CHAPTER 15. PHARMACIES
SUBCHAPTER 3. PHARMACIES

535:15-3-9. Non-resident pharmacies
(a) Definitions. “Non-resident pharmacy” means a pharmacy, not located in Oklahoma, which transacts or does business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(b) Licensing requirements. A non-resident pharmacy shall:
   (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;
   (2) maintain in good standing a pharmacy license in its resident state;
   (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.
   (4) submit on initial licensure and on renewals a written report of an inspection conducted within the previous twenty-four (24) months by the non-resident’s state or by any organization approved by the Board;
   (5) be in a commercial location and not a personal dwelling or residence;
   (6) submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident’s pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC.
   (7) the pharmacy registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to get Oklahoma licensed in emergency or urgent situations. If the Board determines circumstances warrant they may grant up to a 90 day extension

(c) Laws and regulations. Oklahoma pharmacy laws and regulations shall apply to the practice of pharmacy for the Oklahoma portion of the nonresident pharmacy's practice or operation.
   (1) The pharmacist manager (also called pharmacist-in-charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which they are practicing. The PIC must also be licensed by the Board.
   (2) The pharmacist manager (PIC) and/or pharmacy owner(s), or partners, or corporate officer(s) shall be responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of receiving, dispensing, and/or delivering of prescriptions or prescription medications and devices to Oklahoma residents.
   (3) No pharmacist may serve as a PIC in more than one pharmacy at a time.

(d) Inspections. Non-resident pharmacies are subject to inspection and investigation.
   (1) The Board may conduct on-site periodic routine inspections and investigations during reasonable business hours.

(e) Records. Prescription records documenting prescriptions delivered and distributed to Oklahoma residents shall be identifiable, readily retrievable and available for Board review.
(1) Records must be maintained for not less than five years.
(2) Patient records shall comply with 535:15-3-14.
(3) Schedule II, III, IV, and V prescription records. These records shall be sent to the Oklahoma Prescription Drug Monitoring program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide accessible toll-free telephone counseling by a licensed pharmacist for patient drug inquiries during regular working hours. The counseling provided shall comply with the pharmaceutical care requirements listed in OAC 535:10-9.

(g) **Prescription integrity.** A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgement to dispense up to a ninety (90) day supply for maintenance non-controlled dangerous drugs, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited.

(h) **Written drug diversion detection and prevention.** The pharmacy and the pharmacy manager shall implement and follow a written drug diversion detection and prevention policy and procedure. This policy and procedure shall be available for Board review.

535:15-3-11. Prescription drugs

(a) **Authorization; Original and refill prescriptions.** No prescription for a “dangerous drug” (as defined in 59 O.S., Section 353.1) shall be filled or refilled without the authorization of a prescriber licensed by law to prescribe within the scope of his practice.

(b) **Refill time limit; Non-CDS prescriptions.** Prescriptions may only be refilled as authorized by the prescriber. There shall be a maximum of one year from date of original prescription that the prescription may be refilled. After that time a new prescription shall be required.

(c) **Drug expiration dating.** All outdated prescription drugs shall be removed from the active inventory area upon expiration and cannot be used to fill prescriptions. The removal from the pharmacy of these expired drugs must occur within six months of expiration either by shipping to a reverse distributor for destruction or by being returned to the supplier.

(d) **Prescription integrity.** A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber.

535:15-3-12.1. Electronic transfer of prescription refill information

(a) Two or more pharmacies that have established and use a common electronic file to maintain required prescription information may transfer the refill information electronically as described in Subsection (b), except as restricted in 535:15-3-12(1).

(b) Electronic transfer of prescription refill information shall be completed by a licensed pharmacist **or a permitted technician** as follows:

(1) Prior to the transfer or dispensing the pharmacist accessing the file of the original
pharmacy shall review the profile of the patient.

(2) In the electronic transfer file system the pharmacist shall be able to void the original prescription and identify the pharmacy and pharmacist taking the prescription refill information.

(3) The original pharmacy shall be notified electronically of the transfer.

(4) The rules in 535:15-3-12 (1), (3) and (5)(B),(i),(ii), (iii) apply to electronic transfers.

535:15-3-21. Prescription fill, refill and partial fill records and reports

(a) Dangerous drugs.

(1) Refills may be entered on the back of each original prescription.

(2) Refill records may be kept by using an automated data processing system to maintain the refill information.

(b) Controlled dangerous Substances (CDS) - Schedule II. No refills are allowed on Schedule II CDS.

(c) Controlled dangerous Substances (CDS) - Schedule III, IV and V Hard copy method. The refills are entered on the back of the original (hard copy) prescription according to Oklahoma Bureau of Narcotics and Dangerous Drugs' rules in OAC 475:30-1-11 et seq.

(d) CDS automated data processing method. A pharmacy may elect to use an automated data processing system to maintain the prescription files including the original information and the refill information. Caution: The pharmacy must maintain complete and retrievable prescription records for five years whether logbooks, nightly reports, or a manual system are used. If the pharmacy elects the automated system certain compliance reports are required.

(1) Nightly reports. Nightly reports are required for Schedule II and for Schedule III, IV and V. These reports will include but are not limited to:

(A) Schedule II reports will include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports (e.g run date, run by, Rx #, drug name, dose form, quantity, date written, date dispensed; pharmacist, patient and prescriber names, DEA number, and patient and prescriber addresses.)

(B) Schedule III, IV and V reports will include the same information as in (A) above, except patient and prescriber addresses are not required. These reports may be mixed or be Schedule III, IV or V specific.

(C) These nightly reports shall be verified, signed and dated by the pharmacist as required. (See CFR 1306.22 (b)(3) et seq.)

(D) These reports must be kept for five years.

(2) Logbook or file alternate procedure. In lieu of the nightly reports procedure for Schedule II, III, IV & V provided in 535:15-3-21, the pharmacy may choose to use the following method:

(A) The pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such refill dispensing shall sign a statement (in the manner described in CFR 1306.22 (b)) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by them
and is correct as shown.

(B) Such a book or file must be maintained at the pharmacy employing such a system for a period of five years after the date of dispensing the appropriately authorized refill.

(3) **Refill reports.** Any pharmacy using an automated data processing system to track refills shall be able to print such reports as required in CFR 1306.22 (b) et seq.

(4) **Audit reports.** If an automated data processing system is used to maintain refill information, the ability to print upon request the following Controlled Dangerous Substance (CDS) audit reports is required. The following required audit reports must include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports:

(A) CDS Audit Report by Drug
(B) CDS Audit Report by Prescriber
(C) CDS Audit Report by Pharmacist
(D) Patient Profile Report

**SUBCHAPTER 5. HOSPITAL PHARMACIES**

535:15-5-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"**Automated dispensing systems**" means a mechanical system controlled by a computer that perform operations or activities, relative to the storage, packaging, compounding, labeling, dispensing, administration, or distribution of medications, and which collects, controls, and maintains all transaction information.

"**Auxiliary supportive personnel**" or "**auxiliary supportive person**" means all persons, other than pharmacists, interns and techs, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy that do not require a permit or license (e.g. clerk, typist, delivery, or data entry person, etc.).

"**Certified medication order**" means a filled prescription that has been reviewed and certified by a pharmacist.

"**Certified pharmacy technician**" means a pharmacy technician who has a current Board approved pharmacy technician certification in addition to a current Oklahoma pharmacy technician permit.

"**Director of Pharmacy**" means a pharmacist licensed to engage in the practice of pharmacy in Oklahoma who is thoroughly familiar with the specialized functions of a hospital pharmacy and directs the activities of a hospital pharmacy.

"**Drug room**" means a secured room where drug inventories are maintained for use in a facility licensed and regulated by the Oklahoma Health Department, and which may be inspected by the Board.
"Hospital employee" means any individual employed by a hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.

"Hospital" or "Hospital facility" or means hospital as defined in 59 O.S. Section 353 et seq.

"Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are stored, controlled and prepared for distribution and administration for the use and/or benefit of patients in a hospital facility. Hospital pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded and prepared for dispensing to the members of the medical staff, hospital employees, and the members of their immediate families, patients being discharged, and for other persons in emergency situations.

"Medical staff" means a prescriber who has privileges to practice in the hospital facility.

"Medication order" means a prescription as defined in Title 59 O.S. Section 353.1.

"Pharmacist" means any person licensed to practice pharmacy by the Oklahoma Board.

"Pharmacy technician", "Tech", "Technician" or "RxTech" means a person who has been issued a permit by the Board to assist the pharmacist and performs nonjudgmental, technical, manipulative, nondiscretionary functions in the prescription department under the pharmacist's immediate and direct supervision.

