Beaver-Visitec International
Sharps Safety in the Ophthalmic Setting

Prepared for Clinical Staff
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Jan has designed this special education booklet as a guide to help facilities achieve compliance with the Bloodborne Pathogens Standard, revised by the Needlestick Safety and Prevention Law as it applies to the ophthalmic setting. If additional help is required, such as consulting services, seminar presentations, customized programs, or articles for publication on this or other OSHA issues, contact Jan Harris at:
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About This Publication

The Bloodborne Pathogens Standard, revised by the Needlestick Safety and Prevention Act of 2000, set forth requirements for healthcare facilities on the evaluation and use of safety-engineered devices, employee solicitation, record keeping, and employee training. The Bloodborne Pathogens Standard applies to all healthcare employers, including those in physician offices, surgery centers, outpatient clinics, home care and nursing homes. The purpose of this booklet is to provide clear and concise information on what is really required. This publication uses a question and answer format to address common questions about the Needlestick Safety and Prevention Law, and Bloodborne Pathogens Standard.

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

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 or non-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.
Introduction

This document is intended to educate clinical employees in the ophthalmic surgical and ambulatory settings on the Needlestick Safety and Prevention Act of 2000 and its continuing importance for the healthcare worker today. The intent is to understand requirements, achieve compliance, and protect the health and welfare of healthcare workers.
Objectives, Credits and Requirements

PROGRAM OBJECTIVES
At the end of this program, the participant will be able to:
1. Define the Needlestick Safety and Prevention Act of 2000 that was signed into law.
2. Discuss why it was determined to be necessary to pass the Act.
4. Identify facts regarding Hepatitis C Virus (HCV) transmission.
5. Discuss examples of types of safety devices.
6. List the steps in the process of incorporating safety devices into use in a facility.
7. Describe the steps to follow if a needlestick occurs.

EDUCATION CREDITS
This activity for 2.0 contact hours is provided by Josie Stone Consulting LLC, which is accredited as a provider of continuing education in nursing by the California Board of Registered Nursing, Provider Number CEP15231.

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:
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   Josie Stone Consulting LLC
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   Herriman, UT 84096
   OR
   Fax the Registration/Evaluation Form on pages 33-35 to: 801-254-9058
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The 1980s brought the fear of AIDS as well as an increased incidence of Hepatitis B infection. Over 5,000 healthcare workers a year were contracting Hepatitis B (HBV) on the job.² Hepatitis C (HCV) was fast becoming a player. 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 habits such as two-handed recapping and improper disposal of used sharps. On March 6, 1992, the Bloodborne Pathogens Standard (The Standard) became effective. It aimed to protect workers from exposures to blood and other potentially infectious materials which were occurring mainly through needlesticks and other contaminated sharps injuries. The Standard includes requirements such as engineering controls, prevention of two-handed recapping, and personal protective equipment.

After years of research, development, and clinical data collection, it was determined that advancements in safety device technologies had significantly progressed and their use could substantially reduce the risk of sharps injuries.

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 health care workers the emotional and physical trauma associated with needlestick injuries.”

As a result, several states passed legislation mandating the implementation of safety medical devices. Then in October 2000 the United States Congress unanimously passed the federal Needlestick Safety and Prevention Act, which was signed into law by President Clinton on November 6, 2000 (Federal Bill HR 5178).³ OSHA was mandated to enforce the law by updating the Bloodborne Pathogens (BBP) Standard to strengthen the requirements related to the use of safety engineered sharps devices (safety medical devices). Enforcement of the new standard began on July 17, 2001. States with their own OSHA approved plans were required to adopt standards at least as strict as the federal standard by October 18, 2001.
What is the risk of infection after an occupational exposure?17

Hepatitis B Virus (HBV)
Healthcare workers who have received hepatitis B vaccine and have developed immunity to the virus are at virtually no risk for infection. For an unvaccinated person, the risk from a single needlestick or a cut exposure to HBV-infected blood ranges from 6%–30% and depends on the hepatitis B e antigen (HBeAg) status of the source individual. Individuals who are both hepatitis B surface antigen (HBsAg) positive and HBeAg positive have more virus in their blood and are more likely to transmit HBV.

Hepatitis C Virus (HCV)
Based on limited studies, the estimated risk for infection after a needlestick or cut exposure to HCV-infected blood is approximately 1.8% (range 0%-10%). The risk following a blood splash is unknown but is believed to be very small; however, HCV infection from such an exposure has been reported.

Human Immunodeficiency Virus (HIV)
- The average risk for HIV infection after a needlestick or cut exposure to HIV-infected blood is 0.3% (about 1 in 300). Stated another way, 99.7% of needlestick/cut exposures to HIV-contaminated blood do not lead to infection.
- The risk after exposure of the eye, nose, or mouth to HIV-infected blood is estimated to be, on average, 0.1% (1 in 1,000).
- The risk after exposure of the skin to HIV-infected blood is estimated to be less than 0.1%. A small amount of blood on intact skin probably poses no risk at all. There have been no documented cases of HIV transmission due to an exposure involving a small amount of blood on intact skin (a few drops of blood on skin for a short period of time). The risk may be higher if the skin is damaged (for example, by a recent cut), if the contact involves a large area of skin, or if the contact is prolonged.
The Importance of Compliance

Summary

There are many reasons to comply with the Needlestick Safety and Prevention Act (the “Law”). Most agree that the positive affects far outweigh the negative costs to a facility. However, as with any requirement that carries an incremental cost or requires change, some may lose sight of the value of safety, and focus on how to avoid having to make changes. In the discussion of all facility policies, the importance of safety should not be overlooked.

