PLANNING 5

(See Sections 1, 2, and 3 in USP <800>.)

5.1 TYPES OF EXPOSURE

5.1-1 How are healthcare personnel exposed to HDs?

<800> is focused on minimizing unintentional exposure to hazardous drugs (HDs). Healthcare workers could be unintentionally exposed by touching surfaces contaminated with HD residue, inhaling the residue, or ingesting the agents. Contamination could be on the outside of packages received in the organization, on the outside of sterile or nonsterile products compounded, on work surfaces or breakroom tables, or on any number of other containers or surfaces. Pharmacy personnel who compound HDs and nurses and others who administer HDs could have the drugs splashed or spilled or even inadvertently injected by a needle stick. Environmental services personnel could be exposed to HDs when removing linens from a patient's room or removing trash from the pharmacy or patient care unit.

5.1-2 What are the types of exposures addressed by USP <800>?

Exposure can occur when hazardous drugs are inhaled, touched, injected, or ingested.

5.1-3 What are the best ways to protect against exposure to HDs?

The National Institute for Occupational Safety and Health (NIOSH) uses a framework of a Hierarchy of Controls to assess protection. (See http://www.cdc.gov/niosh/topics/hierarchy/.) *Elimination*—physically removing the hazard—and *substitution*—replacing the hazard—are effective controls, but they don't work in this situation. We need to provide these HDs for patient care.

The three remaining controls are incorporated into <800> containment strategies:

1. Engineering controls, which isolate personnel from the hazard.
2. Administrative controls, which define the way people work.
3. Personal protective equipment (PPE), which protect personnel.

5.1-4 What types of HDs need to be considered—nonsterile, sterile, chemo, or others?

All of them—check the NIOSH list of HDs[5] for all the agents that must be evaluated.

5.1-5 Are final dosage forms safer than powders?

Generally, yes, but be sure to assess what other healthcare personnel may be doing with the dosage forms dispensed. The *NIOSH Alert* notes that:

> Some drugs defined as hazardous may not pose a significant risk of direct occupational exposure because of their dosage formulation (for example, coated tablets or capsules—solid, intact medications that are administered to patients without modifying the formulation). However, they may pose a risk if solid drug formulations are altered, such as by crushing tablets or making solutions from them outside a ventilated cabinet.[4]

5.1-6 Why are manufacturers allowed to send us products that are contaminated?

There is no current requirement to mandate manufacturers to ensure the outside of their vials and packaging is free from contamination. The scope of <800> doesn't extend to manufacturers or suppliers.

5.2 NIOSH LIST OF HAZARDOUS DRUGS

5.2-1 Where can I find a list of HDs?

<800> uses the NIOSH list of HDs.[5] This is the list you need to use to be compliant with <800>. The NIOSH list sorts HDs into three tables: (1) antineoplastic agents, (2) non-antineoplastic agents, and (3) reproductive hazards.

5.2-2 Can I make my own list instead of using the NIOSH list?

No, but you can add items to your organization's list that aren't on the NIOSH list.

5.2-3 Why is the NIOSH list used in <800>?

The NIOSH list is an existing list that has been scientifically vetted and reviewed by experts. It is a publically available list, which is updated as new agents enter the market. The process for updating is announced in the *Federal Register* so is open for anyone to provide comments.

5.2-4 What is the definition of a HD?

The definition of a HD was first published in the 1990 *ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs.*[2] With slight changes, the definition was used in the 2004 *NIOSH Alert* on *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings,*[4] the 2006 *ASHP Guidelines on Handling Hazardous Drugs,*[3] and in <800>.[8]

A drug is defined as hazardous if it exhibits any of the following characteristics:

- Carcinogenicity
- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity

If a new drug, which has not yet been considered by NIOSH, mimics existing HDs in structure or toxicity it is also considered hazardous.