Infection Control Assessment and Response (ICAR) Tool for General Infection Prevention and Control (IPC) Across Settings

Module 6. Injection Safety Facilitator Guide

This form is intended to aid an ICAR facilitator in learning about facility policies and procedures for handling controlled substances and performing sterile compounding, if applicable (Part A) and guide observations for preparation and administration of injectable medications (Part B) and immediate use sterile compounding (Part C).

Injection safety includes practices intended to prevent transmission of infectious diseases between one patient and another, or between a patient and healthcare provider, and also to prevent harms such as needlestick injuries.

Examples of practices that have resulted in transmission of viruses (e.g., hepatitis C virus (HCV), hepatitis B virus (HBV)), bacteria (e.g., methicillin-resistant *Staphylococcus aureus* (MRSA)) and/or other pathogens (e.g., fungi) include:

- Using the same syringe to administer medication to more than one patient, including when the needle was changed or the injection was administered through an intervening length of intravenous (IV) tubing;
- Accessing a medication vial or bag with a syringe that has already been used to administer medication to a patient, then using the remaining contents from that vial or bag for another patient;
- Using medications packaged as single-dose or single-use for more than one patient;
- Failing to use aseptic technique when preparing and administering injections (e.g., preparing injections near sinks or other sources of contamination)

Note: Additional information on safe injection practices can be found on the CDC website: **https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Part A. Injection Safety Interview Questions

1. Does the facility have policies and procedures to prevent diversion of controlled substances?

- ○ Yes
- ○ No
- ○ N/A– Controlled substances are not used in the facility

Document in notes details about the process to prevent diversion *(e.g., how does the facility monitor HCP access to controlled substances; how often is data reviewed; how would the facility respond to unusual access patterns)*

Notes

"Healthcare providers who steal prescription medicines or controlled substances such as opioids for their own use put patients at risk.

This can result in several types of patient harm, including:

- Substandard care delivered by an impaired healthcare provider
- Denial of essential pain medication or therapy
- Risks of infection (e.g., with hepatitis C virus or bacterial pathogens) if a provider tampers with injectable drugs"

Source: **https://www.cdc.gov/injection-safety/hcp/clinical-overview/**

"Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion."

Source**:** https://deadiversion.usdoj.gov/21cfr/cfr/1301/1301_71.htm

2. Does the facility perform sterile compounding as defined by the United States Pharmacopeia (USP)?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

*If **YES**:*

2a. Does the facility follow applicable USP general chapters (and any additional state requirements*) when performing sterile compounding?

- ○ Yes
- ○ No
- ○ Unknown
- ○ Not Assessed

If ***NO***, specify what sterile compounding standards are used by the facility:

Sterile compounding is defined as "combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication." Sterile compounding "does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if the product is prepared as a single dose for an individual patient and the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time."

For sterile compounding: refer to USP 797: Pharmaceutical Compounding – Sterile Preparations

- If performing sterile compounding with hazardous drugs (e.g., chemotherapy), USP 800: Hazardous Drugs – Handling in Healthcare Settings also applies. NIOSH has also issued guidance on the PPE and engineering controls necessary for working with hazardous drugs in healthcare settings available at: **https://www.cdc.gov/niosh/docs/2016-161/default.html**
- If working with radiopharmaceuticals refer to USP 825: Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

*Depending on state requirements, adherence to the full requirements described by USP may or may not be required. However, for the purposes of this tool CDC recommends, at a minimum, adherence to USP guidance when performing sterile compounding.

USP Chapters 797, 800 and 825 are available on the USP website: **https://www.usp.org/compounding**

Part B. Injection Safety Facility Observations

Ideally, at least two observations of different staff within the facility are observed. If direct observations cannot be gathered, then information can be obtained by asking staff.

Observation 1

1. Do HCP perform hand hygiene prior to preparing or administering an injectable medication?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"Use an alcohol-based hand rub or wash with soap and water for the following clinical indications:

a. Immediately before touching a patient.

b. Before performing an aseptic task (e.g., placing an indwelling device) or handling invasive medical devices."

Additional indications for when hands must be cleaned can be found in the link below.

***Source*:** https://www.cdc.gov/infection-control/hcp/core-practices/

2. Are injections prepared using aseptic technique in a clean area that is not adjacent to potential sources of contamination (e.g., at least one meter from sinks or other water sources; free from items that could have come in contact with blood or body fluids)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Medications should be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. Water can splash or spread as droplets more than a meter from a sink. In addition, any item that could have come in contact with blood or body fluids, such as soiled equipment used in a procedure, should not be in the medication preparation area. Examples of contaminated items that should not be placed in or near the medication preparation area include: used equipment such as syringes, needles, IV tubing, blood collection tubes, or needle holders (e.g., Vacutainer® holder).

