

## Summary of Safer Medical Device Terms and Defining Parameters

There are many organizations that provide standards and guidance on safer medical devices and the use of “safety-engineered” products for use in preventing needlesticks and sharps injuries. For ease of reference, we have pulled together applicable terms from national agencies. There are also many state-based and professional organizations that have slightly-different definitions, but the definitions and descriptions below capture the essence of nearly all that are available and in use.

### **Occupational Safety and Health Administration (OSHA)**

Safer medical devices are in essence a type of engineering control as defined by the industrial hygiene hierarchy of controls. OSHA defines engineering controls as

*Controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.*

The OSHA Bloodborne Pathogens Standard (BPS), further defines a “sharps with engineered sharps injury protections” as a type or example of engineering controls as:

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

29 CFR 1910.1030(b)

The BPS compliance directive for the BPS offers this further description:

*This term [sharps with engineered sharps injury protections] encompasses a broad array of devices that make injury involving a contaminated sharp less likely. They include, but are not limited to: syringes with guards or sliding sheaths that shield the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering, blunt suture needles; and plastic (instead of glass) capillary tubes.*

CPL 02.02.069 - Enforcement Procedures for the  
Occupational Exposure to Bloodborne Pathogens

By International Safety Center as adapted from the former International Healthcare Worker  
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Needleless systems are included as safer medical devices and are defined by OSHA as:

*A device that does not use needles for: (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.*

1910.1030(b)

The BPS compliance directive offers this additional description:

*“Needleless systems” provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle.*

It is important to remember that when needleless systems are in place that needles, especially for IV access, are not reintroduced for medication delivery thereby negating the reason the occupational engineering control is in place. There can be additional potential adverse outcomes associated with reintroducing needles into a needleless system including infection prevention and control and patient safety issues.

Sharps containers are considered engineering controls and are critical elements to any sharps injury prevention program. According to EPINet data, nearly a quarter (25%) of all needlesticks and sharps injuries occur to non-users (downstream), so not only is activation of the safety feature an important step in reducing injuries, but so is immediate disposal into a sharps container. OSHA requires that sharps containers are closable, leakproof, puncture resistant, labeled, and color-coded (1910.1030 (d)(4)(iii)). It also has to be as close as feasible to the immediate area where sharps are being used.

### **Centers for Disease Control and Prevention (CDC)**

The CDC’s definition is similar to OSHA and defines an “engineered sharps injury prevention device” as:

*A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms; Or*

*A physical attribute built into any other type of needle device or into a non-needle sharp, which effectively reduces the risk of an exposure incident.*

*These engineering modifications generally involve one of the following strategies:*

- *Eliminate the need for a needle (substitution);*
- *Permanently isolate the needle so that it is never poses a hazard; or*
- *Provide a means to isolate or encase a needle after use.*

In addition, CDC discusses the concept of “active” and “passive” safety devices. Active safety features require some action on behalf of the user to activate the safety mechanism, including pushing a button, depressing a plunger, or advancing a hinge or sheath. Passive devices require no action and the safety mechanism becomes activated with normal use of the device. Today, only a few passive safety devices are available (i.e., IV catheters, pen needles, lancets). As it relates to the differences between these device types, the CDC states that,

*Although devices with passive safety features are intuitively more desirable, this does not mean that a safety feature that requires activation is poorly designed or not desirable. In certain situations it is not practical or feasible for the device or for the procedure to have a passive control. Therefore, whether a safety feature is active or passive should not take priority in deciding the merits of a particular device.*

Workbook for Designing, Implementing, and Evaluating a  
Sharps Injury Prevention Program. Appendix B.

### **Food and Drug Administration (FDA)**

The FDA has product design criteria for manufacturers submitting devices for FDA 510K clearance (substantial equivalence) with a “sharps injury prevention feature” that is added or engineered on to the device or as an accessory. The FDA guidance only pertains to the sharps injury prevention feature and not for the device itself.

#### FDA Design Recommendations for Sharps Injury Prevention Features

Type of Feature	Recommendation
All	The user should be able to easily tell whether the sharps injury prevention feature is activated.
All	Once activated, the sharps injury prevention feature cannot be deactivated and should remain protective through disposal.
Active (i.e., feature requires activation by the user)	It should be possible to activate the feature with a single-handed technique, allowing the user’s hands to remain behind the exposed sharp.

Needle Shield	The shield should completely enclose the needle and prevent finger access when activated.
Retractable Sharp	The sharp should be fully retracted within the housing of the device.
Fixed Recessed Needle	The housing should extend beyond, i.e., fully cover the sharp and prevent finger access.
Colored Feature or Component	The use of color should achieve a specific purpose, (e.g., differentiate device models or sizes) and conform with user conventions, (e.g., orange hubs and needle covers for insulin syringes).

Guidance for Industry and FDA Staff: Medical Devices  
with Sharps Injury Prevention Features

**World Health Organization (WHO) & International Organization for Standardization (ISO)**

The WHO has guidance on syringes with “sharps injury prevention” (SIP) features in its 2016 safe injection guideline and defers to the ISO 23908 definition. Their guidance document includes details on both SIP and reuse prevention (RUP) devices, as well as auto-disable (AD) products. The document’s focus is injection practices and does not cover all other uses of a sharp or needle.

Unfortunately, the ISO standards are not available online for free to the public. ISO standards are available only by paying a download fee. They do allow a “preview” of the standard for free and provide requirements and test methods to manufacturers for evaluating the performance parameters of SIP features and functionality. Briefly, ISO describes the 23908:2011 standard as:

*ISO 23908:2011 gives requirements and test methods for evaluating the performance parameters of sharps injury protection features, whether active or passive in design, for medical devices containing (sharp) hypodermic needles for single use, introducers for catheters and lancets, and other needles used in blood sampling. The sharps injury protection devices it covers may be provided integral to the device or combined with the device prior to use to achieve the sharps injury protection.*

ISO definitions include:

*Activation: deployment of the sharps protection mechanism*

*Active safety feature: sharps protection feature that requires an additional step by the user to activate, separate from any action needed to perform the primary intended function of the device*

*Accidental sharps injury: unintentional penetration into human tissue by the sharp after the intended use*

*Passive safety feature: sharps protection feature that does not require an additional step by the user to activate, separate from any action needed to perform the primary intended function of the device*

*Safe mode: state of the device after activation of the safety feature*

*Sharp: part of the device that can penetrate human tissue*

*Sharps injury protection feature: feature that prevents accidental sharps injury*

### **Other Professional Associations**

Several professional associations and societies provide some guidance on sharps safety like the Association of peri-Operative Registered Nurses (AORN), American Nurses Association (ANA), the Association for Professionals in Infection Control and Epidemiology (APIC), and others that typically follow the OSHA terminology and definitions described above. The ANA has a Sharps Injury Prevention Stakeholders Group that is developing terminology to use to align professionals in this field so that terms and parameters of definitions are consistent. Stay tuned for a list of terms from that group.

Training for Development of Innovative Control Technologies Project (TDICT) offers safer device evaluation forms at <http://www.tdict.org/evaluation2.html>. These forms are attached to the OSHA Bloodborne Pathogens Compliance Directive Appendix B. The forms were developed in the mid-1990s and are currently being updated and expanded to reflect currently available technologies and safer features.

### **Web Resource & Reference List**

Association of peri-Operative Registered Nurses. Sharps Safety Webpage (available only to members) <https://www.aorn.org/guidelines/guideline-implementation-topics/patient-and-worker-safety/sharps-safety>

CDC Workbook for Designing, Implementing, and Evaluating a Sharps Injury Prevention Program (2008) [http://www.cdc.gov/sharpssafety/pdf/sharpsworkbook\\_2008.pdf](http://www.cdc.gov/sharpssafety/pdf/sharpsworkbook_2008.pdf)

FDA Guidance for Industry and FDA Staff: Medical Devices with Sharps Injury Prevention Features (August 9, 2005).  
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071663.htm>

International Organization for Standardization. ISO 23908:2011. Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (available for purchase)  
<https://www.iso.org/standard/50680.html>

International Safety Center. EPINet Sharp Object Injury and Blood and Body Fluid Exposure Reports by Year. <http://internationalsafetycenter.org/exposure-reports/>

Massachusetts Sharps Injury Surveillance System.  
<http://www.mass.gov/eohhs/gov/departments/dph/programs/community-health/ohsp/sharps/overview.html>

OSHA Bloodborne Pathogens Standard (2001)  
[https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10051](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051)

OSHA Compliance Directive, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (2001)  
[https://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=directives&p\\_id=2570](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=directives&p_id=2570)

World Health Organization. WHO guideline on the use of safety-engineered syringes for intramuscular, intradermal and subcutaneous injections in health care settings.  
<http://apps.who.int/iris/bitstream/10665/250144/1/9789241549820-eng.pdf?ua=1>