may not be a part of my children's lives.

This brings me to the reason I am telling my story. I cannot turn back the clock and undo the events of October 18, 1997. Nothing will give me back my life as it was before HIV and Hepatitis C were a part of it. It is now my wish that my experiences be used to educate others about the human reality of occupational bloodborne illnesses."

[Adapted with permission from *Lisa Black: One Unnecessary Needle = HIV + HCV* in Advances in Exposure Prevention, Vol.4.no. 3, 1999. Published by the International Healthcare Worker Safety Center, University of Virginia Health System.]

9. We feel safety engineered devices cost too much. Is it acceptable if we delay converting to safety products because of economic reasons?

In short, the answer is no. Before passing the Needlestick Safety and Prevention Act, OSHA conducted an industry-wide cost/benefit analysis and concluded that the use of safety medical devices was cost-advantageous. The total additional cost per facility of using safety devices appears small compared to the total healthcare and personal costs related to non-compliance, which include:

- OSHA Fines
 - Serious, Other Than Serious or Posting Requirements:.....Up to \$7,000
 - Willful and/or Repeat violation:.....Up to \$70,000
 - Falsifying Records:..... Up to \$10,000, up to six months in jail, or both
- Post exposure evaluation/follow-up for the employee:..... \$1,000 – \$3,000
- Post exposure testing of source patient:..... \$500
- Medications, treatments, care, transplants, long term care
for employees who contract disease:.....\$500,000 – \$1,000,000
- Increased insurance coverage costs
- Potential workers compensation costs
- Potential legal actions on part of worker/union
- Employee lost work time due to testing or treatment
- Expenses related to replacing worker

10. Does OSHA have a list of recommended safety medical devices?

OSHA does not recommend any specific brands or types of safety devices. It is up to the individual facility to determine what is best for its staff and practice, as long as safety devices are indeed evaluated and used. Your selection of devices will be based on the procedures performed at your facility. Contact your supplier for devices to evaluate.

11. What is considered a safety medical device?

Today, there are safety devices for all of the most common procedures. Such devices are used to prevent percutaneous injuries before, during or after use. Examples include needless devices, shielded needles, blunt suture needles and plastic capillary tubes.

Examples of Safety Devices

Following are some examples of commonly used safety devices. This is not meant to be a comprehensive listing.

Injection: Needle and syringe products for injection

- Retractable needles that use a spring-loaded mechanism to pull the needle back into the body of the syringe once an injection has been given



- Protective sheath needles that include activation of a protective cover once the device is used



- Syringes with integrated shield that slides over needle after use



Surgical Scalpels:

- Disposable scalpels with locking retractable shields
- Blunt/safety suture needles



IV Catheter Insertion: Devices with a mechanism to retract or cover the used stylet after the catheter has been placed.

- Retractable IV access needles with a push-button shielding mechanism that releases the spring and allows the needle and flash chamber to retract quickly into the safety barrel



Blood Collection: For venous and capillary blood collection

- A blood collection needle with a hinged sheath that is engaged over the needle, covering it after use



- Blood collection set needle that retracts at the push of a button



- Retractable Lancet



- Blood Collection Tubes – tubes made of plastic, rather than glass, to prevent tube breakage and potential injuries



12. How should we determine which safety medical device is best for our practice?

It is important to plan how devices will be incorporated into your practice. Using a recommended step-by-step process can help accomplish this task.

Step 1: Make a list of all tasks in which sharps devices are utilized. Examples may include:

- Infusion therapy
- Blood collection/culture
- Injections
- Surgery
- Sharps disposal

Step 2: Take an inventory of all the specific sharps devices being used. This should include gauge and length of needles, size of syringes, etc. The purchasing department for your facility can help provide this information.

Step 3: Schedule a staff meeting to discuss:

- The requirements for evaluation, selection and implementation of safety products
- A timeline for completion and assignment of tasks, including a prioritization of which devices will be evaluated first, based on the risk of injury
- Selection of non-managerial employees who are involved with direct patient care to participate in the process
- Needlestick/sharps injury data, including near misses in your facility

Step 4: Contact supplier for samples. If your facility uses a Group Purchasing Organization (GPO) for products, be aware that OSHA does not allow price and contractual availability to be the sole basis for selecting a safety device. GPO's can, however, be very helpful in finding a wide variety of devices from which to select.

