HD SOP and Training Summary (per USP <800>)

Scope

1. Applies to all personnel involved with handling HDs including receiving, storage, compounding, dispensing, administering, delivering, disposal, and cleaning of HD compounding and storage areas.
2. Personnel who handle HDs are responsible for understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of HD preparations to prevent harm to patients, minimize exposure to personnel, and minimize contamination of the work and patient-care environment.
3. Personnel must also comply with USP <795> and <797> (and other applicable USP chapters) as well as all applicable state and federal laws.
4. A qualified and trained HD designated person must be responsible for developing and implementing appropriate procedures; overseeing pharmacy compliance with USP <800> and other applicable laws, regulations, and standards; ensuring competency of personnel; and ensuring environmental control of the storage and compounding areas.

Occupational Safety Plan requirements per USP <800>

1. A list of HDs
2. Facility and engineering controls
3. Competent personnel
4. Safe work practices
5. Proper use of appropriate Personal Protective Equipment (PPE)
6. Policies for HD waste segregation and disposal

Hazardous Communication Plan requirements per USP <800>

1. Written plan that describes implementation
2. HD containers labeled with identity of the material and appropriate hazard warnings
3. SDS available, readily accessible during each work shift in personnel work area
4. Personnel who may be exposed to HDs when working must be provided information and training before the initial assignment to work with an HD, and also whenever the hazard changes
5. Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

Standard Operating Procedures are required to ensure worker safety during all aspects of HD handling. SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions must be made as needed and communicated to all

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personnel handling HDs. Required SOPs include:

1. Occupational Safety Program
2. Hazard communication program
3. Use of Safety Data Sheets
4. Designation of HD areas
5. Hand hygiene and use of PPE based on activity
6. Receipt
7. Storage
8. Compounding
9. Use and maintenance of proper engineering controls
10. Use of equipment and devices.
11. Deactivation, decontamination, cleaning, and disinfection controls
12. Labeling
13. Dispensing
14. Transport
15. Disposal
16. Spill Management

Training and Competency All personnel who handle HDs or who perform custodial waste removal or cleaning activities must be trained based on their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administering, and disposing of HDs). Training must occur before the employee independently handles HDs. The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be reassessed at least every 12 months. Personnel must be trained prior to the introduction of a new HD or new equipment and prior to a new or significant change in process or SOP. All training and competency assessment must be documented. The training must include at least the following:

1. Overview of entity's list of HDs and their risks
2. Review of the entity's SOPs related to handling of HDs
3. Proper use of PPE
4. Proper use of equipment and devices (e.g., engineering controls)
6. Spill management and use of a spill kit
7. Response to known or suspected HD exposure
8. Proper disposal of HDs and trace-contaminated materials