2017 Compounding Regulations
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California State Board of Pharmacy
- 141,373 licensees
  - Drug rooms (38)
  - Hospital pharmacies (485)
  - Licensed correctional facilities (53)
  - Non-Resident pharmacies (453)
  - Non-Resident sterile compounding facilities (91)
  - Pharmacies (6,572)
  - Sterile compounding facilities (936)
  - Centralized Hospital Packaging Pharmacy (5)
Background

- 6/7/01 – Doc’s Pharmacy investigation
- 7/1/03 – License for sterile compounding required unless accredited.
- 10/29/04 – Changes in compounding regulations.
- 7/6/10 – Additional compounding regulation changes (sterile and non-sterile)
- 10/12 – New England Compounding Center meningitis outbreak
- 7/1/14 – requirements for a license for sterile compounding regardless of accreditation.
- 1/1/17 – regulations updated to current USP 797 and pending USP 800

Compounding Regulations

- Business and Professions Code (B&PC):
  - 651: Professional Advertising Requirements
  - 4121: Advertisement for Prescription Drug
  - 4123: notification to the Board to compound patient specific parenteral therapy for delivery to another pharmacy.
  - 4127: requirement for a licensed to sterile compound
  - 4127.1: In state requirement for a licensed to sterile compound
  - 4127.2: non-resident requirement for a licensed to ship sterile compounds into California
Compounding Regulations

- Business and Professions Code (B&PC):
  - 4127.3: cease and desist order.
  - 4127.7: environmentally requirement for non-sterile to sterile compounding
  - 4127.9: recalls for sterile compounded drug preparations.
  - 4128- 4128.7: Central Hospital Packaging Pharmacies (CHP)
  - 4380: Unfair trade practices HSP may sell up to 1% of the drugs purchased to walking-in customer

Compounding Regulations

- Code of Federal Regulations (CFR):
  - Title 21 CFR 216.24: FDA’s list drug products withdrawn or removed from the market for reasons of safety or effectiveness
- California Health and Safety Code (H&SC)
  - Adulterated Drugs 111250-111380
  - Misbranded Drugs 111330- 111510
- United States Code (USC)
  - Title 21 USC 353a: Pharmacy compounding – 503A
  - Title 21 USC 353b: Outsourcing facilities- 503b
Compounding Regulations

- Title 16: California Code or Regulations (CCR)
  - 1710: Hospital Pharmacy: sales to walk-in customers do not exceed 1% of pharmacy’s prescriptions.
  - 1735: All compounding
  - 1751: Sterile compounding
- Title 24: California Code or Regulations (CCR)
  - 505.5: compounding area for parenteral solutions
  - 505.51: Laminar Flow Biological Safety Cabinet
  - 1205.4: Compounding Area for Parenteral Solutions

General Compounding Regulations

CCR 1735 to 1735.8: Requirements for all compounding
What is Compounding?

- “Compounding” means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
  - Altering the dosage form or delivery system
  - Altering the strength
  - Combining components or active ingredients
  - Preparing a compounded drug preparation from chemicals or bulk drug substances

What is NOT Compounding?

- “Compounding” does not include reconstitution manufacturer’s direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.
Compounding Definitions 1735.1

- "Ante-area" area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas.
- ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.
- "Beyond use date" the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

Compounding Definitions

- "Biological Safety Cabinet (BSC)" a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
- Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.
- "Bulk drug substance" any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.
Compounding Definitions

- “Cleanroom or clean area or buffer area” a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.
  - (1) nonhazardous compounding a minimum positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.
  - (2) hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

Compounding Definitions

- “Compounding Aseptic Containment Isolator (CACI)” a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations.
  - Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded.
  - Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation.
  - This external venting should be dedicated to one BSC or CACI.
  - Air within the CACI shall not be recirculated nor turbulent.
**Compounding Definitions**

- "Compounding Aseptic Isolator (CAI)" a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air.
- It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes.
- Air within the CAI shall not be recirculated nor turbulent.
- Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded.

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**Compounding Definitions**

- "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).
- "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.
- "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).
Compounding Definitions
- "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a *clinically* significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.
- "Daily" occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

Compounding Definitions
- "Displacement airflow method" a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials.
- This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area.
- The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.
Compounding Definitions

- “Dosage unit” a quantity sufficient for one administration to one patient
- “Equipment” items that must be calibrated, maintained or periodically certified.
- “First air” the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
- “Gloved fingertip sampling” a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganism.

Compounding Definitions

- “Hazardous” all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.
- “Integrity” retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.
- “Lot” one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).
Compounding Definitions

- “Non-sterile-to-sterile batch” any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.
- “Parenteral” a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration.
- “Personal protective equipment (PPE)” clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

- “Potency” active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount.
- Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.
- “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.
Compounding Definitions

- "Prescriber's office" or "prescriber office" an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.
  - This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.
- "Primary Engineering Control (PEC)" a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations.

Compounding Definitions

- "Process validation" demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.
- "Product" a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.
- "Quality" the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.
Compounding Definitions

“Segregated sterile compounding area” a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room.

• Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding.
• The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation.
• The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing sterile-to-sterile compounded preparations.

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Compounding Definitions

“Segregated sterile compounding area”

• (1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).
• (2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it met the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).
Compounding Limitations & Requirements (1735.2)

- No drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing.

- A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

Compounding Limitations & Requirements

- A “reasonable quantity” that may be furnished to a prescriber for office use by the prescriber, means that amount of compounded drug preparation that:
  - an order from the prescriber or the prescriber’s agent is received prior to furnishing;
  - The order lists the number of patients seen or to be seen for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration
  - Is delivered to the prescriber’s office and signed for by the prescriber or the prescriber’s agent;
  - Is sufficient for administration in the office or for furnishing of not more than a 120-hour supply for veterinary medical practices
  - the pharmacist has a credible basis for concluding it is a reasonable quantity for office use

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Compounding Limitations & Requirements

“Office use”

- With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and
- Does not exceed an amount the pharmacy can reasonably and safely compound.

Compounding Limitations & Requirements

- No pharmacy or pharmacist shall compound a drug preparation that:
  - Is classified by the FDA as demonstrably difficult to compound;
  - Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; (21 CFR 216.24);
  - Is a copy or essentially a copy of one or more commercially available drug products,
    - unless product appears on an ASHP or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding.
Compounding Limitations & Requirements

- Written master formula document:
  - (1) Active ingredients
  - (2) Equipment
  - (3) The maximum allowable beyond use date and the rationale or reference source justifying its determination.
  - (4) Inactive ingredients
  - (5) Specific and essential compounding steps
  - (6) Quality reviews required at each step
  - (7) Post-compounding process or procedures required
  - (8) Instructions for storage and handling

Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.

The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
Compounding Limitations & Requirements

- **beyond use date (BUD):**
  - the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

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Compounding Limitations & Requirements

beyond use date (BUD):
- sterile compounded drug preparations, the beyond use date shall not exceed any of the following:
  - (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
  - (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
  - (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
  - (D) The beyond use date assigned for sterility in section 1751.8.

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Compounding Limitations & Requirements

beyond use date (BUD):
- Extension of a beyond use date is only allowable when supported by of the following:
  - (A) Method Suitability Test,
  - (B) Container Closure Integrity Test
  - (C) Stability Studies
- In addition to the requirements above, the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.
- Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
Compounding Limitations & Requirements

- The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.
- Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board.

Packages of ingredients, both active and inactive, that lack a supplier’s expiration date are subject to the following limitations:

1. such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.
2. such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.
Recordkeeping (1735.3)

For each compounded drug preparation, pharmacy records shall include:

- The master formula document.
- Compounding log consisting of a single document containing all of the following:
  - Name and strength of the compounded drug preparation.
  - The date the drug preparation was compounded.
  - The identity of any pharmacy personnel.
  - The identity of the pharmacist reviewing the final drug preparation.
  - The quantity of each ingredient used.
  - The manufacturer, expiration date and lot number of each component.
- Exempt are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" in USP <797>.

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Recordkeeping

For each compounded drug preparation, pharmacy records shall include:

- Compounding log:
  - A pharmacy assigned unique reference or lot number.
  - The beyond use date or beyond use date and time.
  - The final quantity or amount of drug preparation compounded for dispensing.
  - Documentation of quality reviews and required post-compounding process and procedures.
**Recordkeeping**

- Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA).
- The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding.
- Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.
- Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect.