Step 5: Evaluate the product(s)

- The evaluation team assesses products and reviews results
- The team decides, using the objective data gathered, which devices will be implemented

Step 6: Fully implement the safety devices

- Provide adequate training on the new devices, including hands-on practice
- Ensure employees are using the devices. Remove traditional devices from areas where safety devices have been implemented
- Ensure the devices are activated prior to disposal

The Training for Development of Innovation Control Technology Project (TDICT) has developed suggested product evaluation forms. These forms may be downloaded at: <http://www.tdict.org/evaluation2.html>.

Step 7: Document the Process

- Keep copies of all evaluation forms and supporting documentation
- Document the process in the Exposure Control Plan

During an inspection, OSHA is likely to request documentation of the evaluation process and will want to see non-management employees involved in the selection process.

Step 8: Evaluate the Process and Monitor Results

- Request employee opinions regarding the evaluations
- Determine how well the devices are working and if additional training is needed

Most employees will need time to get comfortable with using these new safety devices. However, many devices require only a slight change in technique, so the learning curve should be minimal. It is often more the idea of change that bothers us versus the actual change itself.

13. What if a safety device option is not available for the medical device that I use?

If there is no safer option for a particular medical procedure, you are not required to use something other than the device that is normally used. For example, if your device is used in a neonatal procedure and a safety device is not manufactured in a pediatric size, you would not be expected to use a device that is inappropriate for the patient. Annually inquire about new or prospective safer options from your distributor, and document this fact in your written Exposure Control Plan. Once safer options do become available, proceed through the step-by-step process to ensure compliant implementation.

14. Do I have to keep a confidential Sharps Injury Log?

Employers who are required to maintain injury and illness recordkeeping forms (300, 300A and 301) under OSHA Reporting and Recording regulations (29 CFR 1904) must also establish and maintain a Sharps Injury Log. The Log must contain, at a minimum:

- The type and brand of device involved in the incident
- The department or work area where the exposure incident occurred
- An explanation of how the incident occurred

The log must not include the name of any injured employee in order to maintain confidentiality.

The federal OSHA recordkeeping standard exempts certain settings, such as Offices and Clinics of Physicians, from certain OSHA recordkeeping requirements and from maintaining the Sharps Injury Log⁵. However, some states have their own OSHA plans that may not allow this exemption. It is best to contact your own state for clarification. State plan information may be accessed at: www.osha.gov/fso/osp/index.html or by calling OSHA at 1-800-321-OSHA (6742).

For a full description of OSHA's recordkeeping requirements regarding needlesticks, see OSHA's Recordkeeping Handbook, Section 1904.8 at: <http://www.osha.gov/recordkeeping/handbook/index.html#1904.8>.

15. We already use sharps collectors and we place our collector right next to the patient so that we immediately dispose of the used devices. Isn't this enough?

The sharps collectors must be placed as close as feasible to the point of use. However, the placement of the disposal unit has no bearing on the requirement to use safety-engineered devices, since the risk to the worker still exists during actual use of the sharps device. As shown in the following table taken from the Exposure Prevention Information Network (EPI Net) Uniform Needlestick and Sharp Object Injury Report, of over 10,000 injuries from 2000-2006, 36% of all injuries occurred during use of the sharp, and 16% occurred after use, but prior to disposal.⁶

How Injury Occurred

Before use	0	0%
During use	3,632	36%
Between steps	1,340	13.3%
Disassembling	340	3.4%
Preparing for reuse	161	1.6%
Recapping	337	3.3%
Withdrawing from resistant material	256	2.5%
Other after use, before disposal	1,628	16.1%
Item left on disposal container	34	0.3%
Device left on floor, table, bed or other inappropriate place	583	5.8%
Putting item into disposal container	589	5.8%
After disposal	175	1.7%
Pierced side of disposal container	20	0.2%
Pierced side of inappropriate disposal container	168	1.7%
Restraining patient	80	0.8%
Other	758	7.5%

16. Sometimes our sharps collectors cause us problems like when the used device doesn't fit inside the collector. What can be done to improve the sharps disposal process?