With safety, it is always better to anticipate a potential danger and prevent it rather than make changes after an injury occurs. Choosing to use a safety device is similar to 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 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 sharps.

Of course, the second 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 now true with safety medical devices as a result of the Needlestick Safety and Prevention Law.

Employee Safety

Close to three million Americans are infected with the Hepatitis B virus (HBV). HIV infects 800,000; and almost four million Americans carry the Hepatitis C virus (HCV). The Standard requires employees to be educated on the epidemiology, symptoms and modes of transmission of bloodborne pathogens, such as Hepatitis C, HIV and HBV, as well as other requirements.

FACTS from American Nurses Association on Hepatitis C:

• Testing for HCV after needlestick injuries has only been recommended since 1998. Hepatitis C infection is a silent epidemic. There could be thousands of nurses with occupationally acquired Hepatitis C who do not know it.
• Hepatitis C is the most frequent infection resulting from needlestick and sharps injuries.
• Hepatitis C can lead to liver failure, liver cancer, and liver transplants which can cost hundreds of thousands of dollars.
• Transmission rate is 2.7-10%.

Source: American Nurses Association. Visit the ANA web site to learn more.

A simple sharps injury can have devastating affects. OSHA estimates that “5.6 million health care workers are at risk from occupational exposure to bloodborne pathogens.” Due to sharps injuries, workers are exposed to 20 different bloodborne pathogens, resulting in an estimated 1,000 infections per year. Sharps injuries are the most common cause of occupational exposure.
The greatest numbers of needlesticks occur among:

- Nurses - 38%
- Physicians - 11%
- Surgery attendant - 9%
- Phlebotomy; IV team - 5% \(^2, 3\)

Studies show sharps injuries occur in 7-15% of all surgeries. \(^4\) In addition, according to one study, OR staff is among the least likely to report an exposure. \(^4\)

It is the responsibility of the user to utilize safety devices, and to use them correctly. By doing so, they will not only be protecting themselves, but others as well. No one wants to be responsible for injuring someone else because we made a poor choice.

Safe work practices are mandated by OSHA, but they do not eliminate the need for safety devices. For example, hands-free passing has been a safety technique used in surgery for years. While this practice is recommended by the Association of Operating Room Nurses (AORN) and others, the problem arises when the surgeon cannot look away from the operating field to place the knife in the safety zone. \(^5\)

This hazard can be minimized if the surgeon uses and activates a safety knife prior to handing off. In addition, there is the potential that even if the safety zone is used, an employee could get cut reaching for the knife. Again, if the safety blade was used, this hazard would be minimized.

### Bloodborne Pathogens Exposure - Personal Testimonies

**ER Nurse**

This is a story of a fellow nurse and friend I worked with. We were both experienced Emergency nurses, I for thirty years, and she for twenty-five. We were working together in a Level I Trauma Center, preparing a rather combative patient for admission. She was starting the IV, and needed to draw 9-10 vials of blood before hooking up the IV line, which was a familiar procedure for her to do, applying pressure to the site etc. as required. In the process of drawing the vials of blood however, because of the patient’s erratic movement, some blood was spilled onto the 4x4 gauze at the site.

The procedure was successfully completed, and we cleared the patient area prior to transportation to the floor. In the process, she noticed the 4x4 lying next to the patient's IV site. Without thinking, she picked up the gauze and disposed of it, but was not wearing gloves. She immediately remembered that the prior evening, she had cut herself on the inside of her thumb preparing dinner for her family, but still not thinking it significant, she thoroughly washed her hands and thought it would be okay.

We then went to the nurses’ station and checked the patient’s history and found that the patient had AIDS. As is very common with emergency patients, many do not reveal information about their disease processes at time of treatment. She still did not feel too much concern, and felt the thorough hand washing would have been sufficient.

Approximately two weeks later she acquired flu like symptoms—runny nose, fever, rash, swollen lymph nodes—not feeling very well, but it subsided. Nine months later, she had experienced a 10 pound weight loss, and again symptoms of swollen lymph nodes, not feeling very well, fever and diarrhea. She felt that she probably had a case of the flu, and went
to her physician. Blood work was negative. She was given antibiotics, but it did not cure her. Remembering the incident in the ER all those months before, she mentioned it to her physician, and a CD4 T-Cell count was done, which was positive.

Both of us have reviewed and reviewed everything that we did that night, and how we might have done things differently, or how we might have reminded each other about remembering the gloves and not picking up the sponge. Many “what ifs” and “what should we have done differently,” but as all nurses do, we realize that being nurses is our primary concern; helping people and taking care of people, not always thinking about ourselves, and something as seemingly insignificant as that little sponge resulted in this life-threatening disease. Had there been a device out there at the time that prevented blood loss, perhaps this may not have occurred.

She thinks back to this day everyday and how she might still be working as a nurse in a career she loved and took pride in. She was—she is a great emergency nurse. What keeps her strong now in her illness is that she feels she made a difference in her career and can continue to do so. She saved lives—she’s dying, but she saved lives. “Please tell my story to young nurses,” she says, “and perhaps it might save one nurse, or a team, because we nurses are a team.”

**ICU Nurse**

I was working in the ICU with a combative patient. This is not unusual in my work environment. I was placing an IV. Everything was going fine. I applied digital pressure at the site, and as I unhooked the chamber, the patient pulled her arm away. The blood that was left in the hub went straight across my face and into my eye. Just a few drops, not anything you would normally think about. However, the day before I had Lasik surgery. I had been cleared from my doctor to return to work, but the incision in my eye had not healed. The blood splash went across my face and into that eye. This was a patient who was HIV-positive with a high viral load and HEP-C positive, as well.

I went to the ER, and they drew blood because of the prior day’s surgery and the patient’s history. I was placed on anti-virals for three months. I have never been so sick, ever. I missed 15 days of work, but the worst thing was when I had to go home that night and tell my husband and my children. I was tested six months later, and that came back negative, and so far I am fine. But in those first six months, every time I got a cold or every time I got a few muscle aches I thought, is this it, is this how it starts? So now I get tested once a year and I have to tell every new physician I go to I have this history and why.

I think about it all the time, and putting myself in danger just by being a nurse doing the regular, normal, everyday things that we do. I wasn’t careless. I didn’t do anything wrong. The product that we had did not fail me. The patient didn’t do anything wrong, she was just doing what patients do, which was moving, but that day, at that time, with that patient, I was put in danger, and because of that, I put my family in danger. Every time I start an IV I think, is this the best product that I could be using? Am I as prepared as I could be? Do I need someone to come help me?

My advice to a new nurse would be to make sure that you have the products that you need. That they are up to standard, and that they are the best the hospital can give you. If it’s not so, then go to those people who can help you make a change. Talk to your value analysis committee, your educators, your nursing supervisors, or even your CEO. Be heard, and tell your stories. I know that every nurse I have ever met has a story about blood exposure.
Patient Safety

Patient safety is a prime focus today. Facilities must meticulously assure each aspect of the patient care process is addressed and documented. Proper instrument selection, use, and care are all a part of this process.

Single-Use Knives

Some facilities reuse disposable safety knives to reduce the cost of the more expensive devices. Manufacturers market these devices as single-use products. Sterilization and reuse of single-use knives:

- Dulls the knives, reducing the chance of a clean incision
- Places patient risk of re-use completely on the facility
- Presents potential risk of passing infection or disease to other patients

CJD

While Creutzfeldt-Jakob Disease (CJD) is associated with retinal and optic nerve surgery, the potential risk even in cataract surgery is on the minds of many facilities and surgeons alike. Prions are naturally occurring proteins that may help the brain and nervous system function. But like normal cells turning into cancerous cells and gaining the ability to metastasize, normal prions can go awry. They fold into an abnormal form, able to corrupt other normal proteins in nerve cells faster than the cell can clear them away. As the misfolded prions accumulate, they rupture the cells and create microscopic holes in the brain, which begins to take on a sponge-form appearance. That is why prion diseases are referred to as spongiform encephalopathies.

The most common prion disease in animals is bovine spongiform encephalopathy, or BSE, popularly known as “mad cow disease” because of the behavior of the affected cows when the disease is in its final stages. The most common prion disease in humans is Creutzfeldt-Jakob Disease or CJD. The incubation period for many prion diseases in humans can last up to four decades. The person shows no symptoms but his/her tissue contains diseased prions that could infect anyone who receives that tissue in transplantation and who is exposed to a medical instrument that was contaminated during an earlier procedure on this person. Diseased prions are virtually immortal and can survive being burnt to ash, intense levels of radiation, and chemicals known to kill all other pathogens.

"Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.”

The Needlestick Safety and Prevention Act.
In the June 2005 edition of *Ophthalmology Times*, Dr. Randall Olson was quoted as saying, “Concerns about prion disease transmission have led many countries in Europe to introduce legislation requiring all instrumentation coming in contact with the eye be single-use, disposable devices. However, the United States seems to be far behind in this approach.” Since recommended sterilization methods are unproven for effectiveness, disposable instruments have been designed to eliminate the risk.

**Employee and Patient Retention**

Following safety procedures as a team in a consistent manner allows employees to focus on patient care as opposed to being concerned whether they are going to suffer a sharps injury.

**Employee Safety**

Working in a safe environment where the practice demonstrates a commitment to employee safety can create a happier employee, a lower turnover rate, and fewer accidents. In fact, 88% of nurses in one survey reported that health and safety concerns influence their decisions to continue working in the field of nursing. The three pathogens of greatest concern to health care personnel—HBV, HCV and HIV—are all bloodborne.

**Patient Perception**

Instilling patient confidence can assure those patients come back. Patients want to trust their healthcare providers and feel safe. If employees demonstrate safety, patients are likely to presume the practice places a premium on patient safety as well.

**Preventing OSHA Fines**

Some facilities believe that OSHA only inspects 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.

Whether it is one medical office nurse or 500 hospital nurses, all are covered by the Bloodborne Pathogens Standard. Consequently, all of their employers are subject to OSHA fines.

