Frequently Asked Questions about USP <800>

For a complete list of FAQs, visit **usp.org**

What is the scope of USP <800>?

USP <800> only applies to handling of hazardous drugs (HDs) where there is a risk of exposure to patients, healthcare workers, and the environment. USP <800> is intended to balance patient access to medicines, while supporting patient safety, healthcare worker safety, and environmental protection when handling HDs in healthcare facilities.

How can I obtain more information on USP <800>?

You can find everything related to this general chapter from the USP Website.

What is a Hazardous Drug?

An HD is any drug identified as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six criteria:

- **Carcinogenicity:** *Known or suspected to cause cancer.*
- **Teratogenicity:** *Known or suspected to cause congenital disabilities.*
- **Reproductive toxicity:** *Known or suspected to cause harm to reproductive organs or fertility.*
- **Organ toxicity:** *Causes toxicity to specific organs, such as the liver or kidneys, even at low doses.*
- **Genotoxicity:** *Known or suspected to cause changes in genetic material.*
- **New drugs that mimic existing hazardous drugs:** *New drugs with similar toxic properties to known hazardous drugs.*

What is the most current NIOSH list of hazardous drugs?

NIOSH maintains a list of antineoplastic and other hazardous drugs used in healthcare settings. The most current list is the 2016 List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings. Entities should consult with their regulators and oversight agencies regarding any allowance for an implementation period.

What is an assessment of risk?

The assessment of risk is consideration of the type of HD, dosage form, risk of exposure, packaging, and manipulation. The chapter describes containment requirements for HD Active Pharmaceutical Ingredients (APIs) and antineoplastic drugs requiring manipulation. For all dosage forms of other HDs, facilities should perform an assessment of risk to determine alternative containment strategies and/or work practices, if necessary, to minimize the risk of exposure to HDs.

Can I perform an assessment of risk for an entire group of HDs *(i.e., Table 1, Table 2)* instead of listing each individual HD?

No. The assessment of risk must list each drug and dosage form individually. Dosage forms of drugs within the same group might not have the same risk of exposure. For example, crushing HD tablets or opening HD capsules may have more risk of exposure than dispensing tablets without further manipulation. HDs appear on the NIOSH list based on different characteristics, such as specific reproductive risks. The facility may have the same information for several drugs or dosage forms, but the facility's list needs to be specific to the drug and dosage form.

Continue on page 2.

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What are alternative containment strategies that may be employed under an assessment of risk?

The purpose of an assessment of risk is to identify mitigation (alternative) strategies for handling dosage forms of HDs to minimize exposure to personnel in the healthcare setting and preserve patient access to medicines. Some examples of alternative strategies include purchasing HDs in unit-of-use packaging or unit-dose packaging, reassignment of pregnant personnel, and use of additional personal protective equipment (PPE).

Are there requirements for posting signs that HDs are being handled in the facility?

Yes. Signs designating the hazard must be notably displayed before the entrance to the HD handling areas. Additionally, signs must be available for restricting access to areas where HD spills occur. However, signs are not required to be posted at the entrance of facilities.

USP <800> does not specify PPE requirements for all HD handling activities. Where can I find additional PPE recommendations?

USP <800> provides minimum PPE requirements (see <800> 7. Personal Protective Equipment). Facilities must determine appropriate PPE based on the HD handling activity and the facility's assessment of risk. Adition information can be found in: "Managing Hazardous Drug Exposure: Information for Healthcare Settings"

Are personnel involved in waste removal and cleaning required to use PPE?

Yes, personnel must wear appropriate PPE based on their assigned tasks and as described in the entity's policies

Is it required to fit-test a N95 respirator?

Yes, if a surgical N95 respirator is used, it must be fit-tested.

What PPE is required for compounding HDs?

Gowns, head, hair, shoe covers, and two pairs of gloves that meet the American Society for Testing and Materials (ASTM) standard D6978 are required for compounding sterile and nonsterile HDs. ASTM has published F3267-22 (Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs) standard for chemotherapy gowns which is gaining wide acceptance in the industry.

What PPE is required for administering HDs?

For administering antineoplastic HDs, two pairs of chemotherapy gloves tested to American Society for Testing and Materials (ASTM) D6978 standard must be worn. For administering injectable NIOSH Table 1 antineoplastic HDs, gowns shown to resist permeability by HDs must be worn in addition to two pairs of chemotherapy gloves. ASTM has published F3267-22 (Standard Specification for Protective Clothing for Use Against Liquid Chemotherapy and Other Liquid Hazardous Drugs) standard for chemotherapy gowns which is gaining wide acceptance in the industry. For administering other HDs, the PPE requirements should be specified in the entity's polices.

What is required to show that a gown will resist permeability by HDs?

Manufacturers of PPE gowns should provide this information. Gowns used for HD handling must be shown to resist permeability by HDs. The gown manufacturer should be able to provide permeability data for commonly used HDs.

<800> lists four steps in the cleaning process: *deactivation, decontamination, cleaning, and disinfecting*. What is the correct solution to use for deactivation?

Check the HD labeling for specific agents. If no specific agent is listed, use an EPA-registered oxidizer (e.g., peroxide formulations, sodium).

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