Since up to one third of all needlesticks occur during the disposal process, it is important that the safety device evaluation process also include evaluation of sharps collectors.⁷ Choosing the correct size sharps collector with the appropriate size opening is crucial to preventing disposal injuries. Test currently used sharps collectors to determine if they are the appropriate size and type needed for disposal of the devices.

NIOSH (National Institute for Occupational Safety & Health) has developed a document, "Selecting, Evaluating and Using Sharps Disposal Containers," which presents a comprehensive

framework for selecting sharps collectors and evaluating their efficacy as part of an overall needlestick injury prevention plan.(<http://www.cdc.gov/niosh/sharps1.html>)

Sharps Disposal Container Design Elements

Within this document, NIOSH has clearly described sharps collector design elements that contribute to healthcare worker (HCW) risk reduction. These elements include:

Functionality

- Puncture, leak and impact resistance
- Appropriate in size and design to accommodate the largest sharps used
- Closure mechanism that is secure and will not allow needlestick injury

Accessibility

- Ease of operation
- Guards that prevent hands from entering
- Handles to facilitate safe use, removal and transport
- Placement within arm's reach and below eye level at their point of use
- Free of obstacles, away from wall switches, clear of impact zone
- Appropriate wall mount height (52"-56") to allow for view and safe access of collector door

Visibility

- Visible and recognizable with a biohazard warning label
- Opening completely visible and clear before using
- Fill status visible prior to use

Accommodation

- Ease of storage and assembly
- Intuitive and easy to use
- Promotes one-hand disposal
- Safe mounting systems
- Durable, stable and cleanable

In addition to the above criteria, NIOSH also recommends:

- A facility strategy for selecting appropriate sharps collectors based on a site specific hazard analysis
- Designation of an individual or group to regularly monitor and maintain sharps collectors
 - Frequently and routinely monitor fill levels
 - Change sharps collectors before they are overfilled

The use of a collector with a counterbalanced door in patient exam rooms increases ease of use and decreases risk of exposure by facilitating one-hand disposal and tamper resistance. Collectors mounted in locking cabinets at the appropriate height of 52”–56” will further lower your risk of exposure.

Remember, the fill status should be clearly visible before disposal and collectors should be changed before they are three-quarters full.

Does your sharps disposal system have the following?

- ✓ Counterbalanced doors
- ✓ Tamper resistance
- ✓ Maximum visibility to fill status
- ✓ Handles to facilitate safe handling
- ✓ Ability to mount at a height of between 52”– 56”

***Reduce your risk by addressing any of the above items to which you answered “No.”**

17. We have placed a box of safety products on the shelf to use for select, “high risk” situations. We feel that doing so will suffice to protect our workers. Does this make us compliant with the new safety legislation?

“Universal precautions” is defined by OSHA as a concept of bloodborne pathogens disease control, which requires all human blood and other potentially infectious materials to be treated as if known to be infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived “low risk” of a patient or patient population. This concept of Universal Precautions has been required by OSHA’s Bloodborne Pathogens Standard since 1991. Using safety products only on select patients who appear to be “high risk,” goes against this concept, can lead to employee exposure to bloodborne pathogens, and will warrant a potential OSHA citation.

There are over 20 known pathogens that can be transmitted through human blood. Millions of people in the U.S. are infected with HIV, HBV and HCV and many are unaware of their infection status. It is impossible to intuitively know who carries pathogens in their blood and body fluid and who does not. Therefore, all patients should be considered “high-risk” when dealing with tasks that could expose employees to bloodborne pathogens.

“CITATION GUIDELINES: If the employer has a policy of treating the blood or OPIM of some patients as potentially infectious and the blood or OPIM of others (e.g., the elderly or children) as not infectious, a violation of this provision exists.”⁸ OSHA’s Compliance Directive, 02-02-069.

To reduce risk of employee exposure to bloodborne pathogens through needlesticks, OSHA makes the following statement regarding safety devices:

“Where employee exposure can be eliminated or reduced by removing, eliminating, or isolating the hazard, **they must be used.**⁸”

18. We have made safety devices available to our staff and we leave up to them to decide whether they should use a safety device or not. Is this enough?

The Standard requires employers to both provide and ensure that their employees use safety devices in all cases where safer medical devices are available. The Bloodborne Pathogens Standard requires that the facility Exposure Control Plan (ECP) explains how the identification, evaluation, selection and implementation of these devices shall be accomplished. Simply putting the safety devices on the shelves, and allowing the employees to use them if they desire, is not any more compliant than putting gloves on the shelves and allowing the employees to use them if they desire. The employer is responsible for assuring compliance to the facility safety and health policies, including the use of selected safety devices.