Since the law was passed, OSHA officials have received many employee complaints, and inspected all types of healthcare facilities across the country. Facilities receiving citations and fines include physician practices, surgery centers, senior living communities, and hospitals.
OSHA states that employers must:

- Select and implement appropriate engineering controls. Where engineering controls will reduce either by removing, eliminating, or isolating the hazard, they must be used.
- Implement new device use, as appropriate and available.  

**Comply with the Standard**

- Assure employees are using the devices. Remove traditional devices from areas where safety devices have been implemented.
- Assure the devices are activated prior to disposal.

*Simply putting the safety devices on the shelves and allowing the employees to use them only if they desire, is not acceptable.*

OSHA fines can be issued 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 (ECP) including documentation of device evaluation
- Failure to use the device
- Failure to train employees on device use

The most common violations include absence or lack of engineering controls, annual review of the ECP, sharps injury controls, documentation of employee involvement in device evaluation and selection, annual review of medical devices, and post-exposure medical evaluation.  

Between October 2002 and September 2003, 48% of federal OSHA citations in healthcare were for BBP violations. In fact 457 inspections of non-hospital healthcare facilities resulted in $858,000.00 in penalties for BBP infractions.  

During an inspection, OSHA is likely to check sharps containers for used safety devices to ensure they are being used and properly activated.  

In addition to OSHA, Joint Commission on Accreditation of Healthcare Organizations (JCAHO) requires full compliance to the law.

**Assessing Additional Financial Costs**

Other financial risks can be much greater than any OSHA fine. When assessing cost, account for total financial risk for non-conversion to safety devices. According to the 2001 ASOA Congress on Ophthalmic Practice Management, the U.S. General Accounting Office (GAO) states that facilities could recoup added expenses for safety devices through the money they would save on testing injured workers and treating employees who contract diseases.
The Importance of Compliance

Some risks listed here have costs attached...some can be left to the imagination:

- Post exposure evaluation/follow-up for the employee $1000-$3000
- 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

Of course, the greatest cost of a needlestick is disease transmission, long-term illness and the possible loss of life. There is also the cost both financially and emotionally to family, children, and an entire way of life while struggling to live with a chronic disease. Failure to comply with the law, which is intended to protect the mothers, fathers, children, and friends working in an office, is simply not worth the relatively small savings of non-compliance.
Additional Statistics:

- 79% of all needlestick injuries occur between the time procedure is started and before disposal and 19% during manipulation and disposal of the needle (CDC/NaSH slide presentation, “Workshop for Designing, Implementing and Evaluating a Sharps Injury Prevention Program)

- The three pathogens of greatest concern to health care personnel—HBV, HCV and HIV are all bloodborne. (Infection Control and Hospital Epidemiology July 2007 Vol 28, No. 7)

- The risk of exposure to HBV-infected blood for non-vaccinated personnel is 6-30%. (CDC) Vaccination reduces risk to 0.5% (Infection Control and Hospital Epidemiology. July 2007 Vol 28. No 7/CDC Exposure to Blood Brochure 2003 p. 2)

- The transmission rate of Hepatitis C (HCV) from an accidental needlestick is 1.8% with range of 0%-10%, and of those infected 85% can be anticipated to become chronic carriers. An estimated 3.2 million persons in the United States have chronic hepatitis C virus infection. Most people do not know they are infected. (CDC Hepatitis C FAQ’s for Health Professional www.cdc.gov/hepatitis/hcv/hcvfaq.htm)

- Human Immunodeficiency Virus (HIV) is the virus that causes AIDS. The average risk of HIV infection after a needlestick injury or cut exposure to HIV-infected blood is 0.3 percent. (CDC Exposure to Blood Brochure 2003 p. 3)

- Even when no bloodborne pathogens infection occurs from an exposure, the cost to institutions is estimated to be more than $3,000. (University of Michigan pubH 6120. 2006/Nursing Advance - 07 Sep 10)

- Overall range of costs to manage reported exposures $71-$4,838 (“Costs of Management of Occupational Exposures to Blood and Body Fluids” Infection Control and Hospital Epidemiology, July 2007, Vol. 28, No 7, p 775-782)

- Serious infection by bloodborne pathogens can add up to $1 million or more in lost work time and disability payments per incident. (Curr. Med Res Opin. 2007 Sep; 23 (9) 2093-105 “Costs of Needlestick Injuries...”/(AHA brochure “Needlestick Prevention Guide”)
What are Safety Devices?

**Summary**

The original Bloodborne Pathogens Standard did not enforce the evaluation or use of safety devices, since there were few product choices available at that time. That is not the case now, as safety technology has made significant advancements. Today, there are safety devices for the most common procedures. Such devices are used to prevent percutaneous injuries before, during or after use. Examples include guarded surgical blades, needleless devices, shielded needles, blunt needles and plastic capillary tubes. Devices should have the functional and ergonomic designs that fit into existing surgical techniques as closely as possible in order to facilitate adoption and compliance.

**Examples of Safety Devices**

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

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.

**Note:** 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 facility, as long as safety devices are indeed evaluated and used. Your selection will be based on the procedures performed at your facility.
What Are Safety Devices?

- **Shielded butterfly needle** that uses a protective sheath.
- **Blood Collection Tubes**—tubes made of plastic, rather than glass, to prevent tube breakage and potential injuries.
- **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.
- **Disposable surgical knives** with retractable protective shields or guards. Allow activation of the protective shield during a single patient procedure and once device-use is completed.
- **A blood collection needle** with a hinged sheath that is engaged over the needle, covering it after use.
- **Retractable lancet**.
Summary
It is important to plan how devices will be incorporated into your facility. This section provides a step-by-step description of how the device evaluation and selection process can be accomplished.

