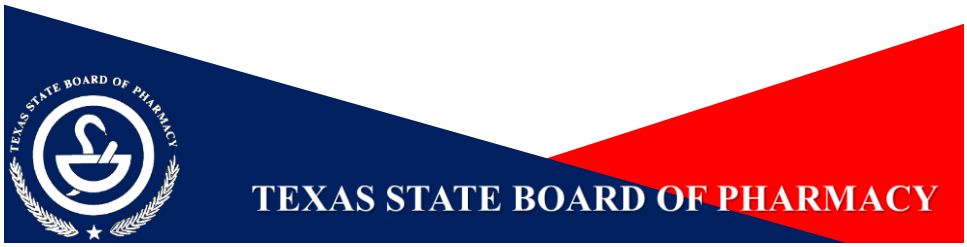
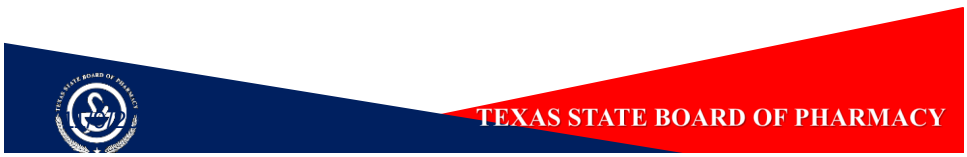
The Inspection Process for Pharmacies Compounding Sterile Preparations (CSPs)



Timeline of the Regulation of CSPs in Texas

1982	First mention of "**IV Admixtures**" in the Texas Pharmacy Act
1991	**Requirements for the preparation of sterile pharmaceuticals the same for Class A and Class C pharmacies**
2002	**First of three Task Forces on Sterile Compounding**
2004	USP 797 becomes enforceable
2005	**Second Task Force on Sterile Compounding**
2007	TSBP Section 291.133, "**Pharmacies Compounding Sterile Preparations**"
2008	USP 797 Revisions
2012	New England Compounding Center incident
2013	**Third TSBP appointed Task Force on Compounding**
2014	TSBP Inspection Form for Sterile Compounding



TSBP Inspection Process

- Part of the inspection of a Class A-S, B, or C-S pharmacy that must occur prior to license renewal
- Uses a 2-page question-based inspection form that parallels TSBP Rule §291.133
- Divided into 15 sections
- Time required for the inspection varies based on size and compliance-level of the pharmacy

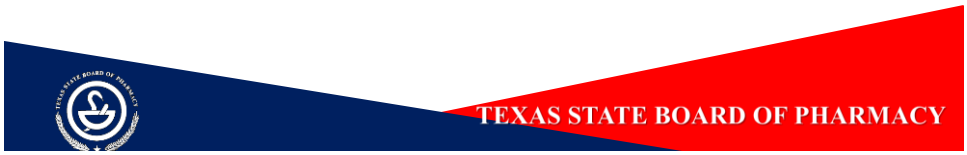
TSBP Inspection Process

- Environment
- Primary Engineering Control Devices
- Equipment and Supplies
- Library
- Personnel Cleansing and Garbing
- Cleaning and Disinfection Procedures
- Environmental Sampling
- Records of Compounded Sterile Preparations
- General Operational Requirements
- Quality Control and Verification of Compounding Accuracy
- Label
- Training and Competency

TSBP Inspection Process

If applicable,

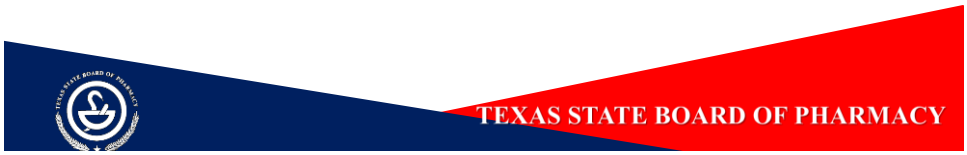
- High-risk Sterile Preparations
- Hazardous Sterile Preparations
- Compounding for Office Use



Environment

Is the cleanroom . . .

- free of objects that shed particles?
- contain only appropriate supplies?
- used only for sterile preparations?



Environment

Does the ante-area . . .

- provide at least ISO Class 8 conditions?
- contain a hands-free sink?

Does the buffer area . . .

- provide at least ISO Class 7 conditions?
- free from sources of water?
- have hands-free access?

Environment

- Are floors, walls, ceilings, and fixtures smooth, impervious, and free from cracks and crevices?
- Does the floor enable regular disinfection?
- Are supplies stored above the floor?

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Environment

Does the cleanroom have a pressure gauge to monitor pressure differential

- between the buffer area and ante-area?
- between the ante-area and the general environment?

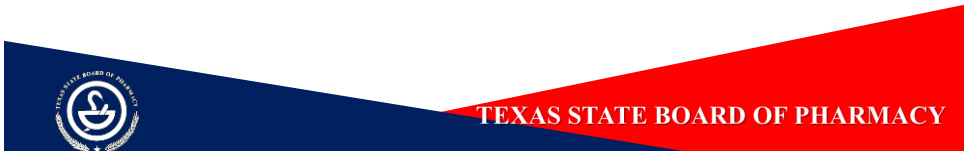
Is the pressure differential monitored and documented (at least daily)?

Are the temperature and humidity monitored and within the required range?

Examples of Commonly Seen Violations

<u>Environment</u>

- Objects that shed particles in the cleanroom – cardboard, exposed particle board, chipped paint, rust
- Cracks and crevices – outlets not sealed, linoleum separating from wall, cracks in linoleum
- Sink is not hands-free
- Access to buffer area is not hands-free
- Temperature and/or humidity is not monitored or not in the required range (≤ 68 degrees F and < 60% humidity)



Primary Engineering Control (PEC) Devices

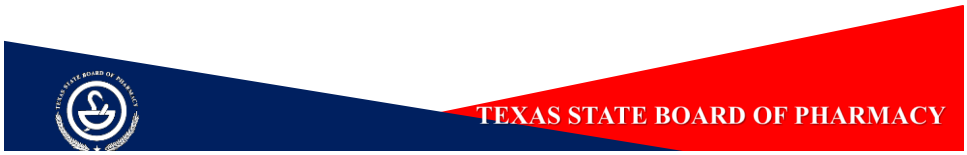
What type(s) of PECs are present?

- Laminar air flow hood (LAFH)
- Biological safety cabinet (BSC)
- Containment aseptic isolator (CAI)
- Compounding aseptic containment isolator (CACI)

Where is the PEC placed?

Primary Engineering Control Devices

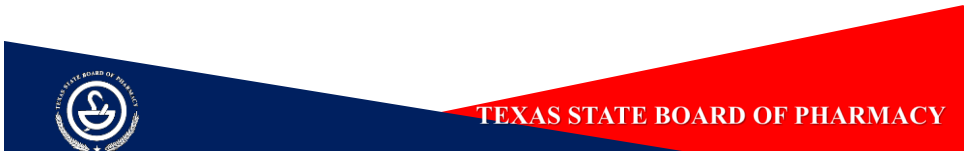
- Are certified by an independent contractor every 6 months and when relocated?
- Have pre-filters that are inspected and replaced as needed periodically?



Examples of Commonly Seen Violations

Primary Engineering Control Devices

- Certification of ISO classified areas and/or PEC is > 6 months
- Prefilter inspection/replacement is not documented
- Incorrect placement of CAI or CACI



Equipment and Supplies

Does the pharmacy have . . .

- Disposable needles, syringes and other applicable supplies?
- Lint-free towels/wipes or electronic hand dryer appropriately located?
- Handwashing agents with bactericidal action including a nail cleaner?
- Appropriate garb – masks, caps, gowns with tight cuffs, shoe covers, beard covers?

Equipment and Supplies

Does the pharmacy have . . .

- Disinfectant cleaning solution(s)?
- Dedicated cleaning supplies?
- Sterile alcohol, sterile gloves and waterless alcohol-based surgical scrub with persistent activity?

Equipment and Supplies

- Does the pharmacy have . . .
  - Filters and filtration equipment?
  - Hazardous spill kit, if applicable?
- If using automated compounding devices (i.e., repeater pumps), does pharmacy staff calibrate, verify accuracy, and document calibration on a daily basis?

Examples of Commonly Seen Violations

Equipment/Supplies

- Lack of:
  - Sterile gloves
  - Sterile isopropyl alcohol
  - Water-less, alcohol-based surgical scrub
- No documentation of calibration of automated compounding devices

Library

In addition to the references required for a Class A, Class B, or Class C pharmacy, does the pharmacy have . . .

- Current reference on injectable drugs?
- Specialty reference, if applicable?
- USP chapters – 71, 85, 795, 797, 1163 and others if applicable (e.g., USP 800)?

Examples of Commonly Seen Violations

Library

- Lack of access to all required USP chapters
- Out-of-date reference on injectable drugs

Personnel Cleansing, Garbing and Hand Hygiene

Do personnel . . .

- perform hand sanitizing and gowning occur outside of the buffer area (in the ante-area)?
- Perform appropriate hand hygiene?
- Not wear cosmetics, jewelry, artificial nails, or have illness/open lesions?
- Use a nail cleaner during hand hygiene?
- Appropriately re-don garb?

Cleaning and Disinfecting Procedures

Does the pharmacy . . .

- Have written procedures regarding cleaning/disinfecting of the direct compounding area by trained personnel using an approved agent?
- Perform appropriate daily and monthly cleaning?
- Document cleaning?
- Are supplies wiped with a disinfecting agent prior to being brought into the clean room?

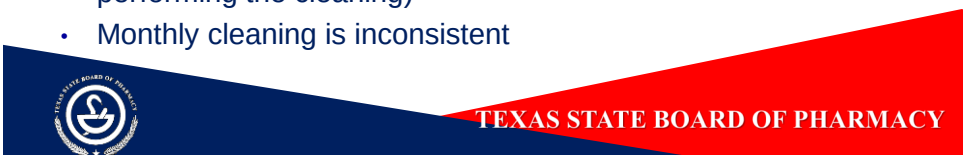
Examples of Commonly Seen Violations

Personnel Cleansing and Garbing

- Inappropriate hand hygiene (not to elbows, no nail cleaner)
- Inappropriate donning of garb (order, placement)
- Inappropriate re-donning of garb (only gown may be reused and only for one shift)

Cleaning and Disinfection Procedures

- No written procedures for when and what is used for cleaning
- Lack of documentation (need date/time and name of person performing the cleaning)
- Monthly cleaning is inconsistent



Environmental Sampling

Is surface sampling performed . . .

- on a periodic basis?
- in all ISO classified areas?

Is air sampling performed . . .

- by trained individuals at least every six months?

Is there an appropriate response to sampling based on action levels?

Examples of Commonly Seen Violations

<u>Environmental Sampling</u>

- Viable air sampling was not done
- Surface sampling was not done, or not done in all ISO classified areas
- No response to reported growth on viable air sampling or surface sampling

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Compounding Records

- Are records maintained for 2 years?
- Does the record include all required information?
- If batch compounding, are the master worksheets . . .
  - complete?
  - developed and approved by a pharmacist?

General Operational Requirements

- Is a pharmacist available 24/7?
- Are there written SOPs on the required topics (including recalls)?
- Are requirements met if compounding commercially available products?
- Are CSPs being dispensed to other states without proper licensure?

Quality Control

- Does the pharmacist review all compounding records for accuracy and perform a final check of the CSP?
- Are periodic in-process checks performed as defined in the pharmacy's written procedures?
- Is a Certificate of Analysis available, if applicable?

Examples of Commonly Seen Violations

- No SOPs for sterile compounding
- Lack of policy for drug recalls of CSPs
- Lack of policy defining in-process checks for the pharmacy

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Label

- Is the CSP properly labeled including . . .
  - generic name?
  - BUD?
  - “compounded by pharmacy,” if applicable?
  - unique facility lot number, if compounded as a batch?
- Are CSPs assigned a BUD based on labeling for the drug, literature sources, and/or direct testing?

Training and Competency

Have all compounding personnel (pharmacist and pharmacy technician) completed the required education and training?

- ACPE-accredited course or ASHP-approved program
- On-the-job training

Is there documentation of an initial competency evaluation that includes . . .

- Observation?
- Media-fill testing?
- Gloved fingertip testing?

Is there documentation of ongoing training and testing?

Initial vs. Ongoing Competency

	Initial (prior to preparing CSPs for patients)	Ongoing
Education	20/40 hours of ACPE-accredited training	2 or 4 hours of continuing education per renewal period
Observation	By a trained compounder	By a trained compounder
Media-fill Test	Representing the most challenging or complex preparation	Representing the most challenging or complex preparation
Gloved Fingertip Test	Thumb and all fingers of both hands on 3 occasions to demonstrate competence at donning garb and sterile gloves	Thumb and all fingers of both hands after preparing a compound or completing media fill test to demonstrate aseptic technique competency

Examples of Commonly Seen Violations

Training and Competency

- Lack of education/training documentation
- Improper initial gloved fingertip testing (not obtained prior to compounding and on 3 occasions)

High-risk Sterile Preparations

- Does the buffer area provide physical separation?
- Is sterility testing performed if . . .
  - CSPs are prepared in groups > 25?
  - MDVs are prepared for multiple patients or when exposed to > 12 hrs at 2-8 degrees C?
  - Exposed > 6 hrs at > 8 degrees C?

High-risk Sterile Preparations

- Are CSPs . . .
  - Pre-filtered using no larger than a 1.2 micron filter?
  - Filtered using a sterile 0.2 to 0.22 micrometer pore size filter in at least an ISO Class 5 environment?
- Are filter integrity tests performed and documented?
- Are pre-sterilization procedures (weighing and mixing) completed in an ISO 8 or better environment?

Hazardous Sterile Preparations

Does the pharmacy have . . .

- protective apparel?
- safety and containment techniques?
- appropriate waste disposal?
- appropriate labeling?
- pressure indicator to readily monitor room pressurization?

Are hazardous drugs stored separately?

Compounding for Office Use

- Does the pharmacy have a written agreement with the prescriber that meets all requirements?

- If the pharmacy is distributing to another pharmacy, are the specified requirements met?

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You are the Compliance Inspector. What is the violation?

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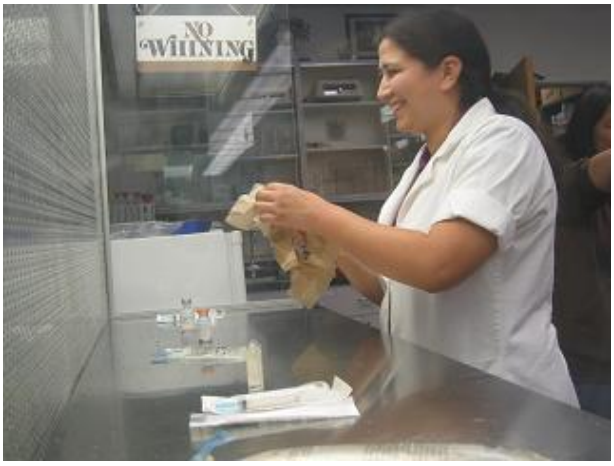

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Questions?

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