19. Does the safety legislation still apply when the physician is both the employer and the employee?

The Bloodborne Pathogens Standard applies to all workplaces, regardless of size, where there is at least one employee at risk for a bloodborne pathogens exposure incident. If the physician is also an employee (i.e., incorporated) the Standard applies. The evaluation and documentation process should also be followed in this situation.

20. Isn’t it true that OSHA will only enforce the safety legislation with hospitals, since they don’t have time to inspect smaller facilities?

OSHA’s Bloodborne Pathogens Standard and its enforcement apply to all employers with employees who have occupational exposures, regardless of how many workers are employed.

Since the Law was passed, OSHA officials have received many employee complaints, and inspected all types of healthcare facilities across the country. Citations and fines have been issued for non-compliance. This has included physician practices, surgery centers, nursing homes and hospitals.

OSHA fines can be issued for as high a \$7,000 per violation and as high as \$70,000 for willful or repeat violations. In addition, an individual healthcare facility can incur several citations for each inspection; for example, individual citations can be issued for:

- Failure to update the Exposure Control Plan including documentation of device evaluation
- Failure to use the device
- Failure to train employees on device use

Whether it is one medical office nurse or 500 hospital nurses, all are covered by the OSHA's Bloodborne Pathogens Standard and consequently, their employers are subject to OSHA fines if found to be non-compliant.

21. What should we do if an employee does have a needlestick?

OSHA has always required that post-exposure follow-up be provided to employees who incur a bloodborne pathogens exposure incident, such as a needlestick. The Law, and subsequently the updated Standard, has expanded the incident documentation requirements.

First, the employee should IMMEDIATELY receive first aid and be evaluated by a healthcare practitioner who is familiar with the CDC recommendations for needlestick injuries.

OSHA has cited employers for non-compliance when employees do not receive prompt, knowledgeable care following a needlestick.

OSHA requires most employers to record needlesticks. (*See Question #14 for details.*) Recordkeeping includes the completion of a Sharps Injury Log and the OSHA forms 300 and 301.⁵ These forms record the specifics regarding the device being used when an injury occurs. The next step is to evaluate the circumstances surrounding the exposure incident itself. This procedure aids the employer in finding the root cause of the incident. Only by finding the root cause will similar accidents be prevented in the future.

Procedures for Evaluating the Circumstances Surrounding an Exposure Incident

Documentation of the circumstances surrounding an exposure incident will follow all parenteral, mucous membrane or non-intact skin exposures. This process will help to determine if appropriate training and control measures were in place.

The circumstances of all exposure incidents should be reviewed to determine:

- ✓ Engineering controls in use at the time
- ✓ Work practices being followed
- ✓ Description, type and brand of device used
- ✓ Protective equipment being used at the time
- ✓ Location of the incident
- ✓ Procedure being performed
- ✓ Employee's training prior to the incident

Utilization of the following checklist will help ensure appropriate action after a needlestick.

Needlestick Incident Checklist

- ☐ Prior to any incident, determine the Healthcare Professional (HCP) to be used for post-exposure treatment and follow-up.
- ☐ Post-exposure evaluation and treatment, must be administered immediately using the Centers for Disease Control and Prevention (CDC) guidelines available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>.
- ☐ Consult in private with the source individual regarding the incident and referral for testing
- ☐ Have source sign a consent/declination form for testing blood and file this document.
- ☐ Complete exposure incident report with employee and send copy to HCP.
- ☐ Have employee sign an employee post exposure consent/declination form for permission or refusal to be tested/treated.
- ☐ Refer employee to HCP and have employee take:
 - Copy of **OSHA's Bloodborne Pathogens Standard**
 - Applicable **employee medical records**, including HBV vaccination status
 - Copy of **Incident Report**
 - Source's blood test results and disease status, if known (HIV, HCV, HBV)
- ☐ Document on the OSHA 300 and 301 forms and the Sharps Injury Log within seven days (if applicable)
- ☐ Receive **HCP's written opinion** within 15 days and file in employee's medical record file
- ☐ Provide **HCP's written opinion** to employee within 15 days of receipt by the office
- ☐ Hold re-training with all employees who perform the same task in which incident occurred
- ☐ Document the circumstances surrounding the incident
- ☐ Evaluate any safety devices used at the time of injury
- ☐ Make any necessary changes to the facility Exposure Control Plan

22. What else can we do to help prevent needlesticks from occurring?

Following the checklist provided below will help assure compliance with the Standard. For additional assistance, refer to the list included at the end of this document.