"Remote medication order processing" or "RMOP" means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

"Remote site" means a site located within the continental United States (US) or District of Columbia (DC) that is electronically linked to the hospital via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of a hospital pharmacy for the purposes of remote medication order processing (RMOP) of a remote medication order processing pharmacy.

"Supportive personnel" means supportive personnel as defined in 59 O.S Section 353.1 et seq.

535:15-5-7.2. Supervision of pharmacy technicians
(a) All tasks performed by pharmacy technicians in the pharmacy must be accomplished under the immediate and direct supervision of an Oklahoma currently licensed pharmacist.
(b) Non-dispensing and non-compounding tasks performed in the floor stock or “satellite” areas must be under the supervision of the pharmacist.
(c) A pharmacy technician may perform certain non-judgmental tasks of dispensing as enumerated in this Subchapter provided that whenever the pharmacist leaves the pharmacy, all dispensing shall cease. Certified medical orders may be delivered during a pharmacist’s absence.
(d) The pharmacist shall include in the Policy and Procedure Manual the specific scope of
responsibilities or procedures delegated to pharmacy technicians and the in-service training of pharmacy technicians.

(e) The ratio of pharmacy technicians to supervising pharmacists shall be set by the Director of Pharmacy and should be a ratio that would be considered safe and reasonable by the certifying pharmacist. The ratio shall not exceed two five pharmacy technicians to one supervising pharmacist. See 535:15-10-52 (e) (4) for technician ratio for sterile compounding.

(f) A pharmacy intern working in the pharmacy will not affect or change this ratio.

(g) A licensed pharmacy intern shall not supervise pharmacy technicians.

(h) The pharmacist shall do the final check and certification of the technical tasks performed by technicians. This certification shall be by means of the certifying pharmacist's signature, initial or other identifying mark on a record, the medication order and/or label.

535:15-5-7.3. Auxiliary supportive personnel tasks
Auxiliary supportive personnel may perform the following tasks:
(1) Retrieve prescriptions or files as necessary;
(2) Clerical tasks such as data entry, typing labels and maintaining patient profiles;
(3) Secretarial tasks such as telephoning, filing, and typing;
(4) Accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
(5) Inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and,
(6) Help maintain a clean and orderly pharmacy.

535:15-5-7.4. Pharmacy technician tasks
Pharmacy technicians may perform the following tasks in a licensed hospital pharmacy facility in accordance with 535:15-5-7.2:
(1) any tasks auxiliary supportive personnel are allowed to perform;
(2) count and/or pour medications;
(3) affix the prescription label to the final container;
(4) affix auxiliary labels to the container as directed by the pharmacist;
(5) assist the pharmacist in the management of the controlled dangerous substance (CDS) inventory. The pharmacist remains responsible for completeness and accuracy;
(6) fill “Modified unit dose distribution systems”, “Automated dispensing systems” and/or “Unit dose distributions systems”;

(A) Pharmacy technicians may perform this task without a final check by the pharmacist provided that appropriate technology assisted safety measures (i.e. bar code scanning check points) are in place;
(B) Pharmacy specific policy and procedures are in place;
(C) Pharmacist must maintain oversight and control of the bar code assignment; and,
(D) Pharmacy technicians can transport non-CDS stock to a licensed drug room
and fill an automated dispensing system provided that both the licensed hospital pharmacy and affiliated licensed drug room are under the same corporate ownership.

(7) prepackage and label multi-dose and unit-dose packages of medication as directed by pharmacist-established procedures for such, including selection of containers, labels and lot numbers, with provisions for the pharmacist to check the finished task prior to dispensing to the patient. (While a pharmacy technician may package and label the drug, the certification is the responsibility of the pharmacist.)

(8) perform bulk reconstitution of prefabricated non-injectable medication utilizing a pharmacist established procedure for the bulk reconstitution of prefabricated noninjectable medications.

(9) perform bulk compounding, including such items as sterile bulk solutions for small-volume injectables, sterile irrigation solutions, products prepared in relatively large volume for internal or external use by patients, and reagents or other products for other departments of the hospital facility. Such intermediate and large scale compounding may be done by a pharmacy technician through the use of a procedural manual and a system of in-process and final checks and controls developed or approved by the pharmacist and which are carefully and systematically enforced.

(10) prepare sterile compounded preparations utilizing a policy and procedure that addresses the verification of the pharmaceutical constituents, the prepared label and the final product by the pharmacist following documented training and demonstrated competency as required in OAC 535:15-10-52(d).

(A) Pharmacy technicians may perform functions involving the:
   (i) reconstitution of single dosage units that are to be administered to a given patient as a unit; and/or
   (ii) addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient.

(B) Pharmacy technicians may add a single ingredient in preparing sterile compounded preparations.

(C) Certified pharmacy technicians as defined in 535:15-5-2 may prepare chemotherapy and add multiple ingredients when preparing sterile products only following documented demonstration of appropriate competency to the Director of Pharmacy or his designated pharmacist on an annual basis.

(11) record patient or medication information for later validation by the pharmacist pursuant to procedures which prevent the information from being utilized in any way until it is validated by the pharmacist. Exempt from the necessity of pharmacist validation shall be records, such as financial, inventory control, etc., which can in no way affect the safety and accuracy of medication administration to patients.

(12) select prepackaged and pre-labeled doses of medication from storage areas and place and transport to the patient area such doses in containers bearing a patient's name in a unit
dose distribution system or a modified unit dose distribution system if the pharmacist personally checks and verifies by signature or initial all patient medication before it is administered to the patient.

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PREPARATIONS

535:15-10-52. Pharmacist responsibilities
(a) All Pharmacists who engage in drug compounding, shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.
(b) Every pharmacist engaging in drug compounding must be familiar with all details of USP Compounding Standards.
(c) The pharmacist has the responsibility to:
   (1) ensure the validity of all prescriptions
   (2) certify all prescriptions.
   (3) approve or reject all components, drug product containers, closures, in-process materials, and labeling.
   (4) ensure preparations are of acceptable strength, quality, and purity.
   (5) verify all critical processes to ensure that procedures will consistently result in the expected qualities in the finished preparation.
   (6) prepare and review all compounding records to ensure that no errors have occurred in the compounding process.
   (7) ensure appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating.
   (8) ensure the proper maintenance, cleanliness, and use of all equipment used in a prescription compounding practice; and,
   (9) ensure only authorized personnel shall be in the immediate vicinity of the drug compounding operation.
   (10) perform final check of preparations prior to their release from the pharmacy.
       (A) A check for compounding accuracy must ensure accuracy of the label and volumes or quantities of all drugs and solutions
       (B) A visual examination procedure must ensure:
           (i) Comparison with original order for initial dispensing
           (ii) Accuracy of calculations
           (iii) Use of proper solutions, additives and equipment
           (iv) Labels are complete
           (v) Proper assignment of beyond use date and time
           (vi) Integrity of the container, including visual defects
(vii) Proper storage
(viii) Absence of particulate matter, precipitates, turbidity, discoloration, evidence of contamination or other signs that the preparation should not be used.

(C) The pharmacist shall reject and destroy all preparations that do not pass the final examination.
(D) Pharmacists shall document final preparation examinations prior to releasing the Compounded Sterile Preparations from the pharmacy.

(d) The pharmacist-in-charge has the responsibility to ensure that all compounders who compound sterile pharmaceuticals meet all requirements for training, testing and education set forth in these regulations and contained in the regulations set forth in USP standards.

1) Competency shall be demonstrated prior to preparing any sterile products for patient use; and
2) Whenever the quality assurance program yields unacceptable results, and
3) Whenever unacceptable or questionable techniques are observed, and
4) Evaluated at least annually.

(e) Pharmacist requirements. Any pharmacist in charge who performs or supervises the preparation or sterilization of sterile medications shall:

1) Have available written policies and procedures for all steps in the compounding of preparations. In addition, said policies and procedures shall address personnel education and training and evaluation, storage and handling, clothing, personal hygiene, hand washing, aseptic technique, quality assurance, expiration dating, and other procedures as needed.
2) Certify that all participating pharmacists, interns and technicians have completed training and testing program in sterile product preparation. Documentation of training and testing shall be available for review.
3) Develop policies and procedures to annually test and review the techniques of participating pharmacists and pharmacy technicians to assure adherence to aseptic procedures.
4) Ensure the ratio of pharmacy technicians to supervising pharmacists shall be a ratio that would be considered safe and reasonable by the certifying pharmacist. For all sterile compounding the ratio shall not exceed two pharmacy technicians for one supervising pharmacist.