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**Labeling of Compounded Drug Preparations (1735.4)**

- At least the following shall be affixed to the container prior to dispensing:
  - (1) Name of the compounding pharmacy and dispensing pharmacy (if different);
  - (2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;
  - (3) Instructions for storage, handling, and administration.
    - For admixed IV solutions, the rate of infusion shall be included;
  - (4) The beyond use date for the drug preparation;
  - (5) The date compounded; and
  - (6) The lot number or pharmacy reference number.
**Labeling**

- Compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label:
  - the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.
  - or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.

**Labeling**

- Prior to dispensing, drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements.
  - Once dispensed, outer packaging must comply with 1735.4(a) - (c).
  - All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous - Dispose of Properly.”
Compounding Policies and Procedures (1735.5)

- Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.
- The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge.
- The policies and procedures shall be updated whenever changes in policies and procedures are implemented.

Policies and Procedures

The policies and procedures shall include at least the following:

1. Procedures for notifying staff of changes in policies or procedures.
2. A written plan for recall.
3. Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures.
4. Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures.
5. Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations.
6. Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
7. Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.

Continued....
Policies and Procedures

The policies and procedures shall include at least the following:

- (8) Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- (9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- (10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- (11) Policies and procedures for proper garbing when compounding with hazardous products.
  - This shall include when to utilize double shoe covers.

Compounding Facilities and Equipment (1735.6)

- Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations.
  - This shall include records of maintenance and cleaning of the facilities and equipment.
  - Where applicable, this shall also include records of certification(s) of facilities or equipment.
- Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.
- Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy.
  - Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.
- Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.
Compounding Facilities and Equipment

Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

- (1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and
- (2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and
- (3) Each PEC in the room shall also be externally vented and
- (4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

Training of Compounding Staff (1735.7)

- A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures.
- This training shall include but is not limited to support personnel, maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.
- The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.
Compounding Quality Assurance (1735.8)

- Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.
- The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

Compounding Quality Assurance

The quality assurance plan shall include:

- Written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing.
- All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document.
- A schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.
- Written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.
- Written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.
Sterile Compounding Regulations

1751 to 1751.10: Additional Requirements for Sterile Compounding

Compounding Area (1751)

- Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.
- Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s).
Compounding Area

The environments within the pharmacy shall meet the following standards:

- Each ISO environment shall be certified at least every six months.
- Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- A sink shall be included. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.
- There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

Sterile Compounding Recordkeeping Requirements (1751.1)

- In addition to the records required by section 1735.3, any pharmacy engaged in any compounding of sterile drug preparations shall maintain the following records, which must be readily retrievable, within the pharmacy:
  - Training and competency evaluations of employees in sterile drug preparation policies and procedures.
  - Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
  - Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
  - Results of viable air and surface sampling.
  - Video of smoke studies in all ISO certified spaces.
  - Daily documentation of room, refrigerator, and freezer temperatures.

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Sterile Compounding Recordkeeping Requirements

- shall maintain the following records within the pharmacy:
  - Certification(s) of the sterile compounding environment(s).
  - Documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas.
  - Other facility quality control records specific to the pharmacy’s policies and procedures (e.g., cleaning logs for facilities and equipment).
  - Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.
  - Preparation records including the master formula document, the preparation compounding log and records of end-product evaluation testing and results.

Sterile Compounding Recordkeeping Requirements

- Pharmacies compounding sterile drug preparations for future use shall make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber.

- Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.
Sterile Compounding Labeling Requirements (1751.2)

- In addition to the labeling information required under B&PC 4076, CCR 1707.5 and CCR 1735.4, a pharmacy that compounds sterile drug preparations shall include the following information on the label for each such preparation:
  - The telephone number of the pharmacy. The telephone number is not required on the label for sterile drug preparations administered to inpatients within the hospital.
  - Instructions for storage, handling, and administration.
  - All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous - Dispose of Properly.”

Sterile Compounding Policies and Procedures (1751.3)

- Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.

  In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:
  - (1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
  - (2) Airflow considerations and pressure differential monitoring.
  - (3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
  - (4) Cleaning and maintenance of ISO environments and segregated compounding areas.
  - (5) Compounded sterile drug preparation stability and beyond use dating.

