COMPOUNDING HAZARDOUS DRUGS 15

(See Section 13 in USP <800>.)

APIs of any type of HDs and antineoplastics must be compounded using the containment strategies and work practices defined in <800>. An entity's Assessment of Risk may exempt specific dosage forms of those agents listed in the NIOSH hazardous list tables for non-antineoplastics and reproductive hazards if alternative containment strategies and/or work practices are identified and implemented.

15.1 What type of policies should I have?

USP <800> details specific policies that must be included. See **Exhibit 15-1**. Your state, accreditation organization, or other agency may require additional policies.

15.2 In 2006, ASHP published guidelines on handling HDs, including a detailed process for decontaminating the final prepared CSP. Does <800> require use of the same steps?

The *ASHP Guidelines on Handling Hazardous Drugs*[3] contains many suggested procedural details. USP <800> leaves development of policy details to each entity. The ASHP document is a valuable resource for development of policies.

15.3 What are good sources to review for developing policies?

In addition to the list of required policies included in USP <800> (see Exhibit 15-1), review these sources:

- *ASHP Guidelines on Handling Hazardous Drugs*[3]
- *NIOSH Alert* on *Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings*[4]
- Critical Point Pearls of Knowledge archives[19]
- Joint Commission Resources Hazardous Drug Toolkit[20]

15.4 What is an *API*?

An API or active pharmaceutical ingredient is defined by USP <800> as "any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body."[8] It's informally referred to as *powder* or *raw material*.

(questions continued on p. 112)

EXHIBIT 15-1

Policies Required and Recommended in USP <800>

- List of HDs and dosage forms handled
  - Review of list every 12 months
  - Add new agents and dosage forms when used
- Assessment of Risk
  - Antineoplastics that require only packaging or counting, non-antineoplastics, and reproductive hazards can be included
  - Include
    - Type of HD
    - Dosage form
    - Risk of exposure
    - Packaging
    - Manipulation
  - Alternative containment and/or work practices used to exempt HDs from full <800> requirements
  - Review and document at least every 12 months
- Designated Person
  - Qualification and training
  - Responsibilities include
    - Develop and implement policies and procedures
    - Oversee entity compliance with USP <800> and other applicable laws, regulations, and standards
    - Ensure competency of personnel
    - Ensure environmental control of the storage and compounding areas
    - Understand rationale for risk-prevention policies and risks to personnel
    - Report potentially hazardous situations to the management team
    - Monitor the facility
    - Maintain reports of testing/sampling performed in the facility and act on the results
- Hazard Communication program
  - Written confirmation acknowledging understanding of risks
- Occupational safety program
  - Medical surveillance
    - Routine
    - Following acute exposure
- Personnel training
  - Compliance with appropriate USP standards for compounding, including <795> and <797>
  - Overview of the entity's list of HDs and their risks
  - Review of the entity's SOPs related to handling of HDs
  - Proper use of PPE
  - Proper use of equipment and devices
  - Response to known or suspected HD exposure
  - Spill management
  - Proper disposal of HDs and bulk and trace contaminated materials