EXPOSURE PREVENTION CHECKLIST

- ☐ Are safety syringes/needles being used for skin injection?
- ☐ Are blood-drawing devices with integrated safety features being used at your facility?
- ☐ Are all unnecessary needles eliminated from use?
- ☐ Does your facility use automatically retracting finger/heel-stick lancets?
- ☐ Is your facility using plastic microbore capillary tubes for measuring hematocrit?
- ☐ Is your facility using plastic blood collection vacuum tubes?
- ☐ Are puncture-resistant disposal containers within arm's reach of blood-drawing personnel for all phlebotomy procedures?
- ☐ Are blood-drawing personnel wearing procedure gloves?
- ☐ Are safety IV catheters being used?
- ☐ Are needleless or recessed needle IV systems being used?
- ☐ Are blunt suture needles, stapling devices, adhesive strips or tissue adhesives used whenever clinically feasible?
- ☐ Are scalpel blades with safety features used?
- ☐ Has all equipment that is unnecessarily sharp been eliminated?
- ☐ Is double-gloving employed in the surgical setting?
- ☐ Does your facility have an adequate supply of personal protective equipment, i.e., gloves, liquid-resistant gowns, face and eye protection? For more information, please visit <http://www.osha.gov/SLTC/bloodbornepathogens/index.html>.
- ☐ Are specimen and body fluid containers made of plastic and have tight positive-locking seals?
- ☐ Are your sharps disposal containers:
 - ☐ Puncture-resistant?
 - ☐ Close to point-of-use?
 - ☐ Replaced before $\frac{3}{4}$ full?
 - ☐ The appropriate size?
- ☐ Are at-risk employees provided training once a year?
- ☐ Does your facility comply with Universal or Standard Precautions established by the Bloodborne Pathogens Standard?
- ☐ Are regular In-Services provided on safe handling of needles and sharp items?
- ☐ Does your facility have a written exposure control plan?
- ☐ Does your facility provide Hepatitis B vaccine free to all at-risk employees?
- ☐ Does your facility provide free post-exposure follow up?

Adapted from Advances in Exposure prevention (1999:4(3):33-34) published by the International Health Care Worker Safety Center, University of Virginia. For additional information, please visit www.med.virginia.edu/epinet and click on About EPINet™.

REFERENCES

1. RECORD SUMMARY OF THE REQUEST FOR INFORMATION ON OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS DUE TO PERCUTANEOUS INJURY. EXECUTIVE SUMMARY. Occupational Safety and Health Administration. Accessed on Jan. 4, 2003. Available at: <http://www.osha.gov/html/ndlreport052099.html>.
2. Occupational Safety and Health Administration. 29 CFR Part 1910.1030 Occupational exposure to bloodborne pathogens; Needlestick and other sharps injuries; Final Rule. Federal Register Vol. 66, No. 12:5318-25, Jan. 18, 2001. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051&p_text_version=FALSE
3. What Every Worker Should Know: How to Protect Yourself From Needlestick Injuries DHHS (NIOSH) Publication No. 2000-135. Available at: <http://www.cdc.gov/niosh/docs/2000-135/>.
4. CDC Hepatitis Surveillance. US Department of Health and Human Services, [Surveillance Data for Acute Viral Hepatitis – United States, 2008](http://www.cdc.gov/hepatitis/Statistics/index.htm) Available at: <http://www.cdc.gov/hepatitis/Statistics/index.htm>.
5. Occupational Safety and Health Administration. 29 CFR Parts 1904. Occupational injury and illness recording and reporting requirements see: <http://www.osha.gov/recordkeeping/handbook/index.html>.
6. International Healthcare Worker Safety Center, University of Virginia. US EPINet™ Sharps Injury and Blood and Body Fluid Exposure Surveillance Research Group. Sharps Injury Data Report for January 1, 2000 to December 31, 2006. Report available at: <http://www.healthsystem.virginia.edu/internet/epinet/EPINet-2000-2006-SOI-report.doc>.
7. National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers. DHHS (NIOSH) Publication No. 97-111, Jan. 1998. US Department of Health and Human Services. Accessed December 29, 2002. Available at: <http://www.cdc.gov/niosh/sharps1.html>.
8. CPL 02-02-69 - Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. Available at: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570&p_text_version=FALSE.