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Sterile Compounding Policies and Procedures

there shall be written policies and procedures regarding the following:

- (6) Compounding, filling, and labeling of sterile drug preparations.
- (7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- (8) Depyrogenation of glassware (if applicable)
- (9) Facility management including certification and maintenance of controlled environments and related equipment.
- (10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer’s recommended purge time.
- (11) Hand hygiene and garbing.
- (12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

Continued…

Sterile Compounding Policies and Procedures

there shall be written policies and procedures regarding the following:

- (13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- (14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments.
- (15) Preparing sterile compounded drug preparations from non-sterile components. This shall include sterilization method suitability testing for each master formula document.
- (16) Procedures for handling, compounding and disposal of hazardous agents.
- (17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

Continued…
Sterile Compounding Policies and Procedures

there shall be written policies and procedures regarding the following:

- (18) Proper use of equipment and supplies.
- (19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.
- (20) Record keeping requirements.
- (21) Temperature monitoring in compounding and controlled storage areas.
- (22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- (23) Use of automated compounding devices.
- (24) Visual inspection and other final quality checks of sterile drug preparations.

Sterile Compounding Policies and Procedures

- For lot compounding, written policies and procedures regarding the following:
  - (1) Use of master formula documents and compounding logs
  - (2) Appropriate documentation.
  - (3) Appropriate sterility and potency testing.
Sterile Compounding Policies and Procedures

- For non-sterile-to-sterile batch compounding, written policies and procedures regarding the following:
  - (1) Process validation for chosen sterilization methods.
  - (2) End-product evaluation, quantitative, and qualitative testing.
- Policies and procedures shall be immediately available to all personnel involved in compounding activities and to board inspectors.
- All personnel involved must read the policies and procedures before compounding sterile drug preparations. All personnel involved must read all additions, revisions, and deletions to the written policies and procedures.
- Each review must be documented by a signature and date.

Facility and Equipment Standards for Sterile Compounding (1751.4)

- No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy’s written policies and procedures for the safe compounding of sterile drug preparations.
- During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.
- All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.
Facility and Equipment Standards for Sterile Compounding

- Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.
- (1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- (2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.
- (3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- (4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

Facility and Equipment Standards for Sterile Compounding

- Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:
  - (1) At the beginning of each shift;
  - (2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;
  - (3) After each spill; and
  - (4) When surface contamination is known or suspected.
Facility and Equipment Standards for Sterile Compounding

- Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area.
- Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). Certification records must be retained for at least 3 years.

Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

1. Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
2. Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
3. Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.
Facility and Equipment Standards for Sterile Compounding

Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented.

- The negative pressure PEC must be certified every six months.

Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

- (1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

Facility and Equipment Standards for Sterile Compounding

- CAI certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room.

- Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding.

- These sterile gloves must be changed by each individual whenever continuous compounding is ceased and replaced before compounding starts again.

- CAI and CACI used in the compounding of sterile drug preparations shall use non-turbulent unidirectional airflow patterns. A smoke patterned test shall be used to determine airflow patterns.
Facility and Equipment Standards for Sterile Compounding

- Viable surface sampling shall be done at least:
  - every six months for sterile-to-sterile compounding
  - quarterly for all non-sterile-to-sterile compounding.
- Viable air sampling by volumetric air sampling procedures under dynamic
  - at least once every six months.
- When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.
- The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.
- A licensee may request a waiver of these provisions as provided in section 1735.6(f).

Sterile Compounding Attire (1751.5)

When compounding sterile drug preparations the following standards must be met:
- PPE consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times.
  - For hazardous compounding double shoe covers are required.
- PPE must be donned and removed in an ante-area or immediately outside the segregated compounding area
- Personnel shall don PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.
  - Follow (unless the pharmacy has a procedure in place)
    - shoe covers or dedicated shoes
    - head and facial hair covers and face masks
    - washing of hands and forearms up to the elbows for 30 seconds with soap and water,
    - drying hands,
    - donning of a non-shedding gown.
Sterile Compounding Attire (1751.5)

When compounding sterile drug preparations the following standards must be met:

- Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.
- Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required.
- Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.
- Gloves are to be routinely disinfected with sterile 70% isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.
- Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.
- Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

Sterile Compounding Consultation; Training of Sterile Compounding Staff. (1751.6)

- Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy.
- The pharmacist-in-charge shall ensure that all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounding products with hazardous agents.
- Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations.
Pharmacies that compound sterile drug preparations **must** comply with the following training requirements:

- A program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.

This program of training and performance evaluation **must** address at least the following:

- (A) Aseptic technique.
- (B) Pharmaceutical calculations and terminology.
- (C) Sterile preparation compounding documentation.
- (D) Quality assurance procedures.
- (E) Aseptic preparation procedures.
- (F) Proper hand hygiene, gowning and gloving technique.
- (G) General conduct in the controlled area (aseptic area practices).
- (H) Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
- (I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
- (J) Container, equipment, and closure system selection.

Each person engaged in sterile compounding **must** successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual.

- Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.

Evaluation **must** include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.

- Each person's proficiency and continuing training needs **must** be reassessed at least every 12 months.
- Results of these assessments **must** be documented and retained in the pharmacy for three years.
Sterile Compounding Quality Assurance and Process Validation (1751.7)

- Any pharmacy engaged in compounding sterile drug preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities.
- The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications.
- The quality assurance program shall include the following:
  1. Procedures for cleaning and sanitization of the sterile preparation area.
  2. Actions to be taken in the event of a drug recall.
  3. Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

Sterile Compounding Quality Assurance and Process Validation

- The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations.
- The validation process shall be:
  - carried out in the same manner as normal production,
  - be representative of the types of manipulations, products and batch sizes
  - shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process.
  - The same personnel, procedures, equipment, and materials must be used in the testing.
  - Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer’s recommendations.
  - If microbial growth is detected, then each individual’s sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.
Sterile Compounding Quality Assurance and Process Validation

- Each individual’s competency must be revalidated every:
  - 12 months for compounding from sterile ingredients
  - 6 months for compounding from non-sterile ingredients.
- The pharmacy’s validation process on aseptic technique and aseptic area practices must be revalidated whenever:
  - Quality assurance program yields an unacceptable result,
  - There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment.
- The pharmacy must document the validation and revalidation process.

Sterile Compounding Quality Assurance and Process Validation

- All sterile compounding personnel must successfully complete an initial competency evaluation.
- Immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.
- Re-evaluation of garbing and gloving competency shall occur every:
  - 12 months for compounding from sterile ingredients
  - 6 months for compounding from non-sterile ingredients.
Sterile Compounding Quality Assurance and Process Validation

(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.

- Sterility testing shall be USP 71 and pyrogens testing shall confirm acceptable levels of pyrogen per USP 85 limits before dispensing.
- Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

- Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.
- Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 15 days or less pursuant to a prescription.

Beyond Use Dating for Sterile Compounded Drug Preparations (1751.8)

In addition to CCR 1735.2(h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed:

- the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor
- the chemical stability of any one ingredient in the sterile compounded drug preparation, nor
- the chemical stability of the combination of all ingredients in the sterile compounded drug preparation,

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797, that would justify an extended beyond use date, conforms to the following limitations:
Beyond Use Dating for Sterile Compounded Drug Preparations

- **BUD: 48 hours** at controlled room temperature, **14 days** at controlled cold temperature, and **45 days** in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:
  - (1) compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and
  - (2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and
  - (3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

- **BUD: 30 hours** at controlled room temperature, **9 days** at controlled cold temperature, and **45 days** in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations.
  - The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), and the following apply:
    - (1) multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
    - (2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
    - (3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.
**Beyond Use Dating for Sterile Compounded Drug Preparations**

- **BUD: 24 hours** at controlled room temperature, **3 days** at controlled cold temperature, and **45 days** in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using **non-sterile ingredients**, regardless of intervening sterilization of that ingredient and the following applies:
  - The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

- **BUD: 12 hours** where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:
  - The preparation was compounded entirely within an ISO Class 5 PEC that is located in a **segregated sterile compounding area** and
  - The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer’s original containers and
  - The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

- **BUD: 1 hour** where compounded either outside of an ISO Class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e)
  - Shall be labeled “for immediate use only”.

- **BUD for any compounded allergen extracts** shall be the earliest manufacturer expiration date of the individual allergen extracts.
Single-Dose and Multi-Dose Containers; Limitations on Use (1751.9)

- Single-dose ampules: immediate use only
- Single-dose container shall be used in its entirety or labeled with a BUD and discarded within the following time limit, depending on the environment:
  - Needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour
  - Needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.
    - A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
  - If the puncture time is not noted on the container, the container must immediately be discarded.

Single-Dose and Multi-Dose Containers; Limitations on Use

- Multi-dose container stored according to the manufacturer’s specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture.
- Multi-dose container not stored according to the manufacturer’s specifications shall be discarded immediately upon identification of such storage circumstance.
- If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.
Sterile Compounding Reference Materials (1751.10)

- In any pharmacy engaged in compounding sterile drug preparations, there shall be current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy.

Questions?