The medication preparation area should be cleaned and disinfected on a regular basis and any time there is evidence of soiling. In addition, there should be ready access to necessary supplies (such as alcohol-based hand rub, needles and syringes in their sterile packaging, and alcohol wipes) in the medication preparation area to ensure that staff can adhere to aseptic technique.

Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it.

***Source*:** https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html

3. Are needles and syringes used for only one patient/resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Once they are used, the syringe and needle are both contaminated and must be discarded. Use a new sterile syringe and needle for each patient.

The safest practice is for a syringe and needle to be used only once to administer a medication to a single patient, after which the syringe and needle should be discarded. This practice prevents inadvertent reuse of the syringe and protects healthcare personnel from harms such as needlestick injuries.

However, when this is not feasible (e.g., when administration of incremental doses to a single patient from the same syringe is an integral part of the procedure), reuse of the same syringe and needle for the same patient should occur as part of a single procedure with strict adherence to aseptic technique. In such situations it is essential that the syringe never be left unattended and that it be discarded immediately at the end of the procedure.

***Source*:** https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html

Notes

4. Is the rubber septum on a medication vial disinfected prior to piercing?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

5. Are medication containers entered with a new needle and a new syringe, even when obtaining additional doses for the same patient/resident?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

The safest practice is to always enter a medication vial with a sterile needle and sterile syringe, even when obtaining additional doses of medication for the same patient. This adds an extra layer of safety in case, for some reason, the medication vial is not discarded at the end of the procedure as it should be and is inadvertently used on a subsequent patient.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

6. Are single dose medication vials, ampules, and bags or bottles of intravenous solution used for only one patient/resident?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case, procedure, injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

Vials that are labeled as single-dose or single-use should be used for only a single patient as part of a single case, procedure, injection. There have been multiple outbreaks resulting from healthcare personnel using single-dose or single-use vials for multiple patients.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

7. Are medication administration tubing and connectors used for only one patient/resident?

- ○ Not applicable (intravenous tubing is never used)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"Use fluid infusion or administration sets (e.g., intravenous tubing) for one patient only."

***Source*: https://www.cdc.gov/infection-control/hcp/core-practices/**

8. Are multi-dose vials dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial?

Note: *This is different from the expiration date printed on the vial.*

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Notes

A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.

Medication vials should always be discarded whenever sterility is compromised or cannot be confirmed. In addition, the United States Pharmacopeia (USP) General Chapter 797 recommends the following for multi-dose vials of sterile pharmaceuticals:

- If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
- If a multi-dose vial has **not** been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date.

The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date.

For information on storage and handling of vaccines please refer to the CDC Vaccine Storage and Handling Toolkit or the manufacturer's recommendations for specific vaccines.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

9. Are multi-dose vials that will be used for more than one patient/resident kept in a centralized medication area?

Note: *If multi-dose vials enter the immediate patient/resident treatment area (e.g., operating room, patient/resident room/cubicle) they should be dedicated only for use on that individual patient/resident or discarded immediately after use.*

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should only be kept and accessed in a dedicated clean medication preparation area (e.g., nurses station), away from immediate patient treatment areas. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters an immediate patient treatment area, it should be dedicated for single-patient use only.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

10. Are all sharps disposed of in a puncture-resistant sharps container?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

910.1030(d)(4)(iii)(A)(1)(i)

Closable;
1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;
1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and
1910.1030(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.
1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:
1910.1030(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
1910.1030(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and
1910.1030(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill."

***Source*: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030#1910.1030(d)(4)(iii)(A)(1)**

11. Are filled sharps containers disposed of in accordance with state regulated medical waste rules?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories."

***Source*: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030#1910.1030(d)(4)(iii)(A)(1)**

If full or overflowing sharps containers are noted while walking through the facility, the ICAR facilitator should ask about who has responsibility for monitoring and emptying sharps containers when they are full.

12. Are all controlled substances (e.g., Schedule II, III, IV, V drugs) kept locked within a secure area?

- ○ Not applicable (no controlled substances are used in the facility)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.75 Physical security controls for practitioners.

(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances."

***Source*: https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75**

13. Do HCP wear a facemask (e.g., surgical mask) when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)?

- ○ Not applicable (facility does not perform this procedure)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Outbreaks of bacterial meningitis following…spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask),….This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

"Wear a facemask when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)."

***Source*: https://www.cdc.gov/infection-control/hcp/core-practices/**

Notes

Part B. Injection Safety Facility Observations

Ideally, at least two observations of different staff within the facility are observed. If direct observations cannot be gathered, then information can be obtained by asking staff.

Observation 2

1. Do HCP perform hand hygiene prior to preparing or administering an injectable medication?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"Use an alcohol-based hand rub or wash with soap and water for the following clinical indications:

a. Immediately before touching a patient.

b. Before performing an aseptic task (e.g., placing an indwelling device) or handling invasive medical devices."

Additional indications for when hands must be cleaned can be found in the link below.

***Source*: https://www.cdc.gov/infection-control/hcp/core-practices/**

2. Are injections prepared using aseptic technique in a clean area that is not adjacent to potential sources of contamination (e.g., at least one meter from sinks or other water sources; free from items that could have come in contact with blood or body fluids)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Medications should be drawn up in a designated clean medication preparation area that is not adjacent to potential sources of contamination, including sinks or other water sources. Water can splash or spread as droplets more than a meter from a sink. In addition, any item that could have come in contact with blood or body fluids, such as soiled equipment used in a procedure, should not be in the medication preparation area. Examples of contaminated items that should not be placed in or near the medication preparation area include: used equipment such as syringes, needles, IV tubing, blood collection tubes, or needle holders (e.g., Vacutainer® holder).

The medication preparation area should be cleaned and disinfected on a regular basis and any time there is evidence of soiling. In addition, there should be ready access to necessary supplies (such as alcohol-based hand rub, needles and syringes in their sterile packaging, and alcohol wipes) in the medication preparation area to ensure that staff can adhere to aseptic technique.

Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

3. Are needles and syringes used for only one patient/resident (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Once they are used, the syringe and needle are both contaminated and must be discarded. Use a new sterile syringe and needle for each patient.

The safest practice is for a syringe and needle to be used only once to administer a medication to a single patient, after which the syringe and needle should be discarded. This practice prevents inadvertent reuse of the syringe and protects healthcare personnel from harms such as needlestick injuries.

However, when this is not feasible (e.g., when administration of incremental doses to a single patient from the same syringe is an integral part of the procedure), reuse of the same syringe and needle for the same patient should occur as part of a single procedure with strict adherence to aseptic technique. In such situations it is essential that the syringe never be left unattended and that it be discarded immediately at the end of the procedure.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

Notes

4. Is the rubber septum on a medication vial disinfected prior to piercing?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Parenteral medications should be accessed in an aseptic manner. This includes using a new sterile syringe and sterile needle to draw up medications while preventing contact between the injection materials and the non-sterile environment. Proper hand hygiene should be performed before handling medications and the rubber septum should be disinfected with alcohol prior to piercing it.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

5. Are medication containers entered with a new needle and a new syringe, even when obtaining additional doses for the same patient/resident?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

The safest practice is to always enter a medication vial with a sterile needle and sterile syringe, even when obtaining additional doses of medication for the same patient. This adds an extra layer of safety in case, for some reason, the medication vial is not discarded at the end of the procedure as it should be and is inadvertently used on a subsequent patient.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

6. Are single dose medication vials, ampules, and bags or bottles of intravenous solution used for only one patient/resident?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

A single-dose or single-use vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that is meant for use in a single patient for a single case, procedure, injection. Single-dose or single-use vials are labeled as such by the manufacturer and typically lack an antimicrobial preservative.

Vials that are labeled as single-dose or single-use should be used for only a single patient as part of a single case, procedure, injection. There have been multiple outbreaks resulting from healthcare personnel using single-dose or single-use vials for multiple patients.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

7. Are medication administration tubing and connectors used for only one patient/resident?

- ○ Not applicable (intravenous tubing is never used)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"Use fluid infusion or administration sets (e.g., intravenous tubing) for one patient only."

***Source*: https://www.cdc.gov/infection-control/hcp/core-practices/**

8. Are multi-dose vials dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial?

Note: *This is different from the expiration date printed on the vial.*

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
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Notes

A multi-dose vial is a vial of liquid medication intended for parenteral administration (injection or infusion) that contains more than one dose of medication. Multi-dose vials are labeled as such by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria. The preservative has no effect on viruses and does not protect against contamination when healthcare personnel fail to follow safe injection practices.

Medication vials should always be discarded whenever sterility is compromised or cannot be confirmed. In addition, the United States Pharmacopeia (USP) General Chapter 797 recommends the following for multi-dose vials of sterile pharmaceuticals:

- If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial.
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The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date.

For information on storage and handling of vaccines please refer to the CDC Vaccine Storage and Handling Toolkit or the manufacturer's recommendations for specific vaccines.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

9. Are multi-dose vials that will be used for more than one patient/resident kept in a centralized medication area?

Note: *If multi-dose vials enter the immediate patient/resident treatment area (e.g., operating room, patient/resident room/cubicle) they should be dedicated only for use on that individual patient/resident or discarded immediately after use.*

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Multi-dose vials should be dedicated to a single patient whenever possible. If multi-dose vials must be used for more than one patient, they should only be kept and accessed in a dedicated clean medication preparation area (e.g., nurses station), away from immediate patient treatment areas. This is to prevent inadvertent contamination of the vial through direct or indirect contact with potentially contaminated surfaces or equipment that could then lead to infections in subsequent patients. If a multi-dose vial enters an immediate patient treatment area, it should be dedicated for single-patient use only.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/index.html**

10. Are all sharps disposed of in a puncture-resistant sharps container?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

910.1030(d)(4)(iii)(A)(1)(i)

Closable;
1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;
1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and
1910.1030(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.
1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:
1910.1030(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
1910.1030(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and
1910.1030(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill."