RESOURCES

Emergency Needlestick Information

<http://www.cdc.gov/niosh/topics/bbp/emergnedl.html>

This site gives immediate access to treatment protocols following blood exposures involving HIV, HBV and HCV, including a link to the Clinicians' Post Exposure Prophylaxis Hotline (PEpline) at 1-888-448-4911. <http://www.nccc.ucsf.edu/>

EPINet™ at the International Healthcare Worker Safety Center, University of Virginia

<http://www.healthsystem.virginia.edu/internet/epinet/forms/epinet3.cfm>

The EPINet™ surveillance system gathers information from a wide variety of hospitals and provides extensive data on surveillance and demographics of bloodborne pathogens' exposures of all types. The data is available at no cost to the public.

Morbidity and Mortality Weekly Report (MMWR) <http://www.cdc.gov/mmwr/>

This link provides access to the MMWR, a series that is prepared by the CDC. The MMWR contains comprehensive information on prevention and treatment within the CDC's scope of responsibility; for example, data on the prevalence of reportable infectious diseases by state.

National Institute for Occupational Safety and Health (NIOSH/CDC) –

Bloodborne Pathogens <http://www.cdc.gov/niosh/topics/bbp/>

This web site links to information about universal precautions, HIV, HBV and HCV, treatment guidelines for needlesticks and other key CDC documents. Additional assistance is available at 1-800-CDC-INFO (800-232-4636).

OSHA: Bloodborne Pathogens and Needlestick Prevention web page

<http://www.osha.gov/SLTC/bloodbornepathogens/index.html>

This web site includes links to the Bloodborne Pathogens Standard, the Needlestick Prevention Act, letters of interpretation and OSHA training materials. Assistance with the page is available from OSHA at 1-800-321-6742 (OSHA).

OSHA: State Occupational Safety and Health Plans

<http://www.osha.gov/fso/osp/index.html> This site provides a directory of State OSHA Agencies. Employers with their own state OSHA programs can check if there are additional requirements to the federal standards.

Training for Development of Innovative Control Technologies (TDICT) Project

<http://www.tdict.org/> This organization features "Safety Feature Evaluation Forms" and other instructions for a wide variety of safer medical and dental devices.

EDUCATION CREDITS REGISTRATION FORM

Directions

To obtain CE credit for this program, you must completely fill out the registration below and evaluation forms (next page) and mail to:

BD Medical
Clinical Resource Services
9450 South State Street
Sandy, Utah 84070

You should receive your certification of completion within 2-3 weeks.

Registration (Please Print Legibly)

Name: _____

Mailing Address: _____

City, State, Zip: _____

☐ Check here if you do **not** wish to receive notice of future products and/or educational programs.

Profession: _____

State of Licensure: _____

License or SS
Number: _____

EDUCATION CREDITS EVALUATION FORM

Please complete the evaluation by circling the number that best corresponds to your answer.

Upon completion of this program, I am able to:	Above	Average	Below		
Part I. Objectives Evaluation					
1. Describe the Needlestick Safety and Prevention Act that was signed into law.	5	4	3	2	1
2. Discuss the requirements for compliance to the legislation.	5	4	3	2	1
3. Describe four types of safety devices available in the market today.	5	4	3	2	1
4. Discuss the process recommended for selecting a safety device.	5	4	3	2	1
5. Describe acceptable sharps disposal collectors and procedures.	5	4	3	2	1
6. Describe the components of the exposure control plan.	5	4	3	2	1
7. Discuss the procedure to follow if a needlestick injury occurs.	5	4	3	2	1
Part II. Program Evaluation					
1. The content was appropriate to the purpose and objectives.	5	4	3	2	1
2. The independent learning format was effective.	5	4	3	2	1
3. The content was clear and easily understood.	5	4	3	2	1
4. My personal objectives were met.	5	4	3	2	1