Key Process Steps
Step 1: Make a list of all tasks in which sharps devices are utilized
Examples may include:
• Infusion therapy
• Blood collection/culture
• Injection therapy
• Surgery
• Sharps disposal

Step 2: Take an inventory of all the specific sharps devices being used
This should include types of surgical blades used, gauge and length of needles, size of syringes used for IM injections, etc.

Step 3: Schedule a staff meeting to discuss:
• The new requirements for evaluation, selection and implementation of safety products
• A timeline for completion and assignment of tasks
• Volunteers to participate in the process
• Needlestick/sharps injury data and near misses (risk managers must understand that OR staff often does not report incidents, therefore injury and illness data may not be accurate)

Step 4: Contact supplier for samples
If there is no safer option for a particular medical device, you are not required to use something other than the device that is normally used. Annually inquire about new or prospective safer options from your distributor and document this fact in the written Exposure Control Plan. Once safer options do become available, proceed through the step-by-step process to assure compliant implementation.

Step 5: Evaluate the products
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.8 The reason for this requirement is to reduce the potential of employers choosing devices based solely on economics. All employees required to handle, utilize, and dispose of sharps do not have to be involved in the evaluation and selection process, but a representative number from each affected job classification is necessary. The employees involved by the employer should represent the range of exposure situations encountered in the workplace. Documentation of employee involvement can be accomplished by:
• Listing the involved employees and describing how input was solicited
• Presenting safety minutes, evaluation forms, employee interviews
• The employers should also describe the input obtained with regard to identification, evaluation and selection of controls.

Remember, no one knows the hazards of a job better than the one performing it. For that reason, employee involvement in the safety device evaluation process, as well as on-going suggestions, encourages all clinicians to become part of the solution, instead of part of the problem.

The evaluation team should assess products and review results. Using the objective data gathered, devices will be chosen and implemented.

Step 6: Fully implement the safety devices

Employers must implement the safer medical devices that are “appropriate, commercially available, and effective.” Just because sharps injuries have not been reported in a facility, does not mean they have not occurred. The CDC estimates that half of the 800,000 needlesticks approximated to occur each year go unreported. Even if employees have never had sharps injuries 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 2-2.69, “The lack of recorded injuries on the sharps injury log or OSHA 200 (through the end of 2001) or OSHA 300 (effective January 1, 2002) does not exempt the employer from this provision.”

Standard Precautions

Hopefully, employees have been treating all patients with standard precautions. Even so, you may hear, “We have placed a box of safety products on the shelf to use for “high-risk” patients.”

OSHA 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. Selecting which patients to take additional precautions with, goes against this concept, and could lead to employee exposure to bloodborne pathogens, and would warrant a potential OSHA citation.8

There are over 20 known pathogens that can be transmitted through human blood. An estimated 800,000 people in the United States are infected with HIV, 1.25 million with HBV, and 4 million with HCV.8 Many, if not most, of these people are unaware of their infection status. It is impossible to 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.
**Usage is Mandatory**

Sometimes it is difficult to accomplish full compliance with safety device usage. Facilities may state, “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?”

To reduce risk of employee exposure to bloodborne pathogens through sharps injuries, OSHA states the following:

- “Where employee exposure can be eliminated or reduced by removing, eliminating, or isolating the hazard, safety devices must be used.”
- “Implement new device-use, as appropriate and available.”

**Applies to All Employees**

The Bloodborne Pathogens Standard applies to all workplaces, regardless of size, where there is at least one employee at risk for bloodborne pathogens exposure. 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.

The standard applies to all employees, as well as physicians who are not employees of a facility, but work there—such as physicians performing surgery at an outpatient surgery center. According to OSHA’s CPL, physicians may be cited if they create or control bloodborne pathogens hazards that expose employees at hospitals or other sites where they have staff privileges. This is in accordance with the multi-employer worksite citation policy CPL 02-00-124.

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**“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.”**

OSHA’s Compliance Directive, CPL 02-02-069
Applies to Both Private and Public Sectors

Federal OSHA’s Blood Borne Pathogens Standard covers workers in the private sector healthcare settings (for-profit or not-for-profit.) In 25 states with OSHA-approved state plans, the state, county, and municipal public employees are protected under the bloodborne pathogens standard. All other public healthcare facility employees, not already covered by state OSHA plans, are covered under the Medicare Prescription Drug Improvement and Modernization Act of 2003 as of July 1, 2004, as a condition of participation in Medicare.4

Overcoming Objections to Use

Sometimes employees, as well as physicians will resist using safety devices for a variety of reasons, including:

- **“Safety knives aren't as sharp as diamond blades.”** Some physicians may fear that disposable safety knives are not as sharp as traditional blades. Sharpness of the new disposable blades has vastly improved.12
- **“Activating the safety device takes too much time.”** Activating a safety device only takes a second or two. When conventional products are used, much more time is usually spent trying NOT to injure someone.

- **“Safety Knives are too bulky.”** Manufacturers have addressed this problem, and safety knives mimic traditional devices.
- **“Safety activation button is in the wrong place.”** Safety devices have been designed to keep the operator’s hand behind the blade; at the same time, the safety feature should be located close enough to the blade to allow easy use. Knives today are created to do just this.