***Source*: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030#1910.1030(d)(4)(iii)(A)(1)**

11. Are filled sharps containers disposed of in accordance with state regulated medical waste rules?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

"1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories."

***Source*: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030#1910.1030(d)(4)(iii)(A)(1)**

If full or overflowing sharps containers are noted while walking through the facility, the ICAR facilitator should ask about who has responsibility for monitoring and emptying sharps containers when they are full.

12. Are all controlled substances (e.g., Schedule II, III, IV, V drugs) kept locked within a secure area?

- ○ Not applicable (no controlled substances are used in the facility)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
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(a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.

(b) Controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and institutional practitioners may disperse such substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances."

***Source*: https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.75**

13. Do HCP wear a facemask (e.g., surgical mask) when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)?

- ○ Not applicable (facility does not perform this procedure)
- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

Outbreaks of bacterial meningitis following…spinal injection procedures continue to be identified among patients whose procedures were performed by a healthcare provider who did not wear a facemask (e.g., may be labeled as surgical, medical procedure, or isolation mask),….This notice serves as a reminder that facemasks should always be worn by healthcare providers when performing these spinal injection procedures.

***Source*: https://www.cdc.gov/injection-safety/hcp/clinical-safety/**

"Wear a facemask when placing a catheter or injecting material into the epidural or subdural space (e.g., during myelogram, epidural or spinal anesthesia)."

***Source*: https://www.cdc.gov/infection-control/hcp/core-practices/**

Notes

Part C. Sterile Compounding Observations

The observation elements listed below can be used to assess preparation of immediate use compounded sterile preparations (CSPs). Additional requirements addressing aseptic processes, labeling of immediate use CSPs and training of HCP who prepare immediate use CSPs are addressed in the USP 797 chapter.

A detailed assessment of sterile compounding practices, including compounding with blood-derived or other biological materials (e.g., autologous serum), is beyond the scope of this tool. To assess preparation of other CSPs, refer to relevant USP Chapters for the full list of requirements that should be followed by the facility and enlist assistance from an appropriately trained pharmacy specialist.

Sterile compounding outside of the full Category 1, 2, and 3 requirements of USP 797, including the requirement for an ISO Class 5 primary engineering control (e.g., hood), is permitted only in a limited number of circumstances, which include:

- Preparation of immediate use compounded sterile preparations (CSPs) – See Section 1.3 of USP 797
- Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling when the product is: 1) prepared as a single dose for an individual patient and 2) the approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time – See Section 1.4 of USP 797
- Preparation of allergenic extracts – See Section 21 of USP 797
- Preparation of radiopharmaceuticals – See USP 825

USP Chapters 797, 800 and 825 are available on the USP website: https://www.usp.org/compounding

1. Does administration of the immediate use CSP **begin within 4 hours** following the start of the preparation?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

USP 797 specifies that administration of immediate-use CSP must begin within 4 hours following the start of the preparation. If administration will begin more than 4 hours following the start of the preparation, the full Category 1, 2, or 3 requirements described in USP 797 must be followed.

***Source*:** USP22_HQS_Compounding_797_FAQ_Document_V2a.pdf *(PDF will open in downloads)*

From an infection control perspective, the safest practice is to prepare an injection as close as possible to the time of administration to the patient. This is to prevent compromised sterility (i.e., microbial contamination or proliferation) or compromised physical and chemical stability (e.g., loss of potency, adsorption to the container) of the medication when it is transferred outside of its original container and stored for a period of time before administration.

***Source*:** https://www.cdc.gov/injection-safety/hcp/clinical-safety/

2. Is the immediate use preparation made with ≤ 3 different sterile products?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

USP 797 specifies that immediate-use CSPs must not involve more than 3 different sterile products.

***Source*:** USP22_HQS_Compounding_797_FAQ_Document_V2a.pdf

3. Are unused starting components from a single-dose container discarded after immediate use preparation for the individual patient/ resident is complete?

- ○ Yes
- ○ No
- ○ Not observed but endorsed by frontline staff
- ○ Not observed and not endorsed by frontline staff

If a single-dose container will be used to compound for >1 patient, the full Category 1, 2, or 3 requirements described in USP 797 must be followed.

Source: USP22_HQS_Compounding_797_FAQ_Document_V2a.pdf

Notes