Completion Time: Hours _____ Minutes _____

What things were most beneficial about this program? _____

What things were least beneficial about this program? _____

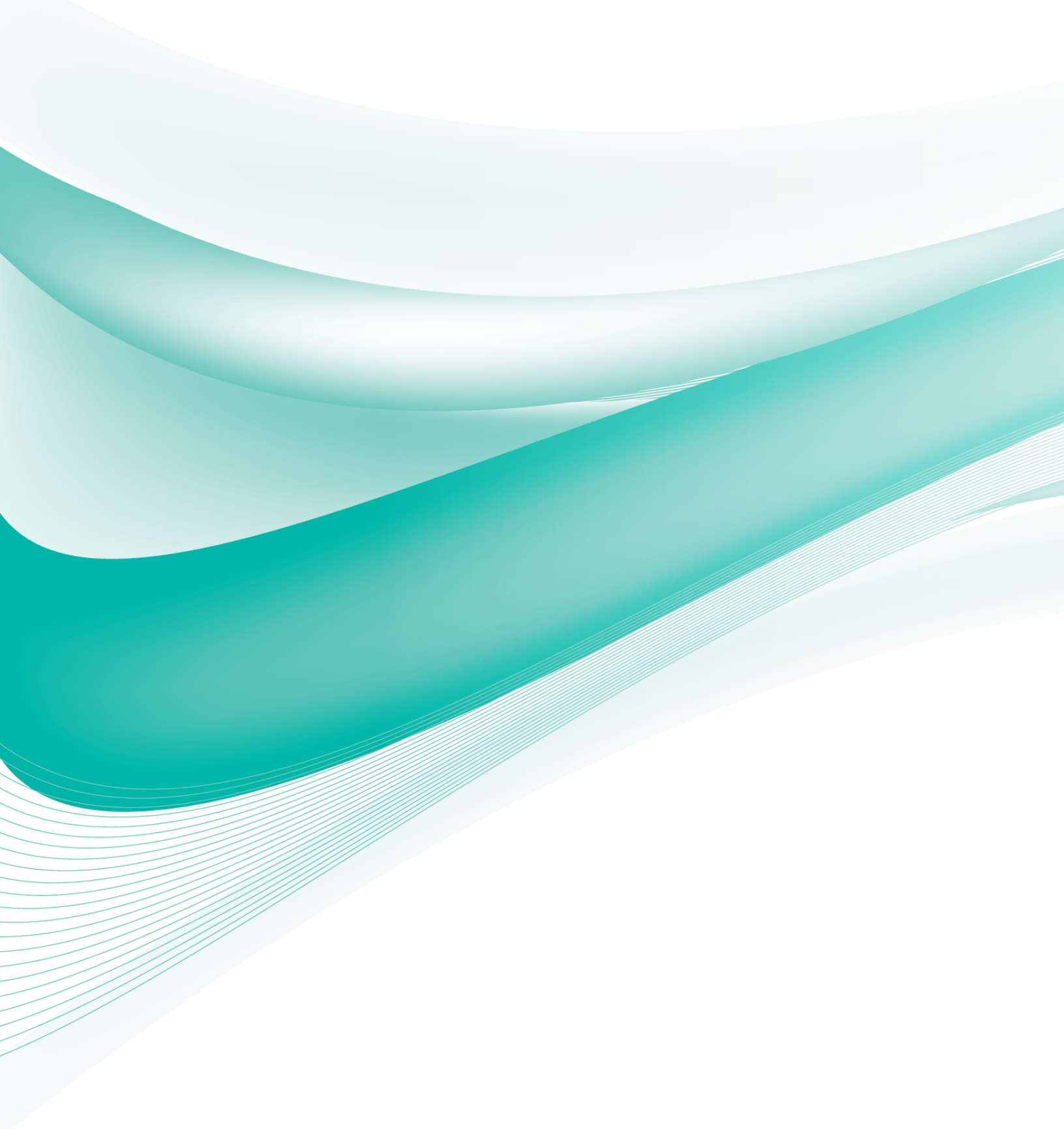
Additional comments or suggestions? _____

Signature Needed:

“I completed the independent learning module in full and acknowledge that the information provided is correct and accurate.”

Participant's signature

Date



Sponsored by:

