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EDUCATIONAL RESOURCES

PHARMACY

Achieving PCAB Accreditation

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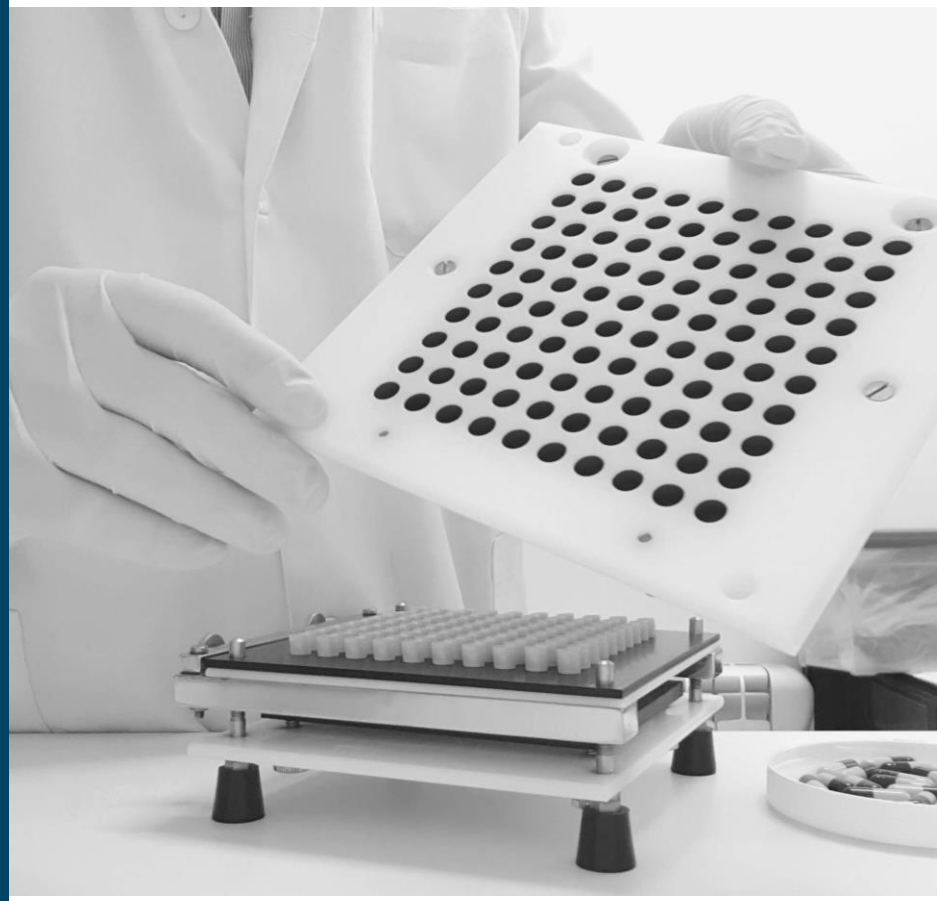
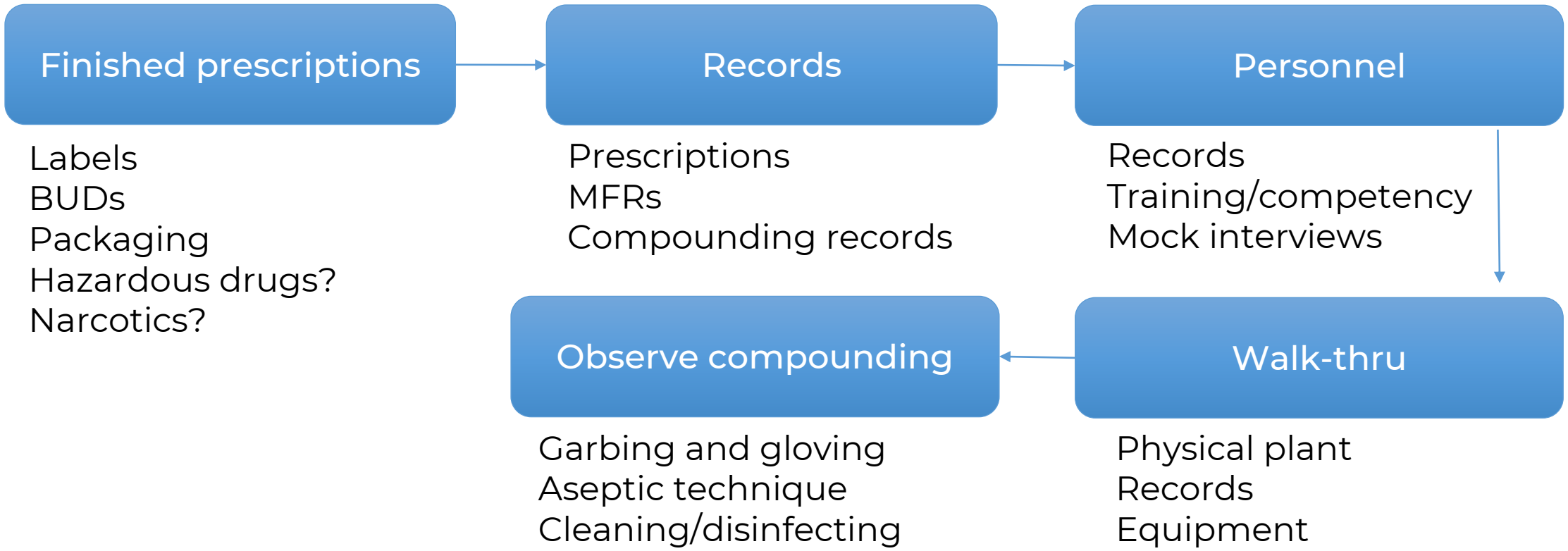


Questions from recorded portion?

- Topics covered:
  - *ACHC Accreditation Guide to Success*
  - ACHC Pharmacy Program and Services
    - Distinctions
    - Inspections
  - Accreditation process
    - Customer Central
    - Standards access
    - Survey/Surveyor
    - Plan of Correction

Tip: Survey Yourself!

- Work backwards



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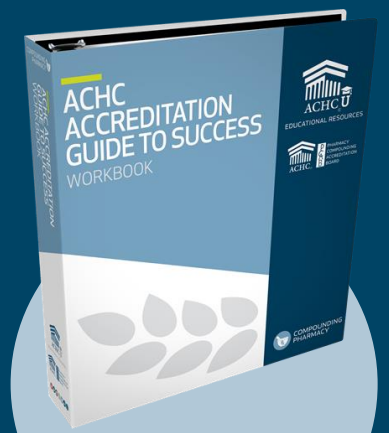
PHARMACY

Pharmacy Management



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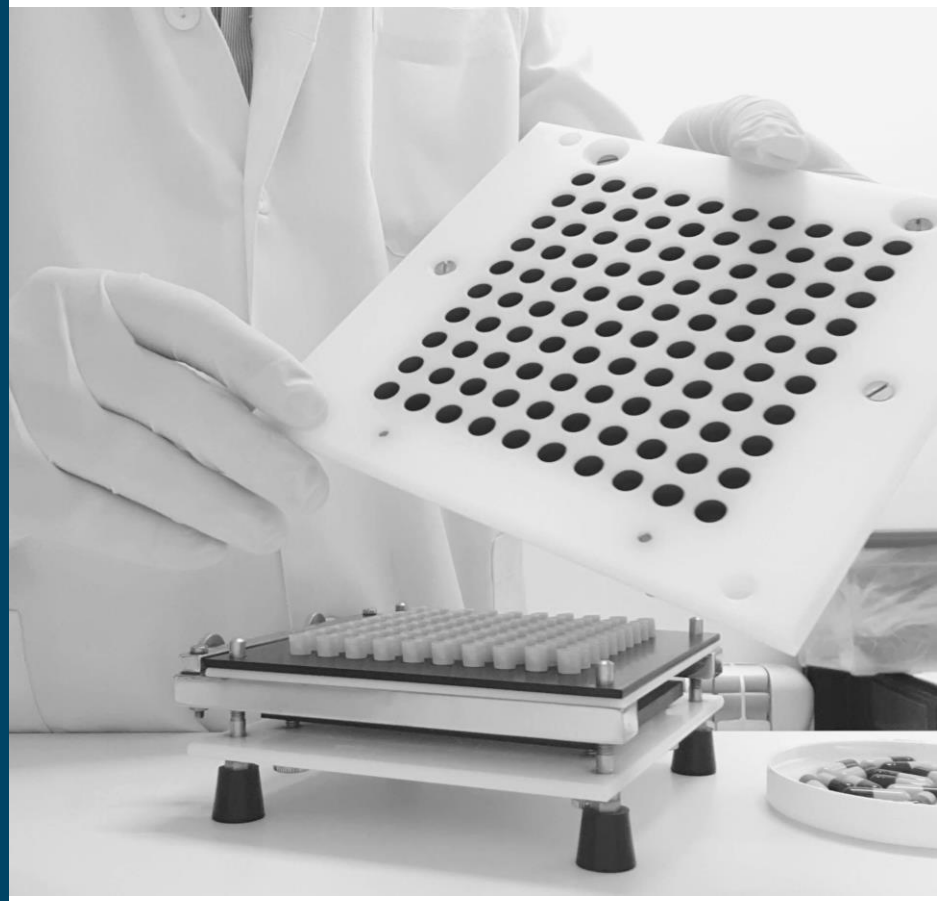


ACHCU IS A BRAND OF ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC

Standard TCRX6-A

Written policies and procedures are established and implemented that address the surveillance, identification, prevention, control and investigation of infectious and communicable diseases and the compliance with regulatory standards.

The organization maintains and documents an effective infection control program that protects clients/patients and personnel by preventing and controlling infections and communicable diseases. The organization's infection control program must identify risks for the acquisition and transmission of infectious agents. There is a system to communicate with all personnel about infection prevention and control issues including their role in preventing the spread of infections and communicable diseases through daily activities.

Written policies and procedures are established and implemented to include accepted standards of practice to prevent the transmission of infections and communicable diseases, including the use of standard precautions.

Standard TCRX6-A (Cont.)

Accepted standards of practice for healthcare providers are typically developed by government agencies, professional organizations and associations.

Written policies and procedures include, but are not limited to:

- General infection control measures appropriate for service provided
- Hand-washing
- Use of standard precautions and personal protective equipment (PPE)
- Needle-stick prevention and sharps safety, if applicable
- Appropriate cleaning/disinfecting procedures
- Infection surveillance, monitoring, and reporting of employees and clients/patients
- Disposal and transportation of regulated waste, if applicable

Standard TCRX6-A (Cont.)

Employee health conditions limiting their activities

Assessment and utilization of data obtained about infections and the infection control program

If the pharmacy compounding activities require the manipulation of a patient's blood-derived or other biological material, the manipulations must be clearly separated from other compounding activities and equipment used in preparation activities. Policies and procedures must guide processes in order to avoid cross-contamination, and handling must comply with jurisdictional standards and guidelines.

Written policies and procedures identify the personnel who are responsible for implementing the infection control activities and personnel education.

Standard TCRX6-B

Standard TCRX6-B: Written policies and procedures are established and implemented for preparation and/or component recall.

The pharmacy has a mechanism for identifying, in a timely and effective manner, which clients/patients received recalled compounded preparations or their components.

External recalls — when a vendor recalls an active pharmaceutical ingredient (API) or excipient:

- APIs — who got this ingredient?
- Excipients — who got this excipient or diluent?

Internal recalls — when a preparation does not meet quality or safety requirements:

- Batches and prescriptions
- Equipment used in the process?
- How are patients and prescribers notified?
- Is the recall documented properly?

Preparation:
Test your recall system … Your Surveyor will!

Standard TCRX6-C

Written policies and procedures are established and implemented relating to the storage of pharmaceuticals, components (including active pharmaceutical ingredients, excipients, ingredients, and devices) and compounded preparations.

Written policies and procedures are established and implemented that include, but are not limited to:

- Storage of pharmaceuticals, components, and compounded preparations in order to maintain their integrity and security
- Establishing appropriate temperatures, humidity, and other storage conditions for pharmaceuticals, components, and compounded preparations as described in USP <659>
- Monitoring and documenting that storage area(s), refrigerator, and freezer temperatures maintain the appropriate storage conditions as described in USP <659>. Temperatures are monitored and documented at least daily
- Regular inspections to remove, quarantine, and dispose of expired pharmaceuticals, components and compounded preparations

Standard TCRX6-C (Cont.)

- Defining a quarantine area for pharmaceuticals, components and compounded preparations removed from inventory due to recall, expiration or other reasons
- Contingency plans addressing situations where storage conditions fall outside of established ranges
- Storage and handling of hazardous and potent drugs, including separate storage from non-hazardous items
- Disposal of pharmaceuticals, components, and compounded preparations
- Labeling of storage containers, including but not limited to name, strength, lot number, transfer date, expiration date and manufacturer or source
- Cleaning and disinfecting of compounding facilities and reusable storage containers
- Cleaning and disinfection process are documented, including the cleaning or disinfection agent used

Pharmaceuticals, components and finished compounded preparations are stored in accordance with manufacturer or USP requirements. Storage conditions are monitored wherever these items are stored to ensure that the requirements are met. Pharmaceuticals, components, and finished compounded preparations are stored in the licensed pharmacy, which is accessible only under the supervision of a Registered Pharmacist.

Standard TCRX6-C

Written policies and procedures are established and implemented relating to the storage of pharmaceuticals, components (including active pharmaceutical ingredients, excipients, ingredients, and devices) and compounded preparations.

Problem areas

- What is wrong with this refrigerator temperature log?

M	T	W	Th	F	S	Su
35 F	34 F	33 F	32 F	32 F	31 F	33 F

- What information should labels of stock bottles filled from bulk containers have?
- How are stock bottles cleaned and disinfected?
- How are the contents of stock bottles verified?

USP <659> *Packaging and Storage Requirements*

- Referenced in both <795> and <797> as well as TCRX6-C
- Provides guidance on storage conditions during storage and shipping
  - Use for setting ranges in your pharmacy! Key definitions for storage:

Condition	Definition
Freezer	Controlled between -25 and -10C (-13 and 14F)
Refrigerator	Controlled between 2 and 8C (36 and 46F)
Room Temperature	Temperature prevailing in a working environment
Warm	Temperature between 30 and 40C (86 and 104F)
Excessive Heat	Temperature above 40C (104F)
Dry Place	Does not exceed 40% avg. relative humidity at 20C

Standard TCRX6-D

Written policies and procedures are developed and implemented in regard to the organization's use of a validated shipping system to ensure pharmaceuticals are maintained under appropriate condition of sanitation, light, and temperature in the course of deliveries.

Key Points:

- SOPs should guide the shipping process
  - Size/type of phase change material and delivery container
  - Staff need to be trained!
- Consider all temperatures that preparations may encounter during shipping
  - Seasons, regional variations
- Validate shipping systems by
  - Third-party or internal studies, or include temperature indicators in each package
  - Take into account environmental extremes and package size

USP <659> *Packaging and Storage Requirements* – AGAIN!

Controlled Cold Temperature

- Maintain 2-8C (36-46F)
- Allows for excursions between 2-15C (36-59F) during storage, shipping, and distribution
  - Not to exceed 24 hours
  - Calculated mean kinetic temperature (MKT, see USP <1079.2>) no more than 8C (46F) with no excursions below 2C (36F) or above 15C (59F)

USP <659> *Packaging and Storage Requirements* – AGAIN!

Controlled Room Temperature

- Maintain 20-25C (68-77F)
- MKT may be used during an excursion provided that:
  - MKT does not exceed 25C (77F)
  - Excursion between 15-30C (59-86F)
  - Transient excursions NMT 40C (104F)
  - Excursion time NMT 24 hours
- May ship *controlled room temperature* items at cool place or refrigerated conditions

Standard TCRX6-E

Written policies and procedures are established and implemented by the Pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.

Interpretation: The written policies and procedures and the implementation must include, but are not limited to:

- Appropriate use and storage of equipment
- Calibration of machines and equipment that states frequency and findings
- Cleaning schedules for equipment
- Disinfection or sterilization procedures and schedules
- Testing of equipment
- Procedure for the use, calibration, maintenance, and accuracy testing of ACDs (applies to sterile compounding only)
- Calibration of temperature sensing devices conform to National Institute of Standards and Technology (NIST) standards

Standard TCRX6-E

Written policies and procedures are established and implemented by the Pharmacy relating to the appropriate use, calibration, cleaning and as appropriate, disinfection or sterilization of equipment used for preparing, dispensing, labeling, and shipping of preparations.

This standard covers a broad area in both sterile and non-sterile compounding!

Problem areas:

- Balances
  - Leveling
  - Cleaning
  - Minimum weighable quantity (MWQ)
  - Calibration
- pH meter calibration
- Thermometers – NIST calibrated

Cleanroom Equipment

- Use appropriate equipment!
  - Convection ovens
  - Suitable for intended use?
- Autoclaves and Convection Ovens properly verified
  - Biological indicators (each batch)
  - Endotoxin challenge vials (annually)

California State Board of Pharmacy
March 21, 2014

Don’t forget your hoods!

- NONSTERILE processes – certify BSCs every 12 months
  - Guidelines still being developed
  - Redundant filters? Port for checking each filter?

- STERILE processes - all hoods need to be certified every 6 months
  - Powder containment for pre-sterilization is included!

Standard TCRX6-F

Written policies and procedures are established and implemented for compounding preparations that outline the selection of ingredients and are in compliance with applicable law, regulations and standards of good practice.

Written policies and procedures are established for compounding preparations that outline the selection of ingredients in a manner that is compliant with applicable laws, regulations, and standards of good practice, which include but are not limited to:

- A process for documenting that suppliers for bulk chemicals are FDA registered, licensed in good standing and are able to provide Certificates of Analysis (COA) and Safety Data Sheets (SDSs)
- Criteria for acceptance or rejection of components based upon CofA review and other criteria
- A process for incorporating pertinent CofA data into MFRs and for the retention of CoAs
- A process for ensuring that the pharmacy does not compound for human patients with medications included on the FDAs “List of Drug Products That Have Been Withdrawn or Removed from the Market for Reasons of Safety or Effectiveness,” or the FDA’s “demonstrable difficulties for compounding” list.

Standard TCRX6-F (Cont.)

- Bulk substances comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists
- If a monograph does not exist, the drug substance(s) in compounded medications for human patients must be a component of an FDA-approved human drug product
- If a monograph does not exist and the drug substance in compounded medications for human patients is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by the FDA
- Official compounded preparations are prepared from ingredients that meet requirements of the compendial monograph for those individual ingredients for which monographs are provided
- For non-sterile preparations, ensuring that components that do not have expiration dates assigned by the supplier are labeled with the date of receipt and are assigned a conservative expiration date based on stability data and not to exceed three years from the date of receipt.
- For sterile preparations, the date of receipt for bulk substances and excipients will be clearly and indelibly marked on each package of ingredient, packages of ingredients that lack a supplier's expiration date cannot be used after one year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality

Read and use your CofA!

Loss on Drying (LOD):

- The amount of moisture that the API has absorbed in the manufacturing and storage process. If this is not adjusted, it can greatly change the final product when compounding.

- Example: An LOD of 7% means that 100mg of an API (weighed) will contain 7mg of water. The water correction factor is: 100/(100-7.0) = 1.075.

Read and use your CofA!

Don’t forget about assays and salt-base conversions!

Common problem areas:

- Antibiotics – assays often vary by lot
- Salt-base issues – inconsistent as to proper nomenclature
  - Rule of thumb – follow manufactured products
  - Lidocaine vs Lidocaine HCl
  - Fentanyl, Morphine
  - Amlodipine vs Amlodipine Besylate

Standard TCRX6-G

Written policies and procedures are established and implemented that outline the contents of the Master Formulation Record (MFR) for each non-sterile and high risk (as defined by USP 797) sterile compounded preparation.

Written policies and procedures are established and implemented in regard to the use of a formulation record that provides the pharmacy with a consistent source document for preparing each non-sterile and high risk sterile compounded preparation. The process is consistent with applicable laws and regulations.

There is a (MFR) for each non-sterile and high-risk sterile preparation (as defined by USP <797>) that includes:

- Name, strength and dosage form
- Ingredients and their quantities
- Pertinent calculations

Standard TCRX6-G (Cont.)

- Equipment and equipment settings used to produce the preparation
- Mixing and/or other pertinent instructions
- Quality control procedures and expected results
- Compatibility and stability information including references when available
- Beyond use date (BUD) and supporting justification/reference
- Container and packaging used for dispensing
- Packaging and storage requirements
- Labeling information including generic name and quantity/concentration of each active ingredient
- A description of the final preparation

Standard TCRX6-H

Written policies and procedures are established and implemented that outline the contents of the Compounding Record (CR) for each preparation.

Written policies and procedures are established and implemented in regard to the use of a CR that documents the actual ingredients in a preparation, the person responsible for compounding, and the Pharmacist who approves the finished preparation. The process is consistent with applicable laws and regulations.

Standard TCRX6-H (Cont.)

There is a CR for each non-sterile and high-risk sterile preparation (as defined by USP <797>) that includes:

- Formulation record used
- Ingredients and quantity of each, lot, expiration date, manufacturer or source
- Quantity prepared
- Names of the individual(s) making the preparation
- Signature or initials of the supervising Pharmacist responsible for in-process and final checks
- Date of preparation
- Prescription or batch number
- Assigned BUD
- Results of quality control procedures (weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing, as appropriate to each dosage form)

Standard TCRX6-H (Cont.)

There is a CR for each low-and-medium-risk sterile preparation (as defined by USP <797>) that includes the correct:

- Identity
- Purity
- Amounts of ingredients

Standard TCRX6-I

Written policies and procedures are established and implemented in regard to compounding non-sterile preparations in accordance with USP Chapter <795> standards, the art and science of pharmacy, applicable laws and regulations.

Personnel use appropriate techniques to compound preparations. Written policies and procedures are established and implemented to ensure preparations are made in accordance with applicable USP standards, the art and science of pharmacy, and applicable laws and regulations.

Written policies and procedures define how compounding is performed, including but not limited to:

- How critical processes are performed (including but not limited to weighing, measuring, mixing, and inspection and handling of components)
- How dosage forms are prepared according to applicable USP standards, the art and science of pharmacy, and applicable laws and regulations

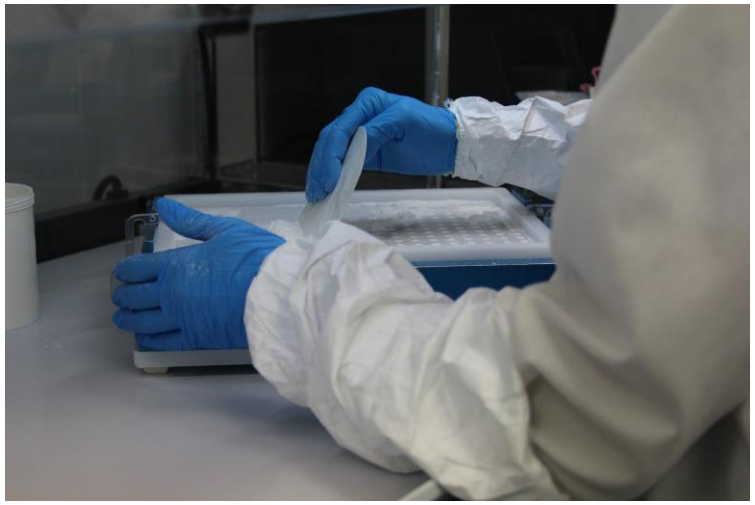
Standard TCRX6-I (Cont.)

- Checks and rechecks for each procedure at each stage of the process
- Compounding preparations using the Master Formulation Record, the Compounding Record, and associated written procedures, documenting any deviation in procedures
- Cleaning and sanitizing compounding areas and equipment prior to compounding
- Segregating compounding activities to prevent mix-ups among ingredients, containers, labels, in process materials, and finished preparations
- Performing compounding activities in a manner designed to prevent cross contamination
- Thoroughly and promptly cleaning the compounding area and all equipment after use
- Avoiding interruption of personnel during the compounding process
- Personal hygiene, hand washing, gowning and gloving for non-hazardous compounding

Personnel are knowledgeable and follow the appropriate steps to ensure that preparations are made are in accordance with applicable USP standards, the art and science of pharmacy and applicable laws and regulations

Assessment Of Non-Sterile Compounding

- Observation
  - Surveyor chooses
  - Any staff member may be selected



- Interview
  - How were you trained?
  - How do you…?
  - What do you consider hazardous?
  - What if you had a spill?
  - Where is your eyewash?
- Documentation Review
  - Does it match observation?
  - Is it complete and accurate?
  - Is it appropriate?

Standard TCRX6-J

Written policies and procedures are established and implemented in regard to hazardous non-sterile preparations are compounded in an environment that meets requirements as defined by USP Chapter <795>, state boards of pharmacy regulations, and standards of good practice.

Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g., gowns, face masks, eye protection, hair covers, shoe covers, and double gloving with chemotherapy gloves) to compound hazardous preparations per the current The National Institute for Occupational Safety and Health (NIOSH) list of Antineoplastic and other Hazardous Drugs in Healthcare Settings.

Standard TCRX6-J (Cont.)

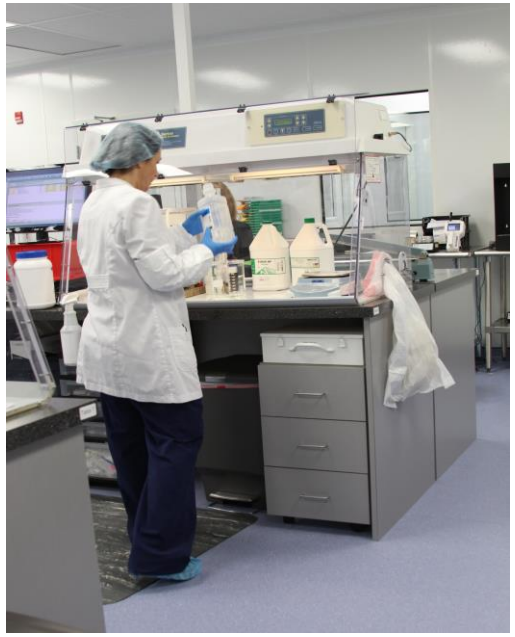
The pharmacy has the proper environment to prepare non-sterile hazardous preparations which, at a minimum, include performing manipulations within a Class I biological safety cabinet (BSC). The Class I BSC environment(s) are maintained and certified per the manufacturer's requirements. A qualified independent contractor performs annual certification according to accepted standards for operational efficiency. The work surface of the BSC is decontaminated after compounding with hazardous drugs.

Key points to outline for compliance:

- Define hazardous drugs (NIOSH list)
- Define PPE for compounding hazardous drugs (hint – NIOSH list!)
- Class I BSC as a safeguard

Class I BSCS Tips Aka “Powder Hoods”

- Certified (Occupational Safety and Health Administration [OSHA], Manufacturer’s requirements)
- Used to:
  - Protect from hazardous drugs
  - Prevent cross-contamination
  - Protect from irritants and potent drugs
- What is hazardous?
  - National Institute for Occupational Safety and Health (NIOSH) List
    - Hormones
    - DES
    - Antineoplastics
  - Not limited to NIOSH list — OSHA requires evaluation:
    - Cantharidin



Make sure it is on!!!

Standard TCRX6-K

Written policies and procedures are established and implemented for compounded non-sterile preparations that outline the use, maintenance and cleaning of compounding facilities that result in an environment that is appropriate to the scope of compounding performed by the pharmacy.

Written policies and procedures address cleaning and sanitization of the compounding areas and how they are documented.

The compounding facilities meet the following criteria:

- Adequate space for the orderly placement of equipment and materials to prevent mix-ups or cross contamination between ingredients, containers, labels, in-process materials, and finished preparations
- Designed to minimize unnecessary traffic
- Well-lighted with adequate heating, ventilation, and air conditioning
- Adequate washing facilities including hot and cold water, soap or detergent, and air dryers or single-service towels
- Surfaces that contact pharmaceutical components, in-process materials, or finished preparations are not reactive, additive, or adsorptive to avoid altering the safety, identity, strength, quality, or purity of the preparation

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Sterile Compounding

Standard TCRX6-L

Written policies and procedures are established and implemented in regard to compounding sterile preparations in accordance with USP Chapter <797> standards, the art and science of pharmacy, applicable laws and regulations.

Personnel use appropriate techniques to compound preparations. Written policies and procedures are established and implemented to ensure preparations are made in accordance with applicable USP standards, the art and science of pharmacy, and applicable laws and regulations.

Written policies and procedures define how compounding is performed, including but not limited to:

- How critical processes are performed (including, but not limited to weighing, measuring, and mixing)
- How dosage forms are prepared according to applicable USP standards, the art and science of pharmacy, and applicable laws and regulations
- Checks and rechecks for each procedure at each stage of the process
- Compounding preparations using the MFR, the Compounding Record, and associated written procedures, documenting any deviation in procedures

Standard TCRX6-L (Cont.)

- Access to the buffer area is restricted to relevant personnel, and interruptions are minimized
- Introduction of only those medications, supplies, and equipment into the controlled air environments, which are necessary for the current preparation
- The use of carts in controlled air environments
- Proper aseptic technique, including attention to the concept of “first air”
- Cleaning and sanitizing compounding areas and equipment prior to compounding
- Segregating compounding activities to prevent mix-ups among ingredients, containers, labels, in-process materials, and finished preparations
- Performing compounding activities in a manner designed to prevent cross-contamination
- Clean room behaviors, including but not limited to food, gum, drinks, jewelry, rashes, sunburn, weeping sores, conjunctivitis, and active respiratory infection, etc.

Standard TCRX6-L (Cont.)

- Thoroughly and promptly cleaning the compounding area and all equipment after use
- Avoiding interruption of personnel during the compounding process
- Personal hygiene, hand washing, gowning, and gloving for non-hazardous sterile compounding
- Preparing hazardous drugs, including using appropriate garb and biological safety cabinets (BSCs)
- Preparation of sterile drugs from non-sterile ingredients, if applicable

Personnel are knowledgeable and follow the appropriate steps to ensure that preparations are made are in accordance with applicable USP standards, the art and science of pharmacy and applicable laws and regulations.

Standard TCRX6-M

Non-Hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate risk level as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

The pharmacy has the proper environment(s) for the preparation of compounded sterile preparations (CSPs), which at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate for the category of CSPs it prepares, including but not limited to:

- Low-risk non-hazardous or radiopharmaceutical preparations with a 12-hour or less Beyond-Use Date: A primary engineering control, ISO Class 5 primary engineering control, (Compounding Aseptic Isolator (CAI), Compounding Aseptic Containment Isolator (CACI), Biological Safety Cabinet (BSC) or Laminar Flow Workstation (LAFW)) located outside of a minimum ISO Class 7 area

Standard TCRX6-M (Cont.)

- Low and medium risk preparations: A ISO Class 5 primary engineering control (CAI, CACI, BSC, LAFW) located in an ISO Class 7 buffer area with an ISO class 7 or 8 ante-area. For buffer areas not physically separated from ante-areas a minimum airflow of 40 feet per minute is maintained across the line of demarcation

Or

- A CAI or CACI meeting the following requirements:
  - The device provides isolation from the room and maintains ISO Class 5 during dynamic operating conditions
  - Particle counts sampled approximately six to 12 inches upstream of the critical exposure site maintain ISO Class 5 levels during compounding operations
  - Not more than 3520 particles (0.5 µm and larger) per m3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer
  - The pharmacy has documentation from the manufacturer that the CAI/CACI will meet the above requirements when located in environments where the background particle counts exceed ISO Class 8

Standard TCRX6-M (Cont.)

- Low-, medium- and high-risk preparations: An ISO Class 5 primary engineering control (CAI, CACI, BSC, LAFW) located in an ISO Class 7 buffer area with an ISO Class 7 or 8 ante-area; ante-areas and buffer rooms are physically separated and maintain a minimum differential positive pressure of at least 0.02-0.05 inch water column.
- For high-risk preparations, pre-sterilization procedures are performed in a minimum ISO Class-8 area.
- The surfaces of ceilings, walls, floors, fixtures, furniture, shelving, counters, and cabinets in the buffer area are impervious, free from cracks, crevices, and rust, are non-shedding, and resistant to disinfectants
- Facilities are comfortable and can maintain a temperature of 68° Fahrenheit or cooler
- Buffer areas do not contain sinks or floor drains

Standard TCRX6-N

Written policies and procedures are established and implemented in regard to how hazardous sterile preparations are compounded in an environment that meets requirements for the appropriate category as defined by USP Chapter <797>, state board of pharmacy regulations, and standards of good practice.

Written policies and procedures define appropriate garb and personal protective equipment (PPE) (e.g., gowns, face masks, eye protection, hair covers, shoe covers, and double gloving with sterile chemotherapy gloves) to compound hazardous preparations per current National Institute of Occupational Safety and Health (NIOSH) list of Antineoplastic and other hazardous drugs in a healthcare setting.

The pharmacy has the proper environment(s) to prepare sterile preparations which, at a minimum, meet the USP Chapter <797>, applicable board of pharmacy requirements and standards of good practice appropriate to the category of its CSPs, including but not limited to:

Standard TCRX6-N (Cont.)

- Pre-sterilization procedures such as weighing, mixing and other manipulations are performed in a minimum Class I BSC in an ISO Class 8 area
- Hazardous sterile preparations are compounded in an appropriate primary engineering control such as an ISO Class 5 BSC or CACI
- The ISO Class 5 or better BSC or CACI is placed in an ISO Class 7 or better area that is physically separated and has not less than 0.01- inch water column negative pressure to the adjacent ISO Class 7 or better ante-room
- In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., closed system vial transfer device CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable in lieu of a negative pressure room
- If a CACI meeting USP Chapter <797> requirements is used outside of a buffer area, the room area must maintain at least 0.01 inch water column negative pressure and 12 air changes per hour (ACH)
- Facility protocols for decontamination of work surfaces that may come in contact with hazardous drugs

Standard TCRX6-O

Standard TCRX6-O: Written policies and procedures are established and implemented for cleaning, disinfecting, and monitoring the controlled air environment(s).

Cleaning, disinfection and monitoring procedures follow requirements set forth by USP General Chapter <797> and the individual state boards of pharmacy. Written policies and procedures include, but are not limited to:

- Processes for cleaning/disinfecting work surfaces, equipment, and work areas including frequency, cleaners/disinfectants and documentation/logs
- Processes for certification of primary and secondary engineering controls at a minimum of every six months, and for the review and documentation of the results.

Standard TCRX6-O (Cont.)

- Processes for monitoring and recording pressure differentials between buffer area and ante-area, and between the ante-area and the general environment
- A program for viable air sampling meeting USP Chapter <797> requirements, including use of active air sampling equipment at a minimum of every six months, definition of sampling locations, method of collection, volume of air sampled, activity in the compounding area during sampling, and action levels
- Documentation of viable air sampling results
- Regardless of the colony forming unit (cfu) identified by airborne particle sampling, identification of microorganisms recovered (at least the genus level) and measures to be taken when pathogenic organisms are identified
- Action levels based on cfu counts for microbial contamination and measures to be taken when action levels are met or exceeded
- Requirements for a surface sampling program meeting USP Chapter <797> requirements, which include but are not limited to: definition of sampling locations, method of collection, sampling frequency, and action levels

Certification

- PECs and ISO-certified areas must be certified every 6 months and testing must include:
  - Airflow testing
  - HEPA filter integrity test
  - Total particle count (under dynamic conditions!)
  - Dynamic airflow smoke pattern test (PEC)

- If out-of-range results occur, a corrective action plan must be implemented

Microbiological Air Monitoring

- Conducted via impact sampling, under dynamic conditions
  - Settling plates do not suffice!
- Conduct in all classified areas at a minimum every 6 months
- Use growth media that supports bacteria and fungi (e.g. TSA)
- Media incubation:
  - TSA – 30-35C for 48-72 hours
  - MEA – 26-30C for 5-7 days
    - Need 2 incubators?

Microbiological Air Monitoring

- Compare cfu results against action levels
- Document results and trend over time
- Investigate and take corrective action if action levels are exceeded
  - Identify the organisms down to the genus level regardless of CFU count!

ISO Class	Recommended Action Level
5	> 1
7	> 10
8	> 100

Microbiological Surface Sampling

- Validates personnel practice as well as cleaning processes and agents
- Must be performed on a *periodic* basis per <797>
  - Develop your own facility plan!
  - Suggestion – frequent monitoring allows you to develop trends and may be your earliest indicator of a problem

ISO Class	Recommended Action Level
5	> 3
7	> 5
8	> 100

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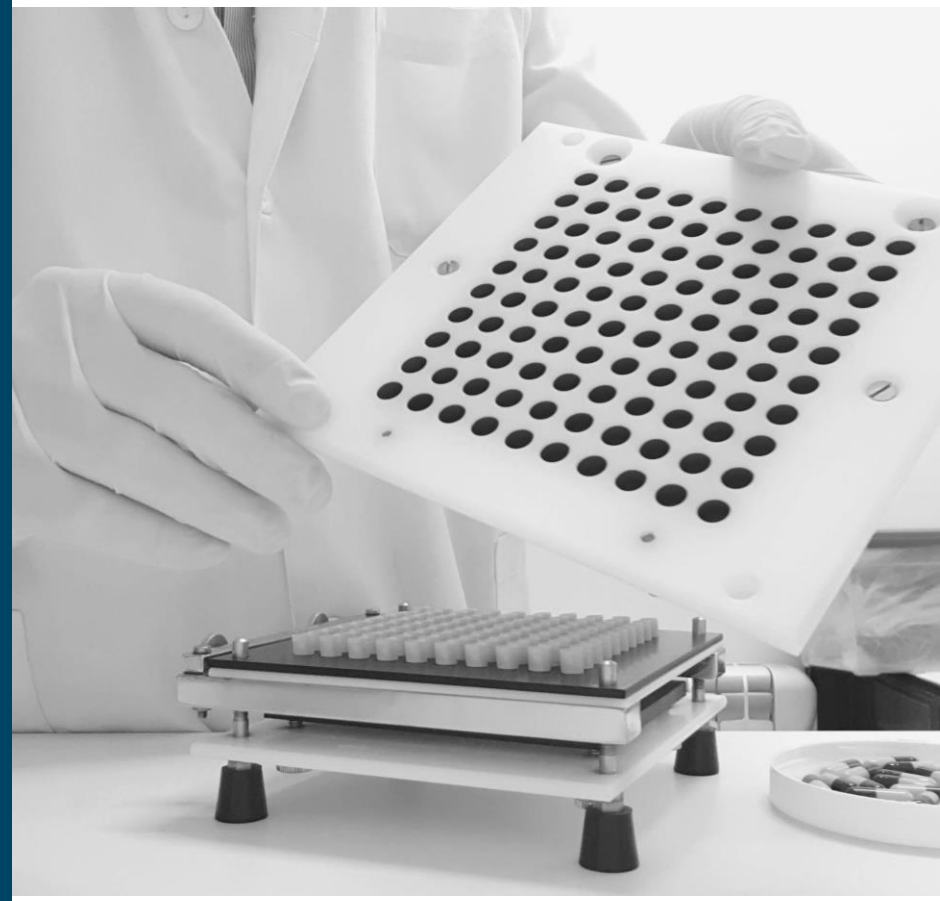
Non–Sterile Compounders

You may look up from your electronic devices now!



Standard TCRX6-P

Written policies and procedures are established and implemented in regard to assigning each non-sterile preparation a Beyond-Use Date (BUD) to assure that the preparation retains its strength, purity, and quality until the labeled BUD date.

Written policies and procedures are established and implemented to ensure that an appropriate BUD is assigned to each non-sterile preparation, which includes:

- When the pharmacy lacks stability information that is applicable to a specific drug and preparation, BUDs for non-sterile preparations are assigned using USP Chapter <795> "General Guidelines for Assigning Beyond-Use Dates":
  - For Non-aqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or six months, whichever is earlier
  - For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures
  - For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days

Standard TCRX6-P (Cont.)

- When BUDs are assigned that exceed USP Chapter <795> “General Guidelines for Assigning Beyond-Use Dates,” the rationale for the BUD assignment is based upon the following in order of priority:
  - Stability information derived from validated testing of the specific preparation, conditions, and container
  - USP/NF Monographs
  - Published stability information for similar compounds and formulations with the specific container and conditions
  - Stability studies published in literature
  - Manufacturer (if a manufactured product is involved)
  - Professional judgment
- The rationale/source for the BUD assignment is documented on the MFR
- Compounded preparations are packaged in a manner that maintains their identity, strength, quality, and purity until the labeled BUD

Personnel should be aware that potency tests are designed to determine how much of the active drug is in the sample, whereas stability tests are used to determine a BUD for the preparation.

Standard TCRX6-Q

Written policies and procedures are established and implemented in regard to assigning each sterile preparation a Beyond-Use Date (BUD) to assure that the preparation retains its strength, purity, and quality until the labeled BUD date.

Interpretation: Written policies and procedures are established and implemented to ensure that an appropriate BUD is assigned to each sterile preparation, which includes:

- When the pharmacy lacks stability information that is applicable to a specific drug and preparation, BUDs for sterile preparations are assigned using USP Chapter <797> guidelines for each CSP risk level:
  - Low-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 48 hours at controlled room temperature, 14 days at a cold temperature, or 45 days frozen.
  - Medium-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 30 hours at controlled room temperature, nine days at a cold temperature, or 45 days frozen.
  - High-risk preparations: In the absence of passing a sterility test, storage periods before administration cannot exceed 24 hours at controlled room temperature, three days at a cold temperature or 45 days frozen.

Standard TCRX6-Q (Cont.)

- When BUDs are assigned that exceed USP Chapter <797> guidelines, the rationale for the BUD assignment is based upon the following in order of priority:
  - Stability information derived from validated testing of the specific preparation, conditions, and container
  - USP/NF Monographs
  - Published stability information for similar compounds and formulations with the specific container and conditions
  - Stability studies published in literature
  - Manufacturer (if a manufactured product is involved)
  - Professional judgment
- The rationale/source for the BUD assignment is documented on the MFR
- Compounded preparations are packaged in a manner that maintains their identity, strength, quality, and purity until the labeled BUD

Personnel should be aware that potency tests are designed to determine how much of the active drug is in the sample, whereas stability tests are used to determine a BUD for the preparation.

Standard TCRX6-R

Written policies and procedures are established and implemented to ensure preparations adhere to requirements for sterility and endotoxin limits.

Applies to facilities that:

- Assign BUDs that exceed USP defaults for each risk level
- Prepare high-risk compounded sterile products (CSPs)

Written policies and procedures are established and implemented to ensure that preparations adhere to established and/or compendial requirements for sterility requirements and endotoxin limits, which include:

Standard TCRX6-R (Cont.)

Sterilization by filtration:

- Filters incorporate a 0.2 micron pore membrane that is chemically and physically compatible with the CSP.
- Filters are approved for human-use applications in sterilizing pharmaceutical fluids
- Filters are of a size and capacity that permit the entire volume to be filtered without replacement
- An integrity test (e.g. bubble point test) is performed on each filter after use. The integrity test follows manufacturer's recommendations and is documented on the compounding record

Sterilization by steam:

- Testing is performed to verify that the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave
- Containers are placed to ensure that live steam contacts all ingredients and surfaces to be sterilized
- Pass solutions are passed through a 1.2 micron or smaller pore size filter into final containers to remove particulates before sterilization
- The effectiveness of steam sterilization is verified using appropriate biological indicators. The testing and results are documented

Standard TCRX6-R (Cont.)

Sterilization by dry heat:

- Dry heat is only used for those materials that cannot be sterilized by steam
- Containers are placed to ensure circulation of hot air over all ingredients and surfaces to be sterilized
- Dry heat sterilization is performed in a device designed for sterilization and capable of distributing heated air evenly throughout the chamber with a blower device
- The effectiveness of dry heat sterilization is verified using appropriate biological indicators. The testing and results are documented

Sterility testing:

- When BUDs are assigned that exceed USP Chapter <797> defaults for CSPs in the absence of a sterility test, sterility is verified by USP Chapter <71>, equivalent, or superior sterility testing
- The testing and results are documented

Standard TCRX6-R (Cont.)

Endotoxin testing:

- All high-risk-level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages or in multiple-dose vials (MDVs) for administration to multiple clients/patients or that are exposed longer than 12 hours at 2° to 8° and longer than six hours at warmer than 8° before they are sterilized are tested to ensure that they do not contain excessive bacterial endotoxins
- The testing results are documented

Depyrogenation:

- Dry heat depyrogenation or an equivalent, superior depyrogenation method is used to render glassware and other containers and utensils free of pyrogens and viable microorganisms
- The specific heat depyrogenation cycle and duration for specific load items is included in written documentation
- The effectiveness of dry heat depyrogenation is verified using endotoxin challenge vials. The vials are tested to verify that the cycle can produce a 3-log reduction in endotoxins

USP <71> — Sterility Tests

- PCAB standards require sterility testing to be in compliance with USP <71>
- Sterility testing has inherent problems
  - Can organisms grow under the conditions of the test?
  - What is the right test?
  - Does the sample size provide an appropriate estimate of sterility of the lot?

Method Suitability

“If the product is contaminated, will the test show it?”

Method Suitability

- Inoculate with six microorganisms
- Incubate NMT three days for bacteria, five days for fungi
- Looking for the presence of growth

Fluid Thioglycollate	Soybean-Casein Digest
Staphylococcus aureus	*Candida albicans*
Pseudomonas aeruginosa	*Aspergillus brasiliensis*
Clostridium sporogenes	*Bacillus subtilis*

Method Suitability

- Complete for ALL FORMULATIONS undergoing sterility testing
- Test highest concentration of each ingredient

Type of Test: USP <71>

- Membrane Filtration
  - To be used whenever the nature of the product permits!
- Direct Inoculation
- Both must include negative controls

Alternate Sterility Tests

- Must be demonstrated as at least as effective and reliable *USP Membrane Filtration or USP Direct Inoculation of the Culture Medium*
- <1223> Validation of Alternative Microbiological Methods

Bryce, 1956

- *"The most that can be claimed is a probability that the product is sterile…"*
- *"The designation sterile is therefore to a certain extent arbitrary…"*

Percent Infected in Batch of 500, 1 organism	Proportion Pass as Sterile
1	99.1
2	96.7
5	84
10	58
20	36
25	20
30	11

USP <71> - Testing Quantity

Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

Number of Items in the Batch	Minimum Number of Items to be Tested for Each Medium (unless otherwise justified and authorized)
Parenteral Preparations	
Not more than 100 containers	10% or four containers, whichever is greater
More than 100, but not more than 500 containers	10 containers
More than 500 containers	2% or 20 containers, whichever is less

USP <71> - Testing Quantity

- Table 3. Minimum Number of Articles to be Tested in Relation to the Number of Articles in the Batch

Number of Items in the Batch	Minimum Number of Items to be Tested for Each Medium (unless otherwise justified and authorized)
Ophthalmic and other non-injectable preparations	
Not more than 200 Containers	5% or two containers, whichever is greater
More than 200 containers	10 containers
Bulk solid products	
Up to four containers	Each container
More than four containers, but not more than 50 containers	20% or four containers, whichever is greater
More than 50 containers	2% or 10 containers, whichever is greater

USP <71> — Testing Quantity

Table 2. Minimum Quantity to be Used for Each Medium

Quantity per container	Minimum Quantity to be Used (unless otherwise justified and authorized)
Liquids	
Less than 1 mL	The whole contents of each container
1-40 mL	Half the contents of each container, but not less than 1 mL
Greater than 40 mL, and not greater than 100 mL	20 mL
Greater than 100 mL	10 % of the contents of the container, but not less than 20 mL
Antibiotic liquids	1 mL

If each article does not contain sufficient quantities for each medium, use twice the number of articles indicated in Table 3.

USP <71>

- USP sterility testing is DESTRUCTIVE
  - Final dosing container is to be tested; this helps ensure the complete process is validated
    - Drug
    - Handling
    - Final container
  - Adding processes AFTER testing is not truly representative

Standard TCRX6-S

The organization ensures that pharmaceuticals are stored under appropriate conditions of sanitation, light, and temperature in the client's/patient's home.

Pharmaceuticals dispensed to the client/patient are clearly labeled with the appropriate storage conditions requirements

The organization educates the client/patient on the appropriate conditions for the storage of pharmaceuticals in the home environment

When necessary, the Pharmacist intervenes, as indicated, to ensure that appropriate conditions are achieved or maintained

Standard TCRX6-T

Written policies and procedures are established and implemented for participating in clinical research/experimental therapies and/or administering investigational drugs.

Written policies and procedures include, but are not limited to:

- Informing clients/patients of their responsibilities
- Informing clients/patients of their right to refuse investigational drugs or experimental therapies
- Informing clients/patients of their right to refuse to participate in research and clinical studies
- Notifying clients/patients that they will not be discriminated against for refusal to participate in research and clinical studies
- Stating which personnel can administer investigational medications/treatments
- Describing personnel's role in monitoring a client's/patient's response to investigational medications/treatments
- Identifying the responsibility for obtaining informed consent
- Defining the use of experimental and investigational drugs and other atypical treatments and interventions

Standard TCRX6-U

Written policies and procedures are established and implemented to assure that compounded preparations are labeled in accordance with applicable laws and regulations, USP standards, and standards of good practice.

Compounded preparations are labeled appropriately per state and federal laws and regulations, USP standards, and standards of good practice. At a minimum labels for compounded preparations include:

- Name, address, and phone number of the pharmacy
- Date prescription was filled
- Prescription number
- Patient's name and species (if applicable)
- Name and strength(s) of active ingredient(s)
- Quantity or total volume

Standard TCRX6-U (Cont.)

- Directions for use including the route of administration and rate of administration if applicable
- Prescriber's name
- Beyond Use Date (BUD)
- Storage and handling instructions
- Notification that the preparation is compounded

CFST only: When regulations permit an exemption to the above requirements, the pharmacy labels the compound with correct name and amount or concentration of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.

Questions about Section 6?

Or in general?

Standard TCRX1-A

The organization is an established entity with legal authority to operate and has a physical location with the appropriate licensure, Articles of Incorporation, or other documentation of legal authority.

The organization is an established entity with legal authority to operate, and has the appropriate Articles of Incorporation, or other documentation of legal authority. Legal authority is granted to one individual, members of a Limited Liability Corporation (LLC), a Board of Directors (usually referred to as the governing body), and as allowed in state statutes for the appropriate type and structure of the organization. The entity, individual or organization has a copy of the appropriate documentation or authorization to conduct business.

If state or applicable local law requires a license or permit, the organization posts the current copy in a prominent spot in all locations/branches, and/or in accordance with appropriate regulations or laws.

Standard TCRX1-A (Cont.)

The organization will display all licenses and/or permits required in the pharmacy operation in an area of public view.

- Resident state board of pharmacy permit/license
- Non-resident board of pharmacy permit/license as required, if applicable
- Drug Enforcement Administration (DEA) registration
- State controlled substance license, if applicable
- Pharmacist licenses
- Pharmacy technician licenses/certificates, if applicable
- Biohazard generator permit or appropriate contract as required
- The organization is in compliance with all applicable federal, state, and local laws and regulation and has access to the pharmacy rules and regulations of all states in which pharmacy services are provided

Standard TCRX1-B

The organization has access to relevant United States Pharmacopeia (USP) standards.

The pharmacy has access to current USP standards that are relevant to the scope of compounding performed.

Pharmacies that perform non-sterile compounding have access to relevant and current United States Pharmacopeia standards, including but not limited to USP Chapter <795>.

Pharmacies that perform sterile compounding have access to relevant and current United States Pharmacopeia standards including, but not limited to, USP Chapter <797>.

Standard TCRX1-C

The organization informs the accrediting body and other state/federal regulatory agencies, as appropriate, of negative outcomes from review/audits.

Negative outcomes affecting accreditation, licensure, or Medicare/Medicaid certification are reported to ACHC within 30 days of the occurrence. The report includes all actions taken and Plans of Correction (POCs).

Incidents reported to ACHC include, but are not limited to:

- License suspension
- License probation; conditions/restrictions to license
- Non-compliance with Medicare/Medicaid regulations identified during survey by another regulatory body
- Civil penalties of ten thousand dollars ($10,000) or more
- Revocation of Medicare/Medicaid/third-party provider number

STANDARD TCRX2-A

Written policies and procedures are established and implemented by the organization requiring that the client/patient be informed at the initiation of service on how to report complaints or grievances to the organization and/or ACHC.

The organization investigates and attempts to resolve all client/patient complaints/grievances and documents the results within a described time frame as defined in policies and procedures. Written policies and procedures include, but are not limited to:

The appropriate person to be notified of the complaint/grievance

Time frames for investigation activities, to include after-hours

Reporting of information

Review and evaluation of the collected information

Communication with the client/patient

Documentation of all activities involved with the complaint/grievance, investigation, analysis, and resolution

The Single Most Problematic Area Is…

This issue has a tendency to affect the rest of your survey!!!!

Personnel Training/Competency

- PCAB Section 3 covers Orientation/Training
- Written Policies and Procedures are required
- The requirements are documented
- All the elements are covered
- Personnel competency is assessed
    - You cannot assume someone is competent because you trained them

Training ≠ Competency

Standard TCRX3-A

Written policies and procedures are established and implemented requiring all non-sterile compounding personnel to receive training and/or education and to competently perform the required client/patient service activities prior to being assigned to work independently.

Written policies and procedures define the minimum education and training, licensure, certification, experience, and the minimum competencies required for each service offered, as well as the method for documenting that personnel have received the required training.

The organization designs and implements a competency assessment program based on the service provided. Competency assessment is an ongoing process and focuses on the primary service being provided. Competency assessment is conducted initially during orientation and annually thereafter. Verification of skills is specific to the employee's role and job responsibilities.

Policies and procedures are in place for determining that personnel are competent to provide quality service. Competency may be verified through observation, knowledge-based tests, and self-assessment. All competency assessments and training are documented. A self-assessment tool alone is not acceptable. There is a plan in place for addressing performance and education of personnel when they do not meet competency requirements.

Standard TCRX3-B

Written policies and procedures are established and implemented requiring all sterile compounding personnel to receive training and/or education and to competently perform the required client/patient service activities prior to being assigned to work independently.

Written policies and procedures define the minimum education and training, licensure, certification, experience, and the minimum competencies required for each service offered, as well as the method for documenting that personnel have received the required training.

The organization designs and implements a competency assessment program based on the service provided. Competency assessment is an ongoing process and focuses on the service being provided. Competency assessments are conducted initially during orientation and annually thereafter except when required more frequently, for example, for high-risk sterile compounding personnel per USP Chapter <797>. Verification of skills is specific to the employee's role and job responsibilities.

USP <797> Requires:

Testing

- Initial garbing and gloving testing* (X 3)
- Annual or biannual fingertip testing during media fill test*
- Annual or biannual media fill tests

Competency Observation

- Principle competency guidelines: Appendix I
- Garbing and gloving assessment tool — Appendix III
- Aseptic technique during media fill test assessment tool — Appendix IV
- Cleaning and disinfection assessment tool — Appendix V
- Hazardous drugs and PPE — no tool provided by USP <797>

Standard TCRX3-C

Pharmacy personnel are trained to operate, clean, maintain, and calibrate compounding equipment.

Personnel responsible for compounding are trained and competent in the use of all equipment as applicable to their job description and/or assigned responsibilities.

Standard TCRX3-E

Written policies and procedures are established and implemented in regard to personnel who work with hazardous drugs receiving training and demonstrating competency in their storage, handling, and disposal.

Prior to handling hazardous drugs, personnel who compound with hazardous drugs are trained in the identification, storage, handling, and disposal of these drugs. This training includes the use of personal protective equipment (PPE), safety equipment such as eyewashes and spill kits, and engineering controls. The competency of personnel who handle hazardous drugs is assessed at least annually.

Personnel of reproductive capability confirm in writing that they understand the risk of handling hazardous drugs.

Standard TCRX3-F

Written policies and procedures are established and implemented in regard to personnel being trained and/or demonstrating competence to perform any new tasks/procedures prior to performing those tasks independently. Personnel are not allowed to perform any task for which they were evaluated as unsatisfactory.

Written policies and procedures define the process to ensure that personnel demonstrate competency in any new task before being assigned to perform that task. The organization also has a process to ensure that personnel are proven competent to perform tasks after re-training is provided.

STANDARD TCRX3-G

All pharmacy services are provided by qualified personnel and administered in accordance with the organization's policies and procedures, job descriptions, and each state board of pharmacy's rules and regulations where medications are shipped or dispensed.

Pharmacists and pharmacy technicians function in accordance with the organization's policies and procedures and job descriptions, accepted ethical and professional practice standards, and in accordance with all applicable federal, state, and local laws and guidelines set by the state board of pharmacy.

If medications are dispensed in other states, the pharmacy has the appropriate license/permits for those states serviced. Current copies of applicable rules and regulations are available.

Standard TCRX3-H

Written policies and procedures are established and implemented in regard to all pharmacy services being provided under the direction of a Registered Pharmacist who has documented training and competency in the scope of services provided.

All pharmacy services are provided under the direction of a Registered Pharmacist with sufficient education and experience in the scope of services offered.

Written policies and procedures identify the method and frequency for assessing the Pharmacist's competency in order to ensure that services are provided appropriately.

Standard TCRX3-I

The Registered Pharmacist supervises pharmacy technicians in accordance with the state board of pharmacy rules and regulations.

The pharmacy follows its state board of pharmacy regulations and the organization's policies and procedures that demonstrate that the Registered Pharmacist supervises the services provided by pharmacy technicians.

Standard TCRX3-J

Supervision is available during all hours that service is provided.

Interpretation: Supervision of personnel in the compounding pharmacy is provided 24 hours a day, 7 days a week, as applicable. Supervision is consistent with state laws and regulations.

Standard TCRX3-K

The organization's personnel have access to a reference library and/or internet access that is appropriate to the level of services provided.

Personnel have available a library of reference books, journals, internet access, etc., that is appropriate for the client/patient population served.

Resources include, but are not limited to:

- Professional journals
- General clinical reference
- Drug reference books
- Clinical guidelines
- Current medical dictionary
- Current statutes and rules for any state in which the personnel provide services

Records

Standard TCRX4-A

A Registered Pharmacist conducts an initial and, as needed, subsequent drug regimen reviews as required by the Omnibus Budget Reconciliation Act (OBRA 90) based on the database described in standard TCRX4-A.01. The client/patient, prescriber, and other health care professionals involved in client/patient care are consulted as needed. All Omnibus Budget Reconciliation Act (OBRA 90) counseling is completed.

A Registered Pharmacist is specifically responsible for recognizing the following as they pertain to compounded medications dispensed by the pharmacy:

- Drug-age precautions
- Drug-allergy interactions
- Drug-disease contraindications
- Drug-drug interactions

Standard TCRX4-A (Cont.)

- Drug-gender precautions
- Drug-pregnancy precautions
- Duplicate therapy
- High or low dosages
- Inappropriate duration of treatment
- Therapeutic appropriateness

The pharmacist consults as needed with the client/patient, prescriber and/or other health care professionals involved in client/patient care in order to address any discovered concerns.

The client/patient is offered verbal counseling by the pharmacist. The pharmacist ensures that the client/patient and/or caregiver is informed of significant concerns or precautions regarding the dispensed medication.

Standard TCRX4-A.01

Written policies and procedures are established and implemented relating to the content of the client/patient record. An accurate record is maintained for each client/patient.

Written policies and procedures define the content of the client/patient record. A reasonable effort will be made to record the following:

- Identification data
- Communication information
- Date of birth
- Gender
- Name of prescriber
- Prescribed drug(s)

Standard TCRX4-A.01 (Cont.)

- Treatment diagnosis
- Other patient medications, prescription and nonprescription
- Other patient health conditions
- Other relevant information, e.g. height and weight
- Allergies and /or sensitivities
- Drugs
- Relevant non-drug substances which may include:
  - Peanuts
  - Soy
  - Latex
  - Shellfish
  - Adhesive/tapes
  - Disinfectants (e.g., iodine, hexachlorophene/phisohex)

Standard TCRX4-A.01 (Cont.)

If the organization has electronic medical records (EMR), the organization has written policies and procedures and a mechanism to maintain all client/patient records in an electronic format. The EMR is in compliance with federal and state requirements.

Standard TCRX4-B

Written policies and procedures are established and implemented that address the timeliness of shipping, shipping errors, turnaround time, and lost shipments.

Written policies and procedures include, but are not limited to:

- Timeliness of shipping to ensure the client/patient receives medication prior to the administration date
- Ability to track the preparations after they leave the organization
- Notifying the client/patient if the shipment will be delayed
- Processes in place to ensure the client/patient has a continuous supply of medication if shipment is delayed or lost

Personnel implement the policies and procedures for the process of tracking shipments

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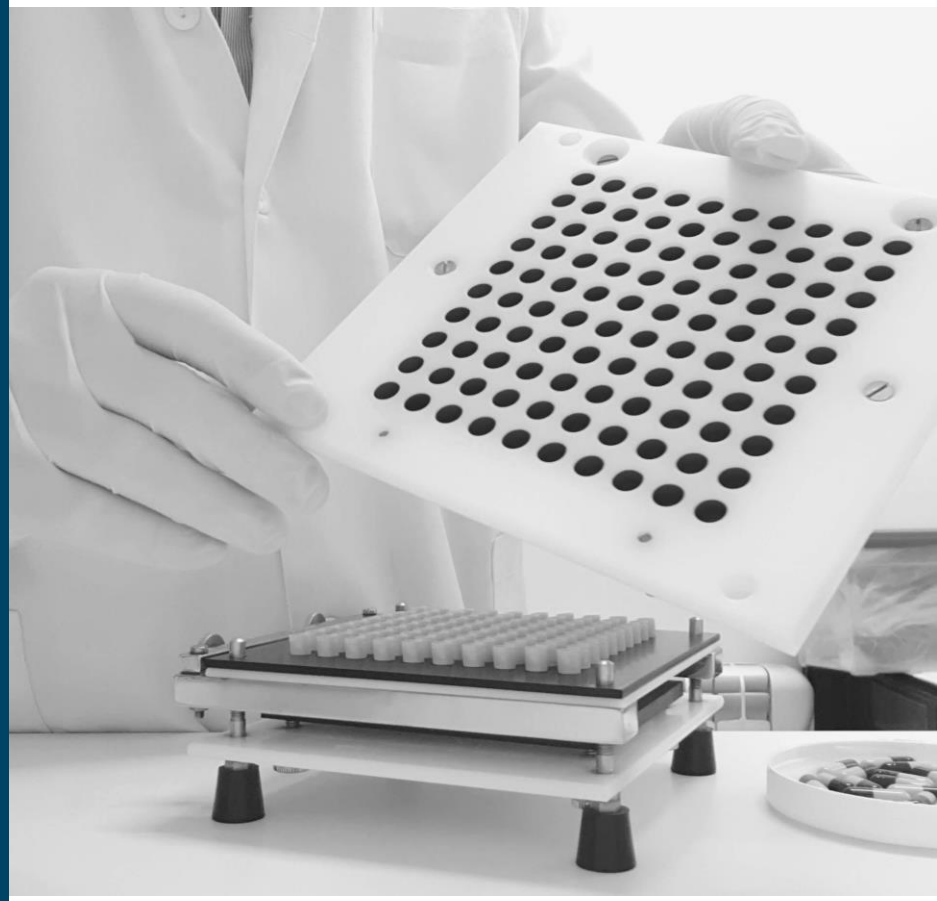
EDUCATIONAL RESOURCES

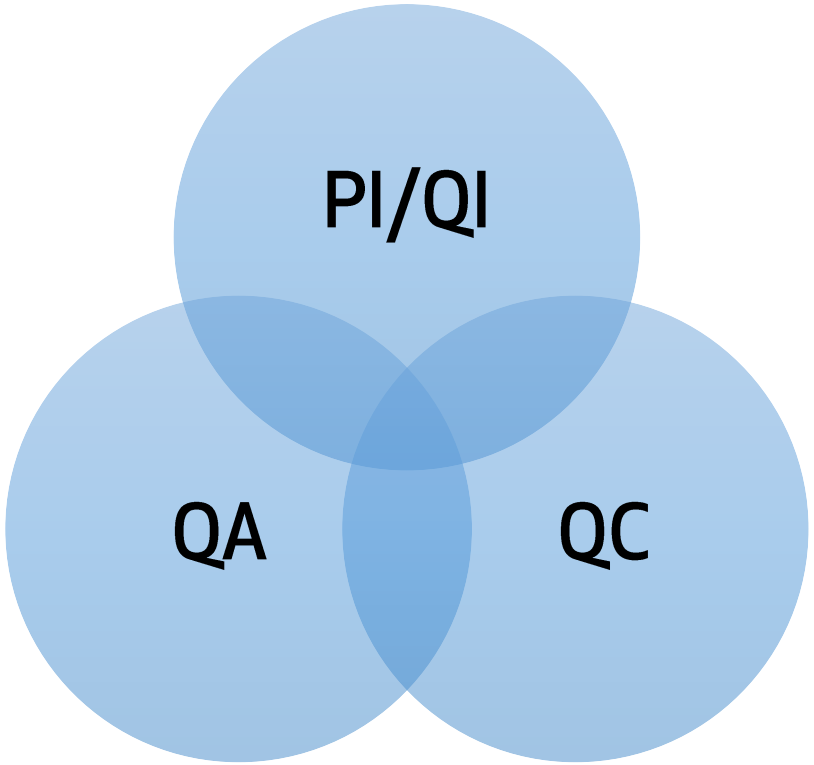
PHARMACY

Overview of Performance Improvement (PI) Standards

Section 5



Overview Of Performance Improvement (PI) Standards



Definition Confusion

- Quality Assurance (QA), Quality Control (QC), and PI are not the same thing
- They do overlap
- PI incorporates both QA and QC but more than QA and QC are required
- To add to the confusion, the terms are often used interchangeably

American Society For Quality Definitions

- Quality Assurance is "the planned and systematic activities implemented in a quality system so that quality requirements for a product or service are fulfilled."
  - Translation: The things you do to ensure that your preparations turn out the way you want them to
- Audience: Give some examples of QA in the typical pharmacy

American Society For Quality Definitions

- Quality Control is "… the observation techniques and activities used to fulfill requirements for quality“
  - Translation: The things you do to verify that your preparations turn out the way you want them to
- Audience: Give some examples of QC in the typical pharmacy

American Society For Quality Definitions

- Quality Improvement is "an ongoing effort to improve products, services or processes. These efforts can seek 'incremental‘ improvement over time or 'breakthrough’ improvement all at once”
- Audience: Give some examples of QI in the typical pharmacy

Standard TCRX5-A

The organization develops, implements, and maintains an effective, ongoing, organization-wide Performance Improvement (PI) Program.

Each organization develops a program that is specific to its needs. The methods used by the organization for reviewing data include, but are not limited to:

- Current documentation (e.g., review of client/patient records, incident reports, and complaints)
- Direct observation
- Interviews with personnel

The data collected by the organization for self-assessment includes, but is not limited to:

- Adverse events
- Client/patient complaints
- Client/patient records
- At least one important aspect related to the service provided
- Ongoing monitoring of processes that involve risks, including infections and communicable diseases

Standard TCRX5-B

The organization ensures the implementation of an organization-wide Performance Improvement (PI) Plan by the designation of a person responsible for coordinating PI activities.

Duties and responsibilities relative to PI coordination include:

- Assisting with the overall development and implementation of the PI Plan
- Assisting in the identification of goals and related client/patient outcomes
- Coordinating, participating in and reporting of activities and outcomes

The individual responsible for coordinating PI activities may be the owner, manager, supervisor or other designated personnel

Standard TCRX5-C

There is evidence of personnel involvement in the Performance Improvement (PI) process.

Personnel receive training related to PI activities and their involvement. Training includes, but is not limited to:

- The purpose of PI activities
- Person responsible for coordinating PI activities
- Individual's role in PI
- PI outcomes resulting from previous activities

Personnel are involved in the evaluation process through carrying out PI activities, evaluating findings, recommending action plans, and/or receiving reports of findings.

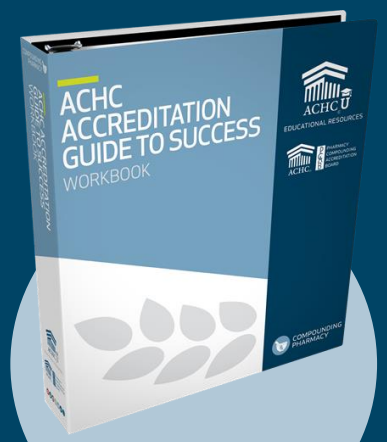
Standard TCRX5-D

Each Performance Improvement (PI) activity or study contains the required items.

Each PI activity/study includes the following items:

- A description of indicator(s) to be monitored/activities to be conducted
- Frequency of activities
- Designation of who is responsible for conducting the activities
- Methods of data collection
- Acceptable limits for findings
- Designation of who will receive the reports
- Plans to re-evaluate if findings fail to meet acceptable limits
- Any other activities required under state or federal laws or regulations

Sample PI Audit



5.15, 5.21

ACHC

[PHARMACY]

ACHC PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Area to Be Audited/Monitored:

Description of Audit/Indicators:

Frequency: Conducted By:

Data Collected From:

Threshold/Goal:

All PI reports will be presented to the PI committee and the governing body/owner.
In the event an audit fails to meet a threshold/goal, a written POC will be created that indicates plans to re-evaluate.

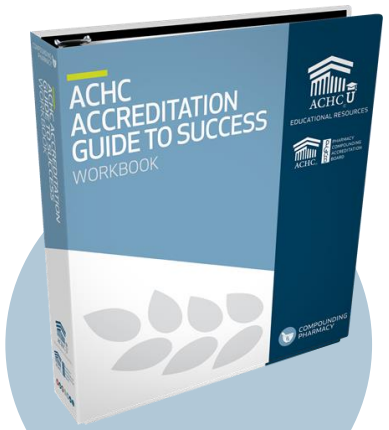
Creation Date Form # X

ACHC

Standard TCRX5-E

Written policies and procedures are established and implemented by the organization to identify, monitor, report, investigate, and document all adverse events, incidents, accidents, variances, or unusual occurrences that involve clients/patients who receive compounded preparations.

Written policies and procedures describe the process for identifying, reporting, monitoring, investigating, and documenting all adverse events, incidents, accidents, variances, or unusual occurrences.



p. 5.12

Standard TCRX5-E (Cont.)

Policies and procedures include, but are not limited to:

- Action to notify the supervisor or after-hours personnel
- Time frame for verbal and written notification
- Appropriate documentation and routing of information
- Guidelines for notifying the physician, if applicable
- Follow-up reporting to the administration/board/owner

The organization investigates all adverse events, incidents, accidents, variances, or unusual occurrences that involve client/patient services and develops a POC to prevent the same or a similar event from occurring again. Events include, but are not limited to:

- Unexpected death
- A serious injury
- Significant adverse drug reaction, if applicable

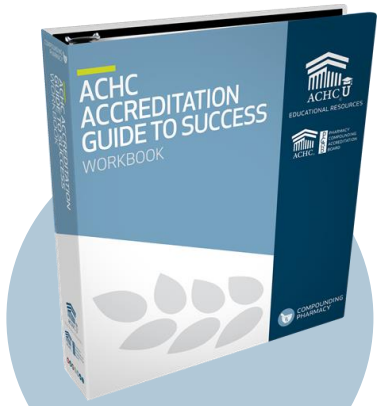
Standard TCRX5-E (Cont.)

- Significant medication error, if applicable
- Other undesirable outcomes as defined by the organization
- Adverse client/patient care outcomes
- Client/patient injury, (witnessed and un-witnessed)
- There are written policies and procedures for the organization to comply with the FDA and state boards of pharmacy to facilitate any recall notices submitted by the manufacturer, if applicable
- The organization has developed a standardized form it uses to report adverse events and to document all incidents, accidents, variances, and unusual occurrences. The organization initiates an investigation within 24 hours after becoming aware of an incident resulting in a client's/patient's hospitalization or death. For other occurrences, the organization investigates within 72 hours after being made aware of the incident, accident, variances or unusual occurrences
- This data is included in the PI plan. The organization assesses and utilizes the data to reduce further safety risks

Standard TCRX5-F

Performance Improvement (PI) activities include an assessment of processes that involve risks, including infections and communicable diseases.

A review of all variances, which includes but is not limited to incidents, accidents and complaints/grievances, is conducted at least quarterly to detect trends and create an action plan to decrease occurrences.



p. 5.12

Standard TCRX5-G

Written policies and procedures are established and implemented regarding continuous quality control for finished preparations.

The pharmacy establishes an on-going quality control program that defines:

- When to test preparations
- What test(s) should be performed
- Appropriate methods and equipment to use
- How to interpret the test
- Limits of the test
- Specific actions required when a preparation does not meet the test
- How quality control information is used to improve the performance of personnel
- How quality control information is incorporated into the pharmacy's PI Program

Standard TCRX5-G (Cont.)

Testing every compounded preparation is not required; ACHC encourages organizations to design quality control programs that can be used to verify the quality of compounded preparations and the competency of compounding personnel.

Below are examples for meeting compliance with this standard:

- For non-sterile preparations:
  - Using the procedure defined in USP Chapter <1163>, each compounder performs weight assessment for each of the following dosage forms they prepare: capsules, tablets, suppositories, inserts and lozenges every six months
  - Each compounder's finished preparation is tested for potency in each of the following dosage forms they prepare: solutions, suspensions, capsules, tablets, suppositories, creams/ointments and lozenges every six months

Standard TCRX5-G (Cont.)

For sterile preparations:

- For accuracy and precision testing for automated compounding devices, a periodic assessment of large volume parenterals to verify fill volume is performed
- For potency testing of finished preparations, each compounder's finished high-risk preparation is tested for potency in each of the following dosage forms they prepare:
  - Preparations sterilized by filtration
  - Sterilization
  - Dry heat every six months
  - Sterility testing of high-risk preparations is performed in accordance with USP Chapter <71>
  - Inspection of low- and medium-risk preparations is performed for proper labeling, absence of cores/particulates ,etc.

Standard TCRX5-H&I

Performance Improvement (PI) activities include ongoing monitoring of at least one important aspect related to the non-sterile/sterile compounding process.

The organization conducts monitoring of at least one important aspect of the non-sterile/sterile compounding process. An important aspect of service reflects a dimension of activity that may be high-volume (occurs frequently or affects a large number of clients/patients), high-risk (causes a risk of serious consequences if the service is not provided correctly), or problem-prone (has tended to cause problems for personnel or clients/patients in the past).

Standard TCRX5-J

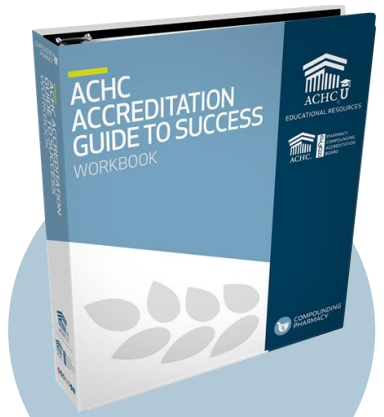
Performance Improvement (PI) activities include the ongoing monitoring of client/patient complaints/grievances.

PI activities include ongoing monitoring of client/patient complaints and the action(s) needed to resolve complaints and improve client/patient service.

STANDARD TCRX5-K

There is a written Plan of Correction (POC) developed in response to any Performance Improvement (PI) findings that do not meet an acceptable threshold as described in standard TCRX5-D (Acceptable limits for findings.

A written POC is developed in response to any PI activity that does not meet an acceptable threshold. The POC identifies changes in policies and procedures that will improve performance.

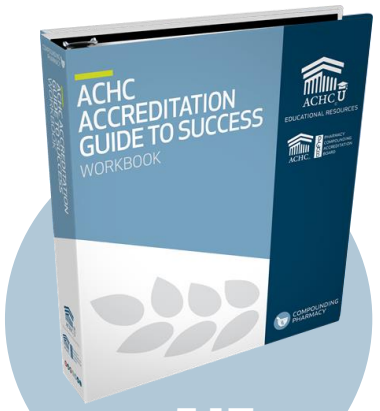


Standard TCRX5-L

There is an annual Performance Improvement (PI) report written.

There is a comprehensive, written annual report that describes the PI activities, findings and corrective actions that relate to the service provided. In a large, multi-service organization, the report may be part of a larger document addressing all of the organization's programs.

While the final report is a single document, improvement activities must be conducted at various times during the year. Data for the annual PI report may be obtained from a variety of sources and methods, such as audit reports, client/patient questionnaires, feedback from referral sources and outside survey reports.



p. 5.17

Case Study

- The pharmacy has developed a PI protocol based on standard TCRX5-A
  - Data reviewed includes:
    - Documents
    - Observation of activities
    - Staff interviews
  - Data is documented per TCRX5-E
    - Adverse Events, Incidents, Accidents, Unusual Occurrence, etc.
  - Review of documentation occurs at least quarterly, per TCRX5-F

Case Study (Cont.)

PI AUDIT DESCRIPTIONS

PI Activity/Audit Descriptions

Description of Audit/Indicators:

Conducted By: S. Monella

Pharmacy errors will be documented and classified according to: wrong dose, wrong drug, wrong route/ form, allergy/interaction, incorrect labeling, wrong patient, wrong route. Incident reports will be filed in a binder under the appropriate tab.

Frequency of Activities:

Monthly at staff meetings

Data Collected From:

Incident reports

Case Study (Cont.)

Threshold/Goal:

95% of all incidents will be properly documented. 100% of all incidents resulting in hospitalization, change of drug or a need for treatment as the result of the event will be documented and reported per policy 123 to the ISMP Patient Safety Organization.

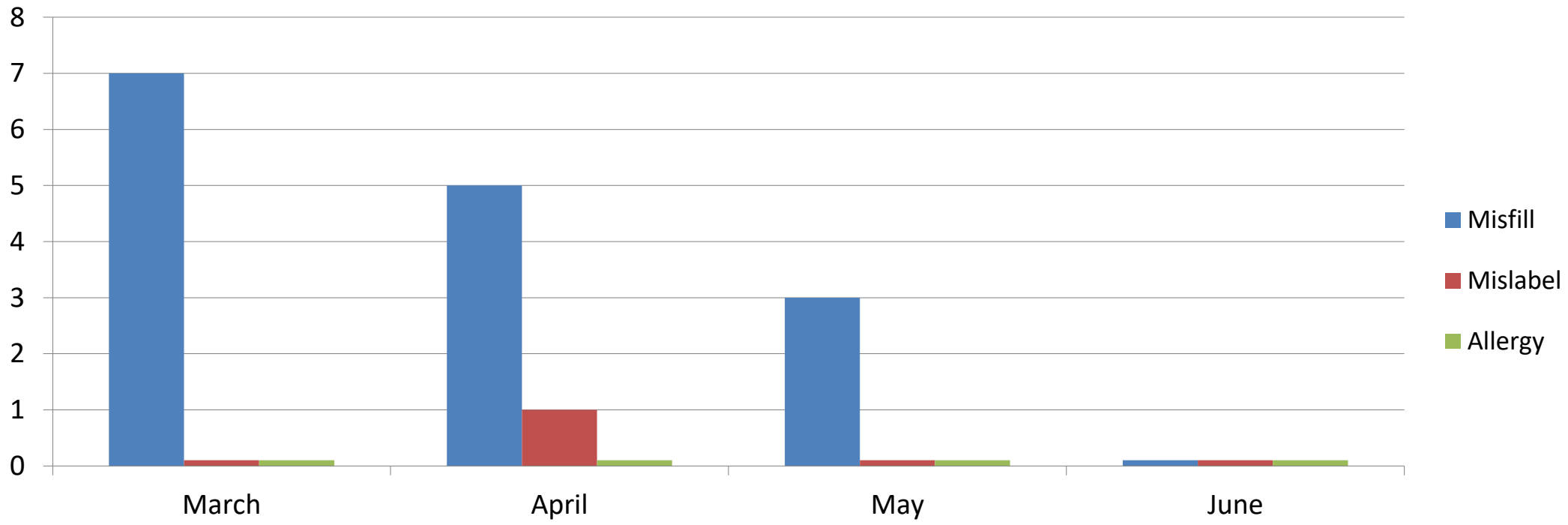
Plan for re-evaluation if threshold/goal is not met:

The initial step will be to retrain affected personnel and continue to monitor performance. Trends in findings will be used to improve organizational performance. Threshold to initiate action incident that involves the same individual or service failure two times in one month.

All PI reports will be presented to the PI committee and the Governing Body/owner.

In the event an audit fails to meet a threshold/goal, a written plan of correction will