(f) Staff will be trained and evaluated as follows:

1) Training is required for any individual who compounds sterile preparations. This training must be completed before the individual is allowed to compound sterile preparations.
2) Training may consist of any combination of didactic and experiential methods which must convey proper technique, infection control procedures, etc. required by USP standards,
A written test shall be administered and passed based on the material referenced above upon initial hire or prior to assignment to compound sterile preparations. Media-fill challenge tests will be used to evaluate sterile technique. Results of the media challenge tests shall be documented and logged. End product testing that results in a failure, will result in a review of the aseptic technique of the individual involved. Testing involving media challenge tests will be conducted annually for every individual involved in sterile preparation compounding. Semiannual testing will be conducted for personnel involved in high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re instructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies. Glove fingertip sampling using processes compliant with the most current USP standards required procedures shall be used to evaluate competency of personnel in performing hand hygiene and garbing procedures initially and at least annually. Such test shall be repeated until the required number of consecutive negative culture results are obtained. An 'Individual Training Record' shall be maintained for every individual involved in sterile preparation compounding. Nothing in these regulations shall prohibit a licensed student pharmacy intern engaged in experiential classes from assisting a properly qualified pharmacist in compounding sterile preparations under that pharmacist's direct supervision.

Complete documentation by a pharmacist of training and testing shall be available for inspection.

All pharmacists who engage in sterile compounding are responsible for complying with all aspects of USP Compounding Standards and these rules.

Pharmacy technicians and interns participating in the compounding of sterile preparations shall have completed a pharmacist supervised training and testing program in sterile compound preparation. Completed documentation by a pharmacist of training and testing shall be available for inspection.

PART 5. HANDLING HAZARDOUS DRUGS IN A PHARMACY

§35:15-10.73. Purpose
§35:15-10-74. Definitions [Reserved]
§35:15-10-75. Categories of Involvement
§35:15-10-76. Pharmacy List of Hazardous Drugs
§35:15-10-77. Responsibilities of Personnel Handling Hazardous Drugs
§35:15-10-78. Pharmacy and Engineering Controls
§35:15-10-79. Personal Protective Equipment
§35:15-10-80. Hazard Communication Program
§35:15-10-81. Personnel Training
535:15-10-82. Receiving and Storage
535:15-10-83. Labeling, Packaging, Transport, and Disposal
535:15-10-84. Dispensing Final/Finished Dosage Forms
535:15-10-85. Compounding, Nonsterile
535:15-10-86. Compounding, Sterile
535:15-10-87. Deactivating, Decontaminating, Cleaning, and Disinfecting
535:15-10-88. Spill Control
535:15-10-89. Documentation
535:15-10-90. Hazardous Waste
535:15-10-91. Medical Surveillance

**PART 5. HANDLING HAZARDOUS DRUGS IN A PHARMACY**

535:15-10-73. Purpose

*Part 5 of Chapter 15 of Subchapter 10* describes practice and quality standards for handling hazardous drugs (HDs) to promote personnel safety and environmental protection. Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of chemicals and sterile and nonsterile products and preparations.

535:15-10-74 Definitions [Reserved]

535:15-10-75 Categories of Involvement

(a) Drugs on the NIOSH list that are not required to follow the containment requirements if an assessment of risk is performed and implemented include:

(1) Final dosage forms of conventionally manufactured HD products and compounded preparations, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)

(2) For dosage forms of other HDs on the NIOSH list, the pharmacy may perform an assessment of risk to determine alternative containment strategies and/or work practices

(b) Some dosage forms of drugs defined as hazardous may not pose a significant risk of direct exposure due to their dosage form (e.g., tablets, capsules, liquids, semisolids). This includes solid, intact medications that are administered to patients without modifying the formulation. However, dust from tablets and capsules may present a risk of exposure by skin contact and/or inhalation.

535:15-10-76 Pharmacy List of Hazardous Drugs

(a) The National Institute for Occupational Safety and Health (NIOSH) maintains a list of antineoplastic and other HDs. Each pharmacy must maintain a list of HDs used in their pharmacy which must include any items on the current NIOSH list used by the pharmacy and any other HD as determined by the pharmacy; this list must be reviewed at least every 12 months and made available to all employees with potential exposure to HDs.

(b) An assessment of risk shall be performed for these drugs and their dosage forms to determine alternative containment strategies and/or work practices. The assessment of risk must, at a minimum, consider the following:

(1) Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
(2) Extent/Time of exposure
(3) Dosage form (tablet, capsule, powder, liquid, semisolid, etc.)
(4) Risk of exposure (inhalation, contact, etc.)
(5) Packaging
(6) Manipulations required

(c) If an assessment of risk approach is used, the pharmacy must document what alternative containment strategies and/or work practices are in effect involving specific dosage forms to minimize exposure. The assessment of risk, if used, must be reviewed and documented at least every 12 months. Generally, this procedure was utilized to develop the “Low Risk” and “High Risk” categories for this document.

(1) Low Risk HD Nonsterile Compounding
   (A) Drugs in NIOSH category Class 2 or 3.

(2) High Risk HD Nonsterile and Sterile Compounding
   (B) Drugs in NIOSH category Class 1

535:15-10-77 Responsibilities of Personnel Handling Hazardous Drugs

(a) A qualified and trained person in HDs must be designated to be responsible for:
   (1) developing and implementing appropriate HD procedures,
   (2) establishing, implementing and annually reviewing the pharmacy Standard Operating Procedures's (SOP's) policies and procedures related to HDs,
   (3) overseeing compliance with all applicable laws, regulations, and standards,
   (4) ensuring personnel competency,
   (5) ensuring environmental control of the storage and compounding areas,
   (6) overseeing the monitoring of the pharmacy,
   (7) maintaining reports of testing/sampling performed in the pharmacy, and
   (8) acting on and documenting the results.

(b) The designated person must understand the:
   (1) rationale for risk-prevention SOP's policies,
   (2) risks to themselves and others,
   (3) risks of noncompliance that may compromise safety, and the
   (4) responsibility to report potentially hazardous situations to the pharmacist in charge.

(c) Personnel handling HDs are responsible for:
   (1) understanding the fundamental practices and precautions and for continually evaluating these procedures and the quality of final HDs,
   (2) minimizing exposure to personnel,
   (3) minimizing contamination of the work environment,
   (4) ensuring "environmental control" of areas where HDs are found and handled through environmental wipe sampling,
   (5) supporting the designated person to ensure they have sufficient training, time and resources to fulfill his/her duties, and
   (6) ensuring they understand the importance of the designated person role and support it.

535:15-10-78 Pharmacy and Engineering Controls
(a) HDs must be handled appropriately to promote employee safety and environmental protection. Signage must be prominently displayed at the entrance to any area where HDs are handled and restrict access to these areas to authorized personnel. HD areas must be located away from breakrooms, refreshment, counseling areas and other areas to minimize the risk of exposure.

(b) Areas must be designated where HDs are handled, including areas for:

   (1) Receipt and unpacking
   (2) Storage
   (3) Nonsterile compounding, and
   (4) Sterile HD compounding

(c) High Risk HD nonsterile and sterile compounding areas must have negative pressure related to surrounding areas to contain HDs and minimize exposure risk.

(d) A negative pressure room is not required for low risk HD nonsterile compounding if appropriate exhaust hoods and CPEC are used.

(e) Receipt and Unpacking. HD products and all HD APIs must be unpacked in a neutral/normal or negative pressure relative to the surrounding areas.

(f) Storage

   (1) The storage area must feature smooth, impervious walls, floors and ceilings similar to a C-SEC if it is a different room.
   (2) Shelving must be smooth, impervious, easily cleaned, and "lipped" if possible to reduce the change of HD containers falling and breaking.
   (3) Refrigerated High Risk HD products should be stored in a dedicated refrigerator in a negative pressure area.

(g) Compounding, General

(1) HDs must be compounded in a controlled area where access is limited to authorized personnel trained in handling HDs. The controlled area is equipped with engineering controls to protect the preparation from cross-contamination and microbial contamination (if preparation is intended to be sterile) during all phases of the compounding process.

(2) Engineering controls for containment are divided into three categories representing primary, secondary, and supplementary levels of control.

   (A) A containment primary engineering control (C-PEC) is a ventilated device designed to minimize worker and environmental HD exposure when directly handling HDs.
   (B) The containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed.
   (C) Supplemental engineering controls [e.g., closed-system drug-transfer device (CSTD)] are adjunct controls to offer additional levels of protection.

(3) The C-PEC meets the following conditions:

   (A) If used for nonsterile compounding of HDs, it is either externally vented or uses "redundant" HEPA filter.
   (B) C-PECs are certified annually if used for nonsterile compounding and every six months if used for sterile compounding.
   (C) A C-PEC is not required if manipulations are limited to handling of final dosage forms (e.g., counting or repackaging of tablets and capsules) that do not produce particles, aerosols, or gasses.
(4) Other considerations include:

(A) A sink must be available for hand washing.

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

(C) Care must be taken to locate water sources and drains in areas where their presence will not interfere with required ISO classifications.

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

(5) Also for entities that compound both High Risk nonsterile and sterile HDs:

(A) 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.

