

**Task Force on Implementation of Rules relating to
USP General Chapter 800 – Hazardous Drug
FINAL REPORT
Presented to the Texas State Board of Pharmacy
August 1, 2017**

INTRODUCTION

The Task Force was established by the Texas State Board of Pharmacy and is charged with reviewing the current laws and standards for pharmacies handling hazardous drugs; and recommending rules to implement the chapter.

The Task Force met two times on January 31, 2017, and March 27, 2017. The Task Force respectfully submits the following recommendations to the Texas State Board of Pharmacy.

RECOMMENDATIONS

The Task Force recommending including rules regarding USP 800. The task force recommended attached information be included in the rules.

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1
2 Pharmacy Health and Safety Management System. The pharmacy shall develop and maintain
3 a health and safety management system which shall, at a minimum, include the following:

- 4 (1) list of HDs;
5 (2) facility and engineering controls;
6 (3) competent personnel;
7 (4) safe work practices;
8 (5) proper use of appropriate Personal Protective Equipment (PPE); and
9 (6) policies for HD waste segregation and disposal.

10
11 Hazardous drugs.

12 (1) The pharmacist-in-charge shall be responsible for determining which drugs will be
13 included on the pharmacy's list of HDs. The pharmacy's list of HDs shall include any drugs
14 identified as Category 1 drugs on the most current list of drugs established by the National
15 Institute for Occupational Safety and Health (NIOSH) that the pharmacy handles.

16 (2) Drugs identified in Categories 2 and 3 on the most current list of drugs established by
17 NIOSH, and final dosage forms of conventionally manufactured drugs that do not require
18 any further manipulation other than counting or repackaging are not required to be handled
19 as specified in this section if the pharmacy performs a risk assessment for the drug(s). The
20 pharmacy shall maintain documentation of any risk assessments of such drugs.

21 (3) For a drug that enters the market after the most recent version of the NIOSH list is
22 established, the pharmacy shall evaluate the drug using the criteria found in the NIOSH list
23 to determine whether the drug is to be added to the pharmacy's list of HDs. If the
24 information available on a drug is deemed insufficient to make an informed decision, the
25 drug shall be considered hazardous until more information is available.

Exposure to hazardous drugs. The pharmacy shall develop and implement policies and procedures to prevent the unintentional entry of HDs into the body due to the handling of HDs and/or touching contaminated surfaces.

Responsibilities of Personnel Handling Hazardous Drugs.

(1) The pharmacist-in-charge shall designate a qualified and trained personnel member or team to develop and implement policies and procedures appropriate for the pharmacy for the safe handling of HDs.

(2) The designated person or team must thoroughly understand:

(A) risk prevention policies;

(B) risks to individuals;

(C) risk of noncompliance; and

(D) responsibility to report potentially hazardous situations to appropriate parties.

(3) All personnel who handle HDs are responsible for understanding the practices and precautions and for continually evaluating these procedures.

Designated areas.

(1) The pharmacy shall designate areas where only HDs are to be handled. The designated HD handling areas shall be restricted to authorized personnel to protect persons not involved in HD handling.

(2) The HD handling areas shall be located away from breakrooms and refreshment areas of the pharmacy.

(3) Designated areas must be available for the following:

(A) Receipt and unpacking

(i) HDs must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas.

(ii) HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas.

(B) Storage

(i) HDs shall be stored in a manner that prevents spillage or breakage if the container falls and shall not be stored on the floor.

(ii) HDs must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. The separate storage area must be an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).

(iii) Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding shall not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

(iv) Refrigerated HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.

(C) Nonsterile HD compounding

(i) Nonsterile HDs must be compounded within a C-PEC located in a C-SEC.

(ii) The C-SEC used for nonsterile compounding shall:

(I) be externally vented;

(II) be physically separated from other preparation areas;

(III) have an air exchange of at least 12 ACPH;

(IV) have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas; and

(V) operate continuously if it supplies some or all of the negative pressure in the C-SEC.

(iii) A pharmacy shall maintain a written plan for recovery from any event that leads to a loss of power to the C-PEC, or if repair or moving occurs, including the requirement that all activities occurring in the C-PEC be suspended immediately.

(iv) Water sources and drains must be located at least 1 meter away from the C-PEC.

(I) A sink shall be available for hand washing

(II) An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations shall be readily available.

(v) The C-PECs used for manipulation of nonsterile HDs must be either externally vented or have redundant-HEPA filters in series.

(vi) Nonsterile HD compounding must be performed in a C-PEC that provides personnel and environmental protection, such as a Class I Biological Safety Cabinet (BSC) or Containment Ventilated Enclosure (CVE). A Class II BSC or a compounding aseptic containment isolator (CACI) may also be used.

(vii) For occasional nonsterile HD compounding, a C-PEC used for sterile compounding may be used but must be decontaminated, cleaned, and disinfected before resuming sterile compounding in that C-PEC.

(viii) A C-PEC used only for nonsterile compounding does not require unidirectional airflow because the critical environment does not need to be ISO classified.

(ix) Surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

(x) In addition to this section, the pharmacy shall meet the requirements as specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(D) Sterile HD compounding

(i) Sterile HDs must be compounded within a C-PEC located in a C-SEC.

(ii) The C-SEC used for sterile compounding must:

(I) be externally vented;

(II) be physically separated from other preparation areas;

(III) have an appropriate air exchange; and

(IV) have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

(iii) The C-PEC must operate continuously.

(iv) A pharmacy shall maintain a written plan for recovery from any event that leads to a loss of power to the C-PEC, or if repair or moving occurs, including the requirement that all activities occurring in the C-PEC be suspended immediately.

(v) Water sources and drains must be located at least 1 meter away from the C-PEC, and in a manner such that their presence will not interfere with required ISO classifications.

(I) A sink must be available for hand washing

(II) An eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available.

(vi) Sterile HD compounding must be performed in a C-PEC that provides an ISO Class 5 or better air quality, such as a Class II or III BSC or CACI. Class II BSC types A2, B1, or B2 are acceptable.

(vii) A laminar airflow workbench (LAFW) or compounding aseptic isolator (CAI) must not be used for the compounding of an antineoplastic HD.

(viii) A BSC or CACI used for the preparation of HDs must not be used for the preparation of a non-HD unless the non-HD preparation is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.

(ix) The C-PEC shall be located in a C-SEC, which may either be an ISO Class 7 buffer room with an ISO Class 7 ante-room or an unclassified containment segregated compounding area (C-SCA).

(I) A C-SEC placed in an ISO Class 7 buffer room with an ISO class 7 ante-room shall:

(-a-) have fixed walls, HEPA-filtered supply air, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas and a minimum of 30 ACPH;

(-b-) be externally vented;

(-c-) have a minimum of 30 ACPH of HEPA-filtered supply air;

(-d-) maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas;

(-e-) maintain an air quality of ISO Class 7 or better;

(-f-) have a hand-washing sink placed in the ante-room at least 1 meter from the entrance to the HD buffer room to avoid contamination migration into the negative pressure HD buffer room; and

(-g-) have the following if the negative-pressure HD buffer room is entered through the positive-pressure non-HD buffer room:

(-1-) a line of demarcation defined within the negative-pressure buffer room for donning and doffing PPE;

(-2-) a method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination. This may be accomplished by use of a pass-through chamber between the negative-pressure buffer area and adjacent space. The pass-through chamber must be included in the facility's certification to ensure that particles are not compromising the air quality of the negative-pressure buffer room. A refrigerator pass-through must not be used;

(-3-) other methods of containment (such as sealed containers); if needed;

(II) A C-PEC I placed in a Containment segregated compounding area (C-SCA) shall:

(-a-) be placed in an unclassified C-SCA that has fixed walls, a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas, and a minimum of 12 ACPH;

(-b-) be externally vented;

(-c-) a hand-washing sink placed at least 1 meter from C-PEC and may be either inside the C-SCA or directly outside the C-SCA; and

(-d-) only be used for the preparation of low- and medium-risk HD CSPs.

(E) Sterile and nonsterile compounding

(i) For pharmacies that compound both nonsterile and sterile HDs, the respective C-PECs must be placed in separate rooms, unless those C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity.

(ii) If the C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process.

(g) Containment Supplemental Engineering Controls

(1) A CSTD must not be used as a substitute for a C-PEC when compounding.

(2) CSTDs shall be used when compounding HDs when the dosage form allows.

(3) CSTDs must be used when administering antineoplastic HDs when the dosage form allows.

(4) CSTDs known to be physically or chemically incompatible with a specific HD must not be used for that HD.

Personal protective equipment

(1) General.

(A) Appropriate PPE must be worn when handling HDs including during:

(i) receipt

(ii) storage

(iii) transport

(iv) compounding (sterile and nonsterile)

(v) deactivation/decontamination, cleaning, and disinfecting

(vi) spill control; and

(vii) waste disposal.

(B) Reusable PPE must be decontaminated and cleaned after use.

(C) The entity's SOP must describe the appropriate PPE to be worn based on its occupational safety plan and assessment of risk.

(D) The pharmacy must develop SOPs for PPE based on the risk of exposure and activities performed.

(E) All PPE worn when handling HDs shall be considered to be contaminated with, at minimum, trace quantities of HDs.

(F) PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations.

(G) PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC.

(2) Gloves.

(A) When chemotherapy gloves are required, they must meet American Society for Testing and Materials (ASTM) standard D6978 (or its successor).

(B) Chemotherapy gloves must be powder-free because powder can contaminate the work area and can adsorb and retain HDs.

(C) Gloves must be inspected for physical defects, such as pin holes or weak spots, before each use. Defective glove shall not be used.

(D) When used for sterile compounding, the outer chemotherapy gloves must be sterile.

(E) Chemotherapy gloves shall be changed every 30 minutes unless otherwise recommended by the manufacturer's documentation and must be changed when torn, punctured, or contaminated.

(F) Hands must be washed with soap and water after removing gloves.

(G) Chemotherapy gloves and sleeve covers worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

(3) Gowns.

(A) Gowns are required for compounding sterile and nonsterile HDs.

(B) When gowns are required, they must be disposable and shown to resist permeability by HDs.

(C) Gowns must be selected based on the HDs handled.

(D) Gowns must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit.

(E) Gowns must not have seams or closures that could allow HDs to pass through.

(F) Washing of non-disposable clothing contaminated with HD residue shall only be done according to facility policy as drug residue may be transferred to other clothing.

(G) Potentially contaminated clothing must not be taken home under any circumstances.

(H) Gowns must be changed per the manufacturer's information for permeation of the gown.

If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash.

(I) Gowns worn in HD handling areas must not be worn to other areas in order to avoid spreading HD contamination and exposing other healthcare workers.

(4) Head, hair, and shoe.

(A) Head, hair, and shoe covers or dedicated shoes are required for compounding sterile and nonsterile HDs.

(B) When compounding HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC.

(C) Shoe covers worn in HD handling areas must not be worn to other areas to avoid spreading HD contamination and exposing other healthcare workers.

(5) Eye and face protection.

(A) Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials when working outside of a C-PEC (e.g., working at or above eye level, or cleaning a spill).

(B) Goggles must be used when eye protection is needed. Eye glasses alone or safety glasses with side shields do not protect the eyes adequately from splashes.

(C) Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes. Face shields alone do not provide full eye and face protection.

(D) Personnel who are unpacking HDs that are not contained in plastic shall wear an elastomeric half-mask with a multi-gas cartridge and P100-filter until assessment of the packaging integrity can be made to ensure no breakage or spillage occurred during transport. If the type of drug can be better defined, a more targeted cartridge can be used.

(E) For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles.

(F) The respirator must be fit-tested and personnel must be trained to use respiratory protection.

(G) All requirements in the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134) shall be followed.

(H) An appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:

(i) attending to HD spills larger than what can be contained with a spill kit;

(ii) deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC; or

(iii) there is a known or suspected airborne exposure to powders or vapors

257 Hazardous Communication Program

258 (1) The pharmacy must develop SOPs to ensure effective training regarding proper labeling,
259 transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on
260 the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

261 (2) Elements of the hazard communication program plan must include:

262 (A) a written plan that describes how the standard will be implemented;

263 (B) all containers of hazardous chemicals must be labeled, tagged, or marked with the identity
264 of the material and appropriate hazard warnings;

265 (C) SDS for each hazardous chemical used;

266 (D) SDSs for each hazardous chemical used is readily accessible to personnel during each
267 work shift and when they are in their work areas;

268 (E) notification and training to personnel who may be exposed to hazardous chemicals when
269 working before the initial assignment to work with a hazardous chemical, and also whenever
270 the hazard changes; and

271 (F) confirmation, documented and maintained by the pharmacy, for personnel of reproductive
272 age that they understand the risks of handling HDs.

273

274 Personnel training

275 (1) All personnel who handle HDs must be trained based on their job functions including the
276 receipt, storage, compounding, repackaging, dispensing, administering, and disposing of
277 HDs.

278 (2) Training must occur before the employee independently handles HDs.

279 (3) The effectiveness of training for HD handling competencies must be demonstrated by each
280 employee.

281 (4) Personnel competency must be reassessed at least every 12 months.

(5) 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.

(6) All training and competency assessment must be documented. The training must include at least the following:

(A) Overview of pharmacy's list of HDs and their risks

(B) Review of the pharmacy's SOPs related to handling of HDs

(C) Proper use of PPE

(D) Proper use of equipment and devices

(E) Response to known or suspected HD exposure

(F) Spill management

(G) Proper disposal of HDs and trace-contaminated materials

Receiving

(1) The pharmacy must establish SOPs for receiving HDs.

(A) HDs shall be received from the supplier in impervious plastic to segregate them from other drugs and to allow for safety in the receiving and internal transfer process.

(B) HDs must be delivered to the HD storage area immediately after unpacking.

(C) PPE, including chemotherapy gloves, must be worn when unpacking HDs as specified in subsection (h) of this section.

(D) A spill kit must be accessible in the receiving area.

(E) The pharmacy must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).

(F) When opening damaged shipping containers, they shall preferably be transported to a C-PEC designated for nonsterile compounding.

(G) If a C-PEC designated for sterile compounding is the only one available, it must be disinfected after the decontamination, deactivation, and cleaning step before returning to any sterile compounding activity.

(H) Damaged packages or shipping cartons must be considered spills that must be reported to the designated person and managed according to the pharmacy's SOPs.

(I) HDs waiting to be returned to the supplier shall be segregated in a designated negative pressure area.

Labeling, packaging, transport and disposal

(1) The pharmacy must establish SOPs for the labeling, packaging, transport, and disposal of HDs. The SOPs must address prevention of accidental exposures or spills, personnel training on response to exposure, and use of a spill kit.

(A) HDs identified by the pharmacy as requiring special HD handling precautions must be clearly labeled at all times during their transport. Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.

(B) The pharmacy must have written SOPs to describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.

(i) Personnel must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility, for sterile preparations, of the HDs during transport.

(ii) Packaging materials must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs.

(C) HDs that need to be transported must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.

(i) HDs must be transported in containers that minimize the risk of breakage or leakage.

- (ii) Pneumatic tubes must not be used to transport any liquid HDs or any antineoplastic HDs because of the potential for breakage and contamination.
- (iii) When shipping HDs to locations outside the pharmacy, the pharmacy must consult the Transport Information on the SDS.
- (iv) The pharmacy must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.
- (D) All personnel who perform routine custodial waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment to prevent HD contamination.
- (E) Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

Compounding

- (1) Pharmacies and personnel involved in compounding HDs shall comply with the requirements of §291.131 (relating to Pharmacies Compounding Non-Sterile Preparations) and §291.133 (relating to Pharmacies Compounding Sterile Preparations) of this title.
- (A) When compounding HD preparations in a C-PEC, a plastic-backed preparation mat shall be placed on the work surface of the C-PEC. The mat shall be changed immediately if a spill occurs and regularly during use, and shall be discarded at the end of the daily compounding activity.
- (B) Disposable or clean equipment for compounding must be dedicated for use with HDs.
- (C) Powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities, such as crushing tablets, opening capsules, and weighing powder.

359

360 Deactivating, decontaminating, cleaning and disinfecting

361 (1) All areas where HDs are handled and all reusable equipment and devices must be
362 deactivated, decontaminated, and cleaned.

363 (2) Sterile compounding areas and devices must be subsequently disinfected.

364 (3) The pharmacy must establish written procedures for decontamination, deactivation, and
365 cleaning, and for sterile compounding areas disinfection.

366 (4) Cleaning of nonsterile compounding areas must comply with the requirements of §291.131
367 (relating to Pharmacies Compounding Non-Sterile Preparations) and §291.133 (relating to
368 Pharmacies Compounding Sterile Preparations) of this title.

369 (A) Written procedures for cleaning must include procedures, agents used, dilutions (if used),
370 frequency, and documentation requirements.

371 (B) All personnel who perform deactivation, decontamination, cleaning, and disinfection
372 activities in HD handling areas must be trained in appropriate procedures to protect
373 themselves and the environment from contamination.

374 (C) All personnel performing these activities must wear appropriate PPE resistant to the
375 cleaning agents used, including two pairs of chemotherapy gloves and impermeable
376 disposable gowns (see Personal Protective Equipment).

377 (D) Eye protection and face shields must be used if splashing is likely

378 (E) If warranted by the activity, respiratory protection must be used.

379 (F) The deactivating, decontaminating, cleaning, and disinfecting agents selected must be
380 appropriate for the type of HD contaminant(s), location, and surface materials.

381 (i) The products used must be compatible with the surface material.

382 (ii) Agents used for deactivation, decontamination, and cleaning shall be applied through the
383 use of wipes wetted with appropriate solution and not delivered by a spray bottle to avoid
384 spreading HD residue.

385 (G) All disposable materials must be discarded to meet EPA regulations and the pharmacy's
386 policies.

387 (H) Cleaning shall be performed in areas that are sufficiently ventilated.

388 (5) Residue from deactivation must be removed by decontaminating the surface. To prevent
389 corrosion, sodium hypochlorite must be neutralized with sodium thiosulfate or by following
390 with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water,
391 germicidal detergent, or sporicidal agent).

392 (6) The solution used for wiping HD packaging must not alter the product label.

393 (7) The work surface of the C-PEC must be decontaminated between compounding of different
394 HDs.

395 (A) The C-PEC must be decontaminated at least daily (when used), any time a spill occurs,
396 before and after certification, any time voluntary interruption occurs, and if the ventilation
397 tool is moved.

398 (B) C-PECs may have areas under the work tray where contamination can build up. These
399 areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the
400 contamination level in the C-PEC.

401 (C) Deactivate, decontaminate, and clean as much as possible of the C-PEC surfaces before
402 accessing the area under the work tray. When deactivating, decontaminating, and cleaning
403 the area under the work tray of a C-PEC, the containment airflows are compromised by
404 opening the cabinets. To provide protection to the worker performing this task, respiratory
405 protection may be required.

406 (8) Cleaning agents used on compounding equipment shall not introduce microbial
407 contamination. No cleaning step may be performed when compounding activities are
408 occurring.

409 (9) Before disinfection can be adequately performed, surfaces must be cleaned. Disinfection
410 must be done for areas intended to be sterile, including the sterile compounding areas.

411 Spill control

412 (1) All personnel who may be required to clean up a spill of HDs must receive proper training in
413 spill management and the use of PPE and NIOSH-certified respirators (see Personal
414 Protective Equipment).

415 (2) Spills must be contained and cleaned immediately only by qualified personnel with
416 appropriate PPE. Qualified personnel must be available at all times while HDs are being
417 handled.

418 (3) Signs must be available for restricting access to the spill area.

419 (4) Spill kits containing all of the materials needed to clean HD spills must be readily available in
420 all areas where HDs are routinely handled.

421 (5) If HDs are being prepared or administered in a non-routine healthcare area, a spill kit and
422 respirator must be available.

423 (6) All spill materials must be disposed of as hazardous waste.

424 (7) The circumstances and management of spills must be documented.

425 (8) Personnel who are potentially exposed during the spill or spill clean up or who have direct
426 skin or eye contact with HDs require immediate evaluation.

427 (9) Non-employees exposed to an HD spill shall follow pharmacy policy, which may include
428 reporting to the designated emergency service for initial evaluation and completion of an
429 incident report or exposure form.

430 (10) SOPs must be developed to prevent spills and to direct the clean up of HD spills.

431 (A) SOPs must address the size and scope of the spill and specify who is responsible for spill
432 management and the type of PPE required.

433 (B) The SOP must address the location of spill kits and clean-up materials as well as the
434 capacity of the spill kit.

(C) Written procedures shall address use of appropriate full-facepiece, chemical cartridge-type respirators if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

Documentation and Standard Operating Procedures

(1) The pharmacy must maintain SOPs for the safe handling of HDs for all situations.

(2) The SOPs must be reviewed at least every 12 months by the designated person, and the review must be documented. Revisions in forms or records must be made as needed and communicated to all personnel handling HDs.

(3) The SOPs for handling of HDs shall include:

(A) Hazard communication program

(B) Occupational safety program

(C) Designation of HD areas

(D) Receipt

(E) Storage

(F) Compounding

(G) Use and maintenance of proper engineering controls

(H) Hand hygiene and use of PPE based on activity

(I) Deactivation, decontamination, cleaning, and disinfection

(J) Dispensing

(K) Transport

(L) Environmental monitoring

(M) Disposal

(N) Spill control

(4) Personnel who transport, compound, or administer HDs must document their training according to OSHA standards and other applicable laws and regulations.