Some strategies to overcoming employee objections included in “Operating Room Risk Management” include:

- Involving surgeons and staff in policy development
- Posting signs reminding staff to use and activate safety devices and use a hands-free technique as often as possible
- Educating surgical personnel on safety device use and hands-free technique on a monthly basis5
Step 7: Training

Employees who are not already familiar with a safety device will take a little time to get comfortable using it. However, many of the newer 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 most people versus the actual change itself.

Including safety in procedural step-by-step training is essential to changing behavior. Unless safety is learned as a part of the task, it is not remembered as part of the task. An example would be the following procedural steps:

• Dilation
• Tray—safety knife, needles, etc.
• Hand blade to surgeon—safety protective shield in place
• Makes an incision into the eye
• Activates safety device
• Places knife in safe-zone—or if necessary, hands to personnel (safety device activated)

Both the doctor and the entire surgical team will know that safety is not something you think about in addition to the procedure—it is a part of the procedure.

Step 8: Document the Process

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

Step 9: 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
The Safe Disposal of Used Sharps Devices

Summary
Up to 1/3 of all sharps injuries occur during the disposal process.13 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 sharps injury prevention plan.

Sharps Disposal Container Design Elements
Within the NIOSH document, sharps collector design elements that contribute to healthcare worker (HCW) risk reduction are clearly described. These elements include:

Functionality
• Puncture, leak and impact resistant
• Appropriate in size and design to accommodate the largest sharps used
• Closure mechanism 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
• Placed within arm’s reach and below eye level at their point of use
• Free of obstacles, away from wall switches, clear of impact zone

• If wall mounted, placed at appropriate 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 Functionality, Accessibility, Visibility and Accommodation criteria, NIOSH also suggests:
• 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 Exposure Control Plan – The Employer’s Plan to Protect Employees

Summary
Since 1991, employers with one or more employees (incorporated physicians are considered employees) that engage in tasks that could expose them to blood or Other Potentially Infectious Materials (OPIM), have been required to develop and annually update a written Exposure Control Plan (ECP). Under the 2001 revisions to the Standard, safety medical devices were required to be addressed as well. In addition to ECP updates previously required by OSHA, plans must document annual consideration and implementation of engineering controls such as safety medical devices, as well as solicit input from non-managerial staff regarding the selection of safety devices. Annually the employer must review each aspect of the ECP and update it if necessary. Even if no changes have occurred, the date of the update or consideration of an update needs to be entered into the ECP. Any need for process, policy, procedural, administrative, or technological change must be addressed. The facility does not have to start all over with regard to safety device evaluation; however devices and their use should be assessed each year, along with any problems that may be occurring in order to assure the facility is using products that continue to best meet its safety needs.

The ECP must include:
- Exposure determination
- Schedule and method of implementing methods of compliance, HBV vaccination and post exposure procedures, communication of hazards to employees, including labeling and training, and record keeping
- Procedure for evaluating circumstances surrounding an exposure incident
- Where and how the ECP is made accessible to employees
- At least annual review and documentation to reflect new or modified tasks and procedures which affect occupational exposure and reflect new or revised positions with occupational exposure
- Annual documentation of consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure
  - 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
- Reflection of changes in technologies that reduce exposure
- Documentation of employee input regarding new and effective engineering and work practice controls

Sharps Safety in the Ophthalmic Setting
What To Do If There Is A Sharps Injury

Summary
According to researchers, 40-70% of all needlestick injuries are unreported. This is a huge problem, and shows that employees are not taking sharps injuries seriously. Post exposure prophylaxis (PEP) for HIV is available which requires taking antiviral medications as soon as possible after exposure to HIV. PEP should begin as soon as possible but certainly within 72 hours. Treatment with 2 or 3 antiviral drugs should continue for 4 weeks, if tolerated.

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

First, there is the requirement for a Sharps Injury Log. This log is for indicating the specifics regarding the device being used if an injury occurs. The second requirement is that of evaluating 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.

Sharps Injury Log
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 necessary. The updated Standard provides for this by requiring the maintenance of a Sharps Injury Log.

Note: The federal standard exempts certain industries such as Offices and Clinics of Physicians from maintaining the Sharps Injury Log. However, twenty-five states and two territories have their own state OSHA plans. Each state plan is required to have “at least as effective needlestick protection as Federal OSHA.” Therefore, certain state OSHA plans may require employers to maintain Sharps Injury Logs. State plan contact information may be accessed at: www.osha.gov/fso/osp/index.html

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 will be reviewed to determine:

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

Quick checklist if a needlestick occurs:

- Prior to any incident, determine the Healthcare Professional (HCP) to be used for post-exposure. Post exposure evaluation and follow up is administered according to the Centers for Disease Control and Prevention
- Source individual is provided consultation regarding the incident and referral for testing
- Source signs a Source Consent/Declination form for blood testing. This document is filed.
- The Employee Exposure Incident Report is completed and a copy sent to HCP
- Employee signs an Employee Post Exposure Consent/Declination form for permission or refusal to be tested/treated

- Employee proceeds to HCP with:
  - Copy of OSHA 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)

- Sharps Injury Log is completed within 7 days
- HCP’s written opinion is received within 15 days and filed in employee’s medical record file
- HCP’s written opinion is provided to employee within 15 days of receipt by this facility
- Re-training is provided to all employees who perform the same task in which incident occurred
- Circumstances surrounding incident are documented
- Needed changes to any engineering devices are made
- Needed changes to Exposure Control Plan are made

Centers for Disease Control and Prevention (CDC) Guidelines available at www.cdc.gov/mmwr/PDF/RR/RR5011.pdf
Definitions

Needlestick Safety and Prevention Act (the Act) and the Bloodborne Pathogen Standard (the Standard) – Everything revolves around them. They set forth the legal requirements by which all healthcare facilities must comply.

HIV, HBV, HCV and the many other dangerous bloodborne pathogens – They are the essence of why the Act was written and the Standard is being enforced. They represent a real threat to healthcare workers.

Traditional Sharps Devices – These represent sharps medical devices without any built-in safety mechanism. The new legislation requires healthcare employers to replace these products with available safety medical devices if available.

Safety Medical Devices – Devices with built-in safety mechanisms to better protect employees from bloodborne pathogens exposures.

Employees (Healthcare Workers) – The law was passed to help make the workplace a safer place for all healthcare workers.

Employer – Required by the Act and the Standard to protect employees through the use of engineering controls such as safety medical devices.

OSHA (Occupational Safety and Health Administration) – Responsible for enforcing the Act.

Sharps Injury Log – Tracks sharps injuries.
Exposure Control Plan – Educates, documents, and explains the rules by which employers shall protect employees from bloodborne pathogens. Every healthcare facility is required to have one.

Engineering Controls – The definition of required engineering controls was expanded to include safety medical devices such as sharps with engineered sharps injury protections (SESIPS) and needleless systems, in addition to sharps containers. These safety devices are designed to isolate or remove the bloodborne pathogens hazard from the workplace.

Sharps with Engineered Sharps Injury Protections (SESIP) – A non-needle sharp or needle device 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, safety (or safer) medical products, safer medical devices, safety syringes, safety sharps, and safety devices.

Needleless system – A device that does not use a needle for collection or withdrawal of body fluids (after initial venous or arterial access is established), administration of medication/fluids, or any other procedure with potential percutaneous exposure to a contaminated sharp.
Frequently Asked Questions

1. What is the Needlestick Safety and Prevention Act of 2000?
Because occupational exposure to bloodborne pathogens from accidental sharps injuries continues to be a serious problem, Congress unanimously passed the Needlestick Safety and Prevention Act (the Act) (Pub. L. 106-430), which President Clinton signed into law on November 6, 2000. The Bloodborne Pathogens Standard, revised by the Needlestick Safety and Prevention Act, requires employers to identify, evaluate, and implement safer medical devices. The Act also mandated additional requirements for maintaining a sharps injury log and for the involvement of non-managerial healthcare workers in evaluating and choosing devices.

2. How does the “Needlestick Act” apply to OSHA’s Bloodborne Pathogens Standard?

3. How does the revision affect states that operate their own occupational safety and health programs?
States and territories that operate their own OSHA-approved state programs must adopt the revisions to the bloodborne pathogens standard, or adopt a more stringent amendment to their existing standard.

4. Does the “Needlestick Act” apply to me?
OSHA’s Bloodborne Pathogens Standard, including its 2001 revisions, applies to all employers who have employees with reasonably anticipated occupational exposure to blood or other potentially infectious materials (OPIM), regardless of how many workers are employed.
This would include hospitals, surgery centers, senior care communities, physician practices, and home care agencies.

5. By what date must we implement safer medical devices?
Safer medical devices were to be implemented no later than July 18, 2001 or as such devices become available.

6. What if I’ve never had an employee needlestick, do I still need to use safer devices?
Yes. OSHA standards are intended to be implemented as a means to prevent occupational injuries and illnesses.
7. Does OSHA have a list of available safer medical devices?
No. OSHA does not approve or endorse any specific product.

8. What if a safer option is not available for the medical device that I use?
If there is no safer option for a particular medical device, you are not required to use something other than the device that is normally used. Annually inquire about new or prospective safer options and document this fact in your written Exposure Control Plan.

9. Do I have to keep a confidential sharps injury log?
Employers required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 (OSHA 300) must also establish and maintain a sharps injury log. Offices of Physicians and Clinics located in Federal OSHA states are exempt from the sharps injury log, but some states may require all employers maintain this log. The log must not include the name of any injured employee in order to maintain confidentiality.

10. We feel safety-engineered devices cost too much. Is it acceptable if we delay converting to safety products until the price comes down?
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.

11. We place our sharps collector right next to the patient, so we immediately dispose of the used devices. Isn't this enough?
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.

12. We have placed a box of safety products on the shelf to use for select, high-risk situations. We feel this will suffice to protect our workers. Does this make us compliant with the new safety legislation?
The Bloodborne Pathogens Standard requires employers to both provide and ensure that their employees use safety devices in all cases where safer medical devices are available.
13. Does the safety legislation still apply when the physician is both the employer and employee?

The BBP standard applies to all workplaces, regardless of size, where there is at least one employee at risk for bloodborne pathogens exposure. If the physician is also an employee (i.e. incorporated) the standard applies.

14. Does the revised Bloodborne Pathogens Standard apply to medical facilities that have fewer than 10 employees?

OSHA's Bloodborne Pathogens Standard applies to all employers with employees who have occupational exposures, regardless of how many workers are employed. However, physicians' offices are exempt from recording and maintaining a Sharps Injury Log. All other applicable provisions of the Bloodborne Pathogens Standard still apply. Note: some state plans do require physicians' offices to maintain a Log.

15. 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 is charged with enforcing the updated Bloodborne Pathogens Standard with all employers with employees who have occupational exposures. Since the law was passed, OSHA officials have received many employee complaints, and inspected all types of healthcare facilities across the country, and have issued citations and fines to many that were not in compliance. This has included physician practices, surgery centers, senior care communities and hospitals.

16. We're a public facility, we're not covered right?

Federal OSHA's Bloodborne Pathogens Standard covers workers in the private sector healthcare settings (for-profit or not-for profit.) In 25 states with OSHA-approved state plans, the state, county, and municipal public employees are protected under the Bloodborne Pathogens Standard. All other public healthcare facility employees, not already covered by state OSHA plans, are covered under the Medicare Prescription Drug Improvement and Modernization Act of 2003 as of July 1, 2004, as a condition of participation in Medicare.

17. We use a safety zone—hands-free passing. Isn't that enough?

Hands-free passing has been a safety technique used in surgery for years. While this practice is recommended by AORN and others, the problem arises when the surgeon cannot look away from the operating field to place the knife in the safety zone. This hazard can be minimized if the surgeon uses and activates a safety knife prior to handing off. In addition, there is the potential that even if the safety zone is used, an employee could get cut reaching for the knife. Again, if the safety knife was used, this hazard would be minimized.
References

17. http://www.cdc.gov/oralhealth/infectioncontrol/faq/bloodborne_exposures.htm
Resources

The Federal Needlestick Safety and Prevention Act text
http://www.healthsystem.virginia.edu/internet/epinet/billtext.cfm

National Institute for Occupational Safety and Health (NIOSH) Healthcare Workers’ Page
http://www.cdc.gov/niosh/topics/healthcare/
800-356-4674

Occupational Safety and Health Administration (OSHA)
www.osha.gov
800-452-9595

OSHA, Health Standards
202-523-7075

Centers for Disease Control and Prevention (CDC)
www.cdc.gov
888-329-4232

CDC / NIOSH Alert on Preventing Needlestick Injuries in Healthcare

National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers
http://www.cdc.gov/niosh/docs/97-111/

Universal Precautions for Prevention of Transmission of HIV and Other Bloodborne Infections
http://www.cdc.gov/nchhstp/dphs/bp_universal_precautions.html

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm

Occupational HIV Transmission and Prevention among Health Care Workers
http://www.cdc.gov/hiv/resources/factsheets/hcwprev.htm

Viral Hepatitis B - Frequently Asked Questions
http://www.cdc.gov/ncidd/diseases/hepatitis/b/faqb.htm

Viral Hepatitis C - Frequently Asked Questions
http://www.cdc.gov/ncidd/diseases/hepatitis/c/faq.htm

Viral Hepatitis C - What Clinicians and Other Health Professionals Need to Know
http://www.cdc.gov/ncidd/diseases/hepatitis/C_Training/edu/default.htm

Training for Development of Innovative Control Technologies (TDICT) Project.

OSHA page on Bloodborne Pathogens and Needlestick Prevention. Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.
EDUCATION CREDITS – EVALUATION FORM

Directions

To obtain CE credit for this program, you must complete the registration information below and evaluation form (continued on page 35), sign and fax both to: 801-254-9058, or email to: josiesrn@aol.com or mail to:
Josie Stone RN CPNP CRNI
Josie Stone Consulting LLC
14249 South Murdock Peak Drive
Herriman, UT 84096

You should receive your certification of completion within 14 business days upon receipt of your registration and evaluation form.

This activity for 2.0 contact hours is provided by Josie Stone Consulting LLC, which is accredited as a provider of continuing education in nursing by the California Board of Registered Nursing Provider Number CEP15231.

REGISTRATION (PLEASE PRINT LEGIBLY)

Name: 
Mailing Address: 
City, State, Zip: 
Profession: 
State of Licensure: 
License or SS Number: 

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

PART I. OBJECTIVE EVALUATION

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<th>Above</th>
<th>Average</th>
<th>Below</th>
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<td>2. Discuss why it was determined to be necessary to pass the Act.</td>
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<td>3. Examine risk factors associated with using non-safety devices.</td>
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<td>4. Identify facts regarding HCV transmission.</td>
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<td>5. Discuss examples of types of safety devices.</td>
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<td>6. List the steps in the process of incorporating safety devices into use in a facility.</td>
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<td>7. Describe the steps to follow if a sharps injury occurs.</td>
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### PART II. PROGRAM EVALUATION

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<td>2. The independent learning format was effective.</td>
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<td>4. My personal objectives were met.</td>
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**Completion Time:** Hours _____ Minutes _____

**What aspects of this program were most beneficial?**

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**What aspects of this program were least beneficial?**

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**Additional comments or suggestions:**

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Participant’s signature is required. “I completed the independent learning module in full, and acknowledge that the information provided is correct and accurate.”

Participant’s signature ____________________________ Date ____________________________