(B) If the C-PECs used for High Risk sterile and nonsterile HD 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.

(h) Nonsterile Compounding

(1) Low-Risk HD Category

(A) For Low Risk HD nonsterile compounding, the following is used:

(i) C-PECs either externally vented (preferred) or with redundant HEPA filters in series.

(ii) 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) could also be used.

(iii) Ensure the surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area are smooth, impervious, free from cracks and crevices, and non-shedding.

(iv) Preparatory activities, such as weighing, are done in an exhaust hood setup and the weighed quantity placed in a closed container for transfer to the C-PEC for compounding.

(2) High Risk HD Category

(A) For High Risk HD nonsterile compounding, the following must be used:

(i) C-PECs either externally vented (preferred) or with redundant HEPA filters in series.

(ii) Compounding 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.

(iii) The C-PEC is placed in a C-SEC that has at least 12 ACPH which can be provided by safety cabinets and negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.
(iv) Ensure the surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area are smooth, impervious, free from cracks and crevices, and non-shedding.

(v) It operates continuously if it supplies some or all of the negative pressure in the C-SEC.

(i) Sterile Compounding

(1) The following apply to HD sterile compounding.

(A) C-PECs used for manipulation of sterile HDs must be externally vented.

(B) 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.

(C) For most known HDs, type A2 cabinets offer a simple and reliable integration with the ventilation and pressurization requirements of the C-SEC.

(D) Class II type B2 BSCs are typically reserved for use with volatile components.

(E) 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.

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

(G) 30 ACPH and negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas.

(H) It operates continuously if it supplies some or all of the negative pressure in the C-SEC.

(I) If there is loss of power to the C-PEC, or if repair or moving occurs, all activities occurring in the C-PEC must be suspended immediately. If necessary, protect the unit by covering it appropriately per the manufacturer's recommendations.

(2) An unclassified C-SCA is similar except for 12 ACPH and is for CSPs prepared in a segregated compounding area.

(3) ISO Class 7 buffer room with an ISO class 7 ante-room:

(A) The C-PEC is placed in an ISO Class 7 buffer room that has 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) The buffer room must be externally vented.

(4) Because the room through which entry into the HD buffer room (e.g., anteroom or non-HD buffer room) plays an important role in terms of total contamination control, the following is required:

(A) Minimum of 30 ACPH of HEPA-filtered supply air

(B) Maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas

(C) Maintain an air quality of ISO Class 7 or better
(D) ISO Class 7 ante-room with fixed walls is necessary to provide inward air migration of equal cleanliness classified air into the negative pressure buffer room to contain any airborne HD.

(E) A hand-washing sink must be 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.

(5) If the negative pressure HD buffer room is entered through the positive-pressure non-HD buffer room, the following is required:

(A) A line of demarcation defining the area within the negative-pressure HD buffer room for donning and doffing PPE.

(B) 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 pharmacy'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. Other methods of containment (such as sealed containers) may be used.

(6) A containment segregated compounding area (C-SCA) is characterized by:

(A) 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) being 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.

(D) only low- and medium-risk Compounded Sterile Preparations (CSPs) of HDs can be prepared in a C-SCA.

(i) General Considerations in using BSCs and isolators for Sterile HD compounding:

(1) The use of BSCs and isolators must be accompanied by a stringent program of work practices, including training, demonstrated competence, contamination reduction, and decontamination.

(2) Only a Class II BSC with outside exhaust should be used for compounding HDs; total exhaust is required if the hazardous drug is known to be volatile.

(3) Decontamination of the Class III BSC or isolator must be done in a way that contains any hazardous drug surface contamination during the cleaning process.

(4) At least daily, wipe down the outside of the Class II BSC front opening and the floor in front of the BSC with detergent, sodium hypochlorite solution, and neutralizer.

(5) Appropriate decontamination within the cabinet must be completed before the cabinet is accessed via pass-through or removable front panels.

(6) The work surface of the BSC or isolator must be decontaminated before and after compounding per the manufacturer’s recommendations or with detergent, sodium hypochlorite solution, and neutralizer.

(7) All needed supplies must be gathered before beginning compounding. Avoid exiting and reentering the work area of the BSC or isolator.

(8) Appropriate handling of the preparation in the BSC or pass-through of the isolator, including spraying or wiping with 70% alcohol or another appropriate disinfectant, is necessary for aseptic compounding.
(9) The hazardous drug contamination burden in the BSC or isolator is reduced by wiping down hazardous drug vials before placing them in the BSC or isolator.
(10) Unnecessary items must not be placed in the work area of the cabinet or isolator where hazardous drug contamination from compounding may settle on them.
(11) The BSC or isolator must not be overcrowded.
(12) Decontamination is required after any spill in the BSC or isolator during compounding.
(13) Surface decontamination of final preparations must be done before labeling and placing into the pass-through.
(14) Final preparations should be surface decontaminated within the BSC or isolator and placed into the transport bags in the BSC or in the isolator pass-through, taking care not to contaminate the outside of the transport bag.
(15) Final preparations must be placed into a transport bag while in the pass-through for removal from the cabinet.
(16) Transport bags must never be placed in the BSC or the isolator work chamber during compounding to avoid inadvertent contamination of the outside surface of the bag.
(17) All surfaces of the BSC or isolator must be decontaminated at the end of the batch, day, or shift, as appropriate to the workflow. Typically, a BSC or isolator in use 24 hours a day would require decontamination two or three times daily. Disinfect the BSC or isolator before compounding a dose or batch of sterile hazardous drugs.
(18) Surfaces of waste and sharps containers must be sealed and decontaminated before removing from the BSC or isolator.
(19) All contaminated materials (e.g., gauze, wipes, towels, wash or rinse water) should be sealed in bags or plastic containers and discarded as contaminated waste.
(20) Gloves or gauntlets must not be replaced before completion of appropriate decontamination within the cabinet.

535:15-10-79 Personal Protective Equipment
(a) Personal protective equipment (PPE) is required to provide worker protection to reduce exposure to HD particles, aerosols and residues. The NIOSH list of antineoplastic and other HDs provides general guidance on PPE for possible scenarios that may be encountered in healthcare settings.
(1) Gowns, head, hair, shoe covers, and gloves are required for compounding sterile and nonsterile HDs.
(2) Two pairs of chemotherapy gloves are required for compounding High Risk HDs.
(3) Gowns shown to resist permeability by HDs are required when compounding injectable High Risk HDs.
(4) Other activities require the PPE to be used be explained in the SOPs based on the risk of exposure and activities performed.
(5) Disposable PPE must not be re-used. Reusable PPE must be decontaminated and cleaned after use.
(6) A risk assessment may be performed allowing pharmacies to perform certain manipulations.
(b) Appropriate PPE must be worn when handling HDs including during:
(1) Receipt
(2) Storage
Gloves

(1) All gloves used must meet industry standards for handling HDs.
(2) Gloves must be powder-free and must be inspected for physical defects before use.
(3) Gloves with pin holes or weak spots must not be used.
(4) When sterile compounding, the outer chemotherapy gloves must be sterile.
(5) Chemotherapy gloves must be changed when torn, punctured, or contaminated.
(6) Hands must be washed with soap and water after removing gloves.
(7) Double Gloves shall be worn for all activities involving High Risk HDs.
(8) HDs, including handling shipping cartons or drug vials, compounding, handling of hazardous drug waste or waste from patients recently treated with hazardous drugs, and cleanup of HDs spills.
(9) Powder-free, high-quality gloves made of latex, nitrile, polyurethane, neoprene, or other materials that meet the ASTM standard for chemotherapy gloves should be selected.
(10) Gloves should be sanitized with 70% alcohol or other appropriate disinfectant before performing any aseptic compounding activity.
(11) When preparing High Risk HDs, outer gloves should be removed after wiping down final preparation but before labeling or removing the preparation from the BSC.
(12) When preparing High Risk HD's outer gloves must be placed in a containment bag while in the BSC.
(13) When preparing High Risk HD's in an isolator, a second glove must be worn inside the fixed-glove assembly.
(14) In an isolator, fixed gloves must be surface cleaned after compounding is completed to avoid spreading hazardous drug contamination to other surfaces.
(15) When preparing High Risk HD's, clean gloves (e.g., the clean inner gloves) should be used to surface decontaminate the final preparation and place the label onto the final preparation.
(16) Hands must be washed before donning and after removing gloves.
(17) Gloves should be removed with care to avoid contamination. Specific procedures for removal must be established and followed.
(18) Gloves should be removed and contained inside the Class II BSC or isolator.
(19) Contaminated gloves should be disposed of as contaminated waste if preparing High Risk HD's.
(20) When wearing two pairs of gloves in the BSC, one pair is worn under the gown cuff and the second pair placed over the cuff.
(21) When removing the gloves, the contaminated glove fingers must only touch the outer surface of the glove, never the inner surface.
(22) If the inner glove becomes contaminated, then both pairs of gloves must be changed.
(23) Whenever there is a doubt as to the cleanliness of the inner or outer gloves, don fresh gloves.
(24) Gloves used to handle High Risk hazardous drugs should be placed in a sealable plastic bag for containment within the BSC or isolator pass-through before disposal as contaminated waste.
(25) If an administration set is attached to the final preparation in the BSC or isolator, care must be taken to avoid contaminating the tubing with hazardous drug from the surface of the gloves, BSC, or isolator.
(26) Class III BSCs and isolators equipped with attached gloves or gauntlets should be considered contaminated once the BSC or isolator has been used for compounding High Risk hazardous drugs.
(27) For compounding sterile preparations, attached gloves or gauntlets must be routinely sanitized per the manufacturer’s instructions to prevent microbial contamination.
(28) Glove and gauntlet surfaces must be cleaned after compounding is complete.
(29) All final preparations must be surface decontaminated by staff, wearing clean gloves to avoid spreading contamination.

(d) Gowns
(1) Disposable gowns that resist permeability to HDs must be used.
(2) Gowns should be selected based on the HDs handled. Disposable gowns made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.
(3) Gowns must close in the back, be long sleeved, and have closed cuffs that are elastic or knit.
(4) Gowns must not have seams or closures that could allow HDs to pass through.
(5) Washing of non-disposable clothing contaminated with HD residue should only be done according to the pharmacy SOPs as drug residue may be transferred to other clothing.
(6) Change gowns as per the pharmacies facilities risk assessment guided by manufacturer's information.
(7) 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.
(8) Gowns should be removed with care to avoid spreading contamination. Specific procedures for removal must be established and followed.
(9) Hands must be washed after removing and disposing of gowns.
(10) Contamination of gowns during glove changes must be a consideration. If the inner pair of gloves requires changing, a gown change should be considered.
(11) Hazardous drug compounding in an enclosed environment, such as a Class III BSC or an isolator, may not require the operator to wear a gown. However, because the process of handling drug vials and final preparations, as well as accessing the isolator’s pass-through, may present an opportunity for contamination, the donning of a gown may be advised.

(e) Head, Hair, Shoe, and Sleeve Covers. Head and hair covers (including beard and moustache, if applicable), shoe covers, and sleeve covers provide protection from contact with HD residue.
(1) (A) When compounding High Risk HDs, a second pair of shoe covers must be donned before entering the C-SEC and doffed when exiting the C-SEC (if preparing sterile HDs).

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

(3) (C) Shoe coverings must be removed with gloved hands when leaving the compounding area.

(4) (D) When removing shoe coverings, gloves should be worn and care must be taken to prevent contamination from spreading to clean areas.

(5) (E) Hair and shoe coverings used in the handling of High Risk hazardous drug handling areas must be contained, along with used gloves, and discarded as contaminated waste.

(6) (F) Use disposable sleeve covers to protect areas of the arm that may come in contact with HDs.

(7) (G) Disposable sleeve covers made of polyethylene-coated polypropylene or other laminate materials offer better protection than those made of uncoated materials.

(f) Eye and Face Protection as Determined by pharmacy risk assessment

(1) Appropriate eye and face protection must be worn when there is a risk for spills or splashes of HDs or HD waste materials.

(2) A full face-piece respirator provides eye and face protection.

(3) Goggles must be used when eye protection is warranted.

(4) Face shields in combination with goggles provide a full range of protection against splashes to the face and eyes.

(g) Respiratory Protection as Determined by Pharmacy Risk Assessment

(1) A surgical N95 respirator provides the respiratory protection and provides a barrier to splashes, droplets, and sprays around the nose and mouth.

(2) For most activities requiring respiratory protection, a fit-tested NIOSH-certified N95 or more protective respirator is sufficient to protect against airborne particles. However, N95 respirators offer no protection against gases and vapors and little protection against direct liquid splashes.

(3) Fit-test the respirator and train workers to use respiratory protection.

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

(A) Attending to HD spills larger than what can be contained with a spill kit

(B) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC

(C) There is a known or suspected airborne exposure to powders or vapors

(h) Disposal of Used Personal Protective Equipment

(1) All PPE worn when handling High Risk HDs should be considered to be contaminated with, at minimum, trace quantities of HDs.

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

(3) PPE worn during compounding must be placed in the proper waste container before leaving the C-SEC.
(4) Chemotherapy gloves and sleeve covers (if used) 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.

(5) PPE should not leave the areas where HDs are handled.

(6) Reusable equipment such as eye and respiratory protection should be treated with a deactivating agent and cleaned after each use, and before being removed from areas where HDs are handled.

(7) Treat all disposable PPE used to prep NIOSH 1 HD's as "trace" contaminated waste unless known to have been significantly contaminated with a HD, in which case it should be treated as "bulk" contaminated waste.

535:15-10-80 Hazard Communication Program

(a) Standard Operating Procedures (SOP's) Policies and procedures are required that ensure worker safety during all aspects of HD handling. Appropriate SOPs must be developed to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS).

(b) The hazard communication program plan must include a written plan describing:

1. how the standard will be implemented,
2. that all containers of hazardous chemicals must be labeled, tagged, or marked with the pharmacy identification of the material and appropriate hazard warnings,
3. the use of a SDS for each hazardous chemical they use (29 CFR 1910.1200),
4. the mechanism for ensuring that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas,
5. how personnel who may be exposed to HDs when working are provided information and training before the initial assignment to work with HDs and whenever the hazard changes, and
6. that personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs.

(c) The hazard communication program also requires the development of a training program including at least the following topics:

1. Current list of HDs
2. Reference materials and their use (HD List, SDSs, SOPs)
3. Risks associated with handling HDs
4. Relevant SOPs
5. Personal protective equipment (PPE)
6. Use of engineering controls and other equipment
7. Exposure and spill management
8. HD waste disposal
9. Deactivation, cleaning and disinfection
10. Compounding techniques unique to HDs, e.g. negative pressure technique, or use of CSTDs for sterile compounding

(d) In addition, SOPs must be implemented describing how:

1. this training will be delivered and documented,
2. this training will be delivered to new personnel.
(3) reinforcement training will be periodically provided,
(4) a competency testing process for all personnel exposed to HDs will be accomplished,
(5) to observe and document competencies, and
(6) how similar competency testing will be performed at least annually.

535:15-10-81 Personnel Training
(a) All personnel handling HDs must be trained according to their job functions (e.g., in the receipt, storage, compounding, repackaging, dispensing, administrating, and disposing of HDs). Personnel compounding hazardous drugs must be trained in the stringent aseptic and negative-pressure techniques necessary for working with sterile hazardous drugs.
   (1) Personnel must receive this training prior to independently handling HDs.
   (2) Training effectiveness for HD handling competencies must be demonstrated by each employee.
   (3) Personnel competency must be reassessed at least every 12 months.
   (4) 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.
   (5) All training and competency assessment must be documented.
(b) This training must include the following at a minimum:
   (1) Overview of the list of HDs involved and their risks
   (2) Review of the SOPs related to the handling of HDs
   (3) Proper use of PPE
   (4) Proper use of equipment and devices (e.g., engineering controls)
   (5) Response to known or suspected HD exposure
   (6) Spill management
   (7) Proper disposal of HDs and trace-contaminated materials

535:15-10-82 Receiving and Storage
(a) Receiving
   (1) Establish SOPs for receiving HDs. Receive the HDs from the supplier in impervious plastic and segregated from other drugs. [When received from manufacturers or distributors, it is not the pharmacist's responsibility to confirm the packaging and shipping materials are clean and HD free when received.]
   (2) Wear appropriate PPE, which may include chemotherapy gloves, when unpacking HDs and a spill kit must be accessible in the receiving area.
   (3) Prior to opening, visually examine the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).
   (4) Do not unpack HDs from their external shipping containers in sterile compounding areas or in positive pressure areas.
   (5) Manufacturers are required to ensure their packaging and shipping containers are not contaminated.
(b) If the shipping container appears damaged:
   (1) Seal container without opening and contact the supplier
   (2) If the unopened package is to be returned to the supplier, enclose the package in an impervious container and label the outer container "Hazardous"
Damaged HDs must be contained in sealed containers and placed in quarantine until either returned to the company or disposed of as "bulk" hazardous waste. If the supplier declines return, dispose of as hazardous waste.

If a damaged shipping container must be opened:
1. Seal the container in plastic or an impervious container
2. Transport to a C-PEC, preferably designated for nonsterile compounding, and place on a plastic-backed preparation mat. If not available, a C-PEC designated for sterile compounding can but used but it must be disinfected after the decontamination, deactivation, and cleaning step before returning to any sterile compounding activity.
3. Open the package and remove undamaged items
4. Wipe the outside of the undamaged items with a disposable wipe
5. Enclose the damaged item(s) in an impervious container and label the outer container "Hazardous"
6. If the supplier declines return, dispose of as hazardous waste
7. Deactivate, decontaminate, and clean the C-PEC and discard the mat and cleaning disposables as hazardous waste
8. 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.
9. Segregate HDs waiting to be returned to the supplier in a designated negative pressure area. High Risk HD's should be stored under negative pressure. Clean-up must comply with established SOPs.
10. Deliver intact HDs to their specific HD storage area immediately after unpacking.

Storage
1. HDs must be stored to prevent spillage or breakage in the event the container falls.
2. HDs should not be stored on the floor.
3. HDs such as capsules or tablets that will only be counted and packaged need not be stored under special conditions.
4. HDs requiring manipulation must be stored separately from non-HDs to prevent contamination and personnel exposure.

535:15-10-83 Labeling, Packaging, Transport, and Disposal
(a) SOPs are required for the labeling, packaging, transport, and disposal of HDs. The SOPs must address:
1. Prevention of accidental exposures or spills.
2. Personnel training on response to exposure, and
3. Use of a spill kit.
(b) Labeling
1. Drug packages, bins, shelves, and storage areas for hazardous drugs must bear distinctive labels identifying those drugs as requiring special handling precautions.
2. SOPs must be followed to ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.
3. Ensure that HD final product labeling complies with state board of pharmacy requirements.
4. Review compliance with the following best practice recommendations concerning HD labeling, packaging, transport and dispensing of High Risk HDs.
(c) **Packaging**

1. Proper packaging containers and materials must be selected and used that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
2. Packaging materials must protect from damage, leakage, contamination, and degradation, while protecting personnel transporting them.
3. SOPs are required that describe appropriate shipping containers and insulating materials, based on information from product specifications, vendors, and mode of transport.

(d) **Transporting**

1. Transported HDs must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.
2. They must be transported in containers that minimize the risk of breakage or leakage.
3. Pneumatic tubes must not be used to transport any liquid HDs or any High Risk HDs.
4. When transporting to outside locations, one must consult the Transport Information on the SDS.
5. For transporting HDs, use "reasonable" packaging and protection that will prevent product damage and spillage. For transport within a pharmacy, do not use a pneumatic tube system for the transport of "liquid HDs or any High Risk HDs.
6. Carts or other transport devices that are used must be designed with guards to protect against falling and breakage.
7. All individuals transporting HDs must have safety training that includes spill control and have spill kits immediately accessible.

(e) **Disposal**

1. Personnel performing waste removal and cleaning activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment.
2. Disposal of all HD waste must comply with all applicable federal, state, and local regulations.

(f) Ensure that High Risk HDs shipped via common or premium carrier, e.g. FedEx, UPS, USPS, comply with the following requirements:

1. The amount of HD transported by ground does not exceed 4 liters per box.
2. The amount of HD transported by air does not exceed 1 liter per box, and
3. Containers comply with "Packaging Group III" requirements as verified with the vendor providing containers used in shipment.

**535:15-10-84 Dispensing Final/Finished Dosage Forms**

HD products not requiring any manipulation (other than counting or repackaging), may be prepared for dispensing without any requirements for containment unless required by the manufacturer or if visual observation shows dust or leakage. Dispensing HDs must be done carefully, as follows:

1. Clean and dedicated equipment must be used with HDs,
2. Equipment must be decontaminated after each use,
3. Tablet and capsule forms of High Risk HDs must not be placed in automated counting or packaging machines, and
(4) Dispensed HDs must not be subjected to stress (mechanical or temperature) that may result in leakage or create powdered contaminants.
(5) High Risk HDs must be labeled or otherwise identified as such to prevent improper handling.

535:15-10-85 Compounding, Nonsterile
Pharmacies and personnel involved in non-sterile compounding HDs must be compliant with State Board of Pharmacy regulations. Compounding must be done in a pharmacy utilizing proper engineering controls for the category (Low or High Risk) as previously described. Procedures in the compounding process can include:

(1) All needed supplies, equipment, ingredients and containers should be assembled and introduced into the C-PEC prior to compounding.
(2) Dedicated disposable or clean reusable equipment must be used for compounding (mortars/pestles, spatulas, etc.) with HDs
(3) Bulk containers of liquid and API HD must be handled carefully to avoid spills.
(4) APIs or other powdered HDs must be handled carefully in a C-PEC to protect against occupational exposure, including any particle-generating activities such as crushing tablets, opening capsules, etc.
(5) Crushing tablets or opening capsules should be avoided if possible; use liquid and/or semisolid ingredients whenever possible.
(6) Non-permeable gowns and double gloves must be worn during the compounding of High Risk HDs (e.g., crushing, dissolving, or preparing a solution or an ointment).
(7) All used containers, supplies and other waste must be disposed of with care to avoid contamination according to pharmacy SOPs.
(8) Deactivate and clean the interior of the C-PEC after each compounding activity.

535:15-10-86 Compounding, Sterile
Pharmacies and personnel involved in sterile compounding HDs must be compliant with State Board of Pharmacy regulations. Compounding must be done in a pharmacy utilizing proper engineering controls for the category (Low or High Risk) as previously described. Procedures in the compounding process can include:

(1) Good organizational skills are essential to minimize contamination and maximize productivity.
(2) The work surface must be cleaned of contamination with detergent, sodium hypochlorite, and neutralizer or disinfected with alcohol, depending on when it was last cleaned.
(3) Surface decontamination may be accomplished using alcohol, sterile water, peroxide, or sodium hypochlorite solutions, provided the packaging is not permeable to the solution and the labels remain legible and intact.
(4) All drugs and supplies needed to aseptically compound a dose or batch should be gathered and sanitized with 70% alcohol or appropriate disinfectant.
(5) Exiting and reentering the work area should be avoided. Being careful not to place any sterile objects below them, i.v. bags and bottles may be hung from the bar.
(6) All activities not requiring a critical environment (e.g., checking labels, doing calculations) should be completed before accessing the BSC or isolator.
(7) All items needed for compounding must be gathered before beginning work.
(8) All needed supplies, equipment, ingredients and containers should be assembled and introduced into the C-PEC prior to compounding.

(9) Closed-system transfer devices (CSTDs) can be used whenever appropriate.

(10) Negative pressure techniques should be used when extracting a liquid from a sealed container if a CSTD is not used.

(11) Two pairs of gloves should be used to gather High Risk drug vials and supplies. Remove and discard these gloves; then don fresh gloves and appropriately sanitize them before aseptic manipulation.

(12) Only supplies and drugs essential to compounding the dose or batch should be placed in the work area of the BSC or main chamber of the isolator.

(13) BSCs and isolators should not be overcrowded to avoid unnecessary hazardous drug contamination.

(14) Luer-Lok syringes and connections must be used whenever possible for manipulating hazardous drugs.

(15) Spiking an i.v. set into a solution containing hazardous drugs or priming an i.v. set with hazardous drug solution in an uncontrolled environment must be avoided.

(16) Attach and prime the appropriate i.v. set to the final container in the BSC or isolator before adding the hazardous drug.

(17) Closed-system drug-transfer devices should achieve a dry connection between the administration set and the hazardous drug’s final container.

(18) Final preparations must be surface decontaminated after compounding is complete.

(19) In either the BSC or isolator, clean gloves must be worn when labeling and placing the final preparation into the transport bag.

(20) Transport bags must never be placed in the BSC or in the isolator work chamber during compounding to avoid inadvertent contamination of the outer surface of the bag.

(21) Handling final preparations and transport bags with gloves contaminated with hazardous drugs will result in the transfer of the contamination to other workers.

(22) Hazardous drug contamination from the work area of the isolator may be brought into the workroom environment through the pass-through or air locks and on the surfaces of items removed from the isolators (e.g., the final preparation).

(23) Surface decontamination of the preparation before removal from the isolator’s main chamber should reduce the hazardous drug contamination that could be transferred to the workroom, but no wipe-down procedures have been studied.

535:15-10-87 Deactivating, Decontaminating, Cleaning, and Disinfecting

(a) General

(1) All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. Also, sterile compounding areas and devices must be subsequently disinfected.

(2) Establish written procedures for decontamination, deactivation, and cleaning, and for sterile compounding areas disinfection. Also, cleaning of nonsterile compounding areas must comply with nonsterile compounding regulations and cleaning of sterile compounding areas must comply with sterile compounding regulations. Written procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.
(3) All personnel who perform deactivation, decontamination, cleaning, and disinfection activities in HD handling areas must be trained in appropriate procedures to protect themselves and the environment from contamination.

(4) All personnel performing these activities must wear appropriate PPE (impermeable disposable gowns) resistant to the cleaning agents. Where High Risk HDs are involved, two pairs of chemotherapy gloves must be used. Also, eye protection and face shields must be used if splashing is likely. If warranted by the activity, respiratory protection must be used.

(5) The deactivating, decontaminating, cleaning, and disinfecting agents selected must be appropriate for the type of HD contaminant(s), location, and surface materials. The products used must be compatible with the surface material. Consult manufacturer or supplier information for compatibility with cleaning agents used.

(6) Agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and NOT delivered by a spray bottle to avoid spreading HD residue.

(7) Perform cleaning in areas that are sufficiently ventilated.

(8) On at least a daily basis, equipment used in HD compounding, including C-PECs, scales, etc. are routinely treated with a decontaminating oxidizing agent such as sodium hypochlorite or hydrogen peroxide followed by cleaning with a detergent solution.

(9) In the case of sterile compounding, this is followed by the use of a disinfectant (unless the product used for decontamination or cleaning also serves this function).

(b) Deactivation

(1) Deactivation renders a compound inert or inactive.

(2) Residue from deactivation must be removed by decontaminating the surface.

(3) There is no single method for deactivating all compounds.

(4) The ultimate goal is complete surface decontamination.

(5) Products that have known deactivation properties (EPA-registered oxidizing agents that are appropriate for the intended use) should be used when possible.

(6) Care should be taken when selecting materials for deactivation due to potential adverse effects (hazardous byproducts, respiratory effects, and caustic damage to surfaces).

(7) Damage to surfaces is exhibited by corrosion to stainless steel surfaces caused by sodium hypochlorite if left untreated. To prevent corrosion, sodium hypochlorite must be neutralized with sodium thiosulfate or by following with an agent to remove the sodium hypochlorite (e.g., sterile alcohol, sterile water, germicidal detergent, or sporicidal agent).

(c) Decontamination

(1) Decontamination of BSCs and isolators should be conducted per manufacturer recommendations.

(2) Decontamination occurs by inactivating, neutralizing, or physically removing HD residue from non-disposable surfaces and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned.

(3) Surface decontamination may be accomplished by the transfer of hazardous drug contamination from the surface of a non-disposable item to disposable ones (e.g., wipes, gauze, towels).
(4) When choosing among various products available for decontaminating HDs, consideration should be given to surface compatibility and pharmacy requirements. It is imperative to adhere to manufacturer's use instructions.
(5) The amount of HD contamination introduced into the C-PEC may be reduced by wiping down HD containers. The solution used for wiping HD packaging must not alter the product label.
(6) The work surface of the C-PEC must be decontaminated between compounding of different HDs. The C-PEC must be decontaminated at least daily (when used), any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
(7) C-PECs may have areas under the work tray where contamination can build up. These areas must be deactivated, decontaminated, and cleaned at least monthly to reduce the contamination level in the C-PEC. Accessing this area may be difficult.
(8) Deactivate, decontaminate, and clean as much as possible of the C-PEC surfaces before accessing the area under the work tray.
(9) When deactivating, decontaminating, and cleaning the area under the work tray of a C-PEC, the containment airflows are compromised by opening the cabinets.
(10) To provide protection to the worker performing this task, respiratory protection may be required.

d) Cleaning
(1) Cleaning is a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.
(2) Cleaning agents used on compounding equipment should not introduce microbial contamination.
(3) No cleaning step may be performed when compounding activities are occurring.

e) Disinfection
(1) Before disinfection can be adequately performed, surfaces must be cleaned.
(2) Disinfection must be done for areas intended to be sterile, including the sterile compounding areas.

535:15-10-88 Spill Control
(a) Spill control standard operating procedures (SOP’s)
(1) Spill control SOP’s Policies and procedures must be available to address spill prevention and to describe/document the cleanup of hazardous drug spills. These procedures specify who is responsible for spill management and must address the size and scope of the spill.
(2) SOPs must be developed to prevent spills and to direct the clean-up of HD spills. SOPs must address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required.
(3) The management of the spill (e.g., decontamination, deactivation, and cleaning) is dependent on the size and type of spill.
(4) The SOP must address the location of spill kits and clean-up materials as well as the capacity of the spill kit.
(5) Written procedures should address use of appropriate full-face piece, 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.
(6) All personnel who may be required to clean up a spill of HDs receive proper training in spill management and the use of PPE and NIOSH-certified respirators (see Personal Protective Equipment).
(7) Qualified personnel must be available at all times to handle spills while HDs are being handled.
(8) Spills must be contained and cleaned up immediately only by trained workers with appropriate PPE.
(9) Signs must be available for restricting access to the spill area.
(10) Spill kits containing all of the materials needed to clean HD spills must be readily available in all areas where HDs are routinely handled.
(11) All spill materials must be disposed of as hazardous waste.
(12) The circumstances and management of spills must be documented.
(13) Personnel who are potentially exposed during the spill or spill cleanup or who have direct skin or eye contact with HDs require immediate evaluation.
(14) Non-employees exposed to an HD spill should follow pharmacy SOP's policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.

(b) Spill Kits
(1) At least one spill kit, either assembled by the pharmacy or purchased commercially, must be "readily available" where HDs are received, stored, compounded, prepared for shipment, and disposed of.
(2) Spill kits must be periodically inspected to ensure they are present and have not been used.
(3) A list of workers authorized to use HD spill kits must be posted and least one such person is present at all times the pharmacy is occupied.
(4) At least annually, all workers authorized to use HD spill kits are given a documented training on kit location and use.

535:15-10-89 Documentation
(a) Safety Data Sheets (SDSs)
(1) An important element of the overall program is the Material Safety Data Sheet (MSDS), or Safety Data Sheets (SDSs) as described by pharmacy SOP's.
(2) Pharmacies Facilities must have SDSs available for all HDs.
(3) A comprehensive HD safety program must include a process for monitoring and updating the SDS database.
(4) As a new HD is purchased for the first time, an SDS must be received from the manufacturer or distributor.
(5) The SDS should define the appropriate handling precautions, including protective equipment, controls, and spill management associated with the HD.
(6) Many SDSs are available online through the specific manufacturer or through safety-information services.
(b) Standard Operating Procedures (SOPs)
(1) SOPs for the safe handling of HDs for all situations in which HDs are used throughout a pharmacy must be developed, implemented and maintained. This includes professional and nonprofessional staff, housekeeping, transportation, maintenance, etc.

(2) Handling HDs properly is dependent upon the pharmacy, personnel and having SOPs in place. As there are three different classes of HDs in the NIOSH list, the following categories of involvement reflect the potential hazards to which personnel may be exposed; Low and High.

(3) The SOPs must be reviewed and documented at least annually by the designated person. SOPs must be revised as needed and communicated to all personnel handling HDs.

(c) SOPs for handling of HDs should include at least the following activities and topics:

(1) Administrative and General
   - List of HDs
   - Engineering controls
   - Safe work practices
   - Exposure prevention / reduction
   - Environmental monitoring
   - Safe work practices
   - Training and competency
   - Hazard communication program
   - Occupational safety program
   - Designation of HD areas
   - Medical surveillance

(2) Process
   - Receipt
   - Storage
   - Hand hygiene and PPE
   - Compounding
   - Labeling
   - Packaging
   - Transport
   - Dispensing
   - Administration
   - Deactivation / Decontamination / Cleaning / Disinfection
   - Spill control
   - Disposal
   - Environmental monitoring
   - Hand hygiene and use of PPE based on activity performed

535:15-10-90 Hazardous Waste
(a) The Resource Conservation and Recovery Act (RCRA) was enacted in 1976 to provide a mechanism for tracking hazardous waste from its generation to disposal. Regulations are enforced by the Environmental Protection Agency and apply to pharmaceuticals and chemicals discarded by pharmacies, hospitals, clinics, and other commercial entities. The RCRA outlines four “characteristics” of hazardous waste and contains lists of agents that are to be considered hazardous waste when they are discarded. Any discarded drug that is on one of the lists (a
“listed” waste) or meets one of the criteria (a “characteristic” waste) is considered hazardous waste and requires handling, containment, and disposal as RCRA hazardous waste. (b) The RCRA allows for the exemption of “empty containers” from hazardous waste regulations as defined in the Act. General categories of hazardous waste found in health care settings would include trace-contaminated hazardous waste, bulk hazardous waste, hazardous drugs not listed as hazardous waste, and hazardous waste and mixed infectious–hazardous waste.

1. By the NIH definition of trace chemotherapy waste, “RCRA empty” containers, needles, syringes, trace-contaminated gowns, gloves, pads, and empty intravenous (i.v.) sets may be collected and incinerated at a regulated medical waste incinerator. Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees.

2. While not official, bulk hazardous drug waste has been used to differentiate containers that have held either (1) RCRA-listed or characteristic hazardous waste or (2) any hazardous drugs that are not RCRA empty or any materials from hazardous drug spill cleanups. These wastes should be managed as hazardous waste.

3. Concerning hazard drugs not listed, the federal RCRA regulations have not kept up with drug development, as there are over 100 hazardous drugs that are not listed as hazardous waste, including hormonal agents.

4. All disposable materials must be discarded to meet EPA regulations and the pharmacy's SOP's policies.

535:15-10-91 Medical Surveillance
(a) Medical surveillance can involve:
(1) identifying workers who are exposed or potentially exposed to HDs on the basis of their job duties.
(2) use of a health service (in-house or outsourced) to monitor patient health and exposure limits.
(3) initial baseline assessment (pre-placement) of a worker's health status and medical history.
(4) evaluating records of HDs handled, with quantities and dosage forms.
(5) health/medical records of surveillance should be maintained according to OSHA regulations.
(6) monitoring obtained data to identify health effects.
(7) follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure.
(8) exit examination when a worker's employment terminates to document the information on the employee's medical, reproductive, and exposure histories.

(b) Follow-Up Plan-The occurrence of exposure-related health changes, should prompt immediate re-evaluation of primary preventive measures (e.g. administrative and engineering controls, PPE, and others). In this manner, medical surveillance acts as a check on the effectiveness of controls already in use. The pharmacy should take the following actions:
(1) Perform a post-exposure examination tailored to the type of exposure (e.g., spills or needle sticks from syringes containing HDs). An assessment of the extent of exposure should be conducted and included in a confidential database and in an incident report. The physical examination should focus on the involved area as well as other organ systems commonly affected. (i.e., the skin and mucous membranes for direct contact or inhalation; the pulmonary system for aerosolized HDs) Treatment and laboratory studies will follow as indicated and be guided by emergency protocols.

(2) Compare performance of controls with recommended standards; conduct environmental sampling when analytical methods are available.

(3) Verify and document that all engineering controls are in proper operating condition.

(4) Verify and document that the worker complied with existing SOP's policies. Review SOP's policies for the use of PPE and employee compliance with PPE use-and SOP's policies. Review availability of appropriate PPE (See Personal Protective Equipment).

(5) Develop and document a plan of action that will prevent additional exposure of workers.

(6) Ensure confidential, two-way communication between the worker and the employee health unit(s) regarding notification, discussions about a change in health condition, or detection of an adverse health effect.

(7) Provide and document a follow-up medical survey to demonstrate that the plan implemented is effective.

(8) Ensure that any exposed worker receives confidential notification of any adverse health effect. Offer alternative duty or temporary reassignment.

(9) Provide ongoing medical surveillance of all workers at risk for exposure to HDs to determine whether the plan implemented is effective.

**SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL**

535:15-13-5. Supervision of pharmacy technicians

(a) All tasks performed by pharmacy technicians must be in a licensed pharmacy located in Oklahoma and must be accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board.

(1) Failure by the licensed pharmacy and pharmacist manager (PIC) to provide adequate supervision; and/or failure of a pharmacist to adequately supervise a technician is a violation of these rules.

(2) An intern cannot supervise a technician.

(3) Failure to adequately supervise a pharmacy technician is a violation of these rules by the pharmacist, pharmacy and pharmacist manager.

(b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in this Subchapter, provided that whenever the pharmacist leaves the prescription department, other than for in-pharmacy counseling of a patient, all dispensing functions listed shall cease.
(c) The ratio of pharmacy technicians to supervising pharmacists shall be a ratio that would be considered safe and reasonable by the certifying pharmacist. The ratio shall not exceed five. A ratio of no more than two pharmacy technicians per supervising pharmacist on duty shall be maintained.

(d) The ratio shall not exceed two pharmacy technicians to one supervising pharmacist on duty for all sterile compounding.

(e) A pharmacy intern working in the pharmacy will not affect or change this ratio.

(f) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. An intern cannot certify the completion of a technician filled prescription.

535:15-13-6. Duties

(a) The following tasks may be performed by auxiliary supportive personnel:
   (1) retrieval tasks such as retrieving prescriptions or files as necessary;
   (2) clerical tasks such as data entry, typing labels and maintaining patient profiles;
   (3) secretarial tasks such as telephoning, filing, and typing;
   (4) accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
   (5) inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and
   (6) help maintain a clean and orderly pharmacy.

(b) The following tasks may be performed by pharmacy technicians:
   (1) count and/or pour medications;
   (2) prepackage (e.g. unit dose) and properly label medications;
   (3) affix the prescription label to the proper container;
   (4) affix auxiliary labels to the container as directed by the pharmacist;
   (5) reconstitution of medications (i.e. liquid antibiotics);
   (6) bulk compounding, including such items as non-sterile topical compounds, sterile bulk solutions for small volume injectables, sterile irrigation solutions and products prepared in relatively large volume for internal or external use. Documentation of a system of in-process and final checks and controls must be developed or approved by the certifying pharmacist and carefully and systematically enforced;
   (7) functions involving reconstitution of single dose units of sterile compounded preparations that are to be administered to a given patient as a unit, and functions involving the addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient. The pharmacist must establish the procedures for compounding sterile preparations and certify the ingredients, label and finished preparation;
   (8) any duties auxiliary personnel are allowed to perform;
   (9) assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,
(9) take verbal authorizations from licensed prescriber or licensed prescriber’s authorized agent (when allowed) for refill of non-controlled prescriptions with no changes to strength or directions.

(10) data entry and initial order entry of prescriptions.

(11) clarify non-CDS prescription. If omitted, the date, quantity, route of administration, and the number of refills may be added to a prescription after confirming with the prescriber or prescriber's authorized agent. Such clarification shall be notated by the technician on the back of the prescription.

535:15-13-7. Prohibited duties

These duties shall not be performed by supportive personnel:

(1) The pharmacist must interpret the original prescription.

(2) The pharmacist must perform the prospective drug utilization review and determine action to be taken when there is an indication of a drug interaction.

(3) The pharmacist must receive new orally communicated prescriptions from prescribers or their agents.

(4) The pharmacist must determine product selection if substitution is requested or approved.

(5) The pharmacist must prepare multi-ingredient, non-repetitive, cytotoxic or experimental drug I.V.'s, enteral or other sterile multi-ingredient medications; and the pharmacist shall be responsible for weighing, measuring and calculating ingredients for sterile compounded preparations.

(6) The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. This process shall be completed before the prescription is given to the patient.

(7) The pharmacist must provide patient counseling or drug information as necessary.

535:15-13-13. Pharmacy technician training

(a) The pharmacy manager shall be responsible for the development and/or implementation of a pharmacy technician training program.

(1) The instructional text of the training program shall be kept in the pharmacy and only upon request submitted to the Board for approval.

(2) The program shall be designed to train personnel to perform allowed nonprofessional functions, as described in OAC 535:15-5 and 535:15-13.

(3) Minimum standards for technician training programs shall be those set out in the Board approved "Pharmacy Technician Training Guidelines".

(A) Pharmacy technician applicants shall complete Phase I training before they may apply for an Oklahoma Pharmacy Technician permit. A pharmacy technician
permit must be received before performing any of the duties of pharmacy technicians authorized in OAC 535:15-5 and 535:15-13.

(B) A technician has not met Board requirements until he has successfully completed Phase II of pharmacy technician training.

(C) A pharmacy technician must complete Phase II within ninety (90) days after issuance of a pharmacy technician permit.

(D) Pharmacy technician applicants shall not have fully received their permits until they have completed Phase II of pharmacy technician training.

(E) If the pharmacy technician fails to complete Phase II within 90 days, the pharmacist manager shall notify the Board in writing,

   (i) If the pharmacy technician fails to complete Phase II within 90 days,

      (I) the pharmacy technician permit is automatically void; and,

      (II) the pharmacy technician shall return such permit to the Board.

   (ii) Such pharmacy technician may apply for a new pharmacy technician permit when he has again satisfactorily completed Phase I training with an employing pharmacy, provided the provisions of these rules have not been violated by the pharmacy technician.

(b) The pharmacist manager, or another pharmacist in the pharmacy whom the pharmacist manager may designate, shall conduct the training and attest to its successful completion.

(c) The pharmacist manager shall assure that the pharmacy technician remains competent through annual continuing on-the-job training. The pharmacist manager must document such training in the pharmacy and provide it at inspection.

(d) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire at such pharmacy. Documentation of this training must be kept in the pharmacy and be available for Board inspection.

(e) The pharmacist manager shall be responsible for assuring proof of annual technician training is maintained in the pharmacy and such proof is available for Board inspection. The annual training must include the pharmacy technician law exam provided by the Board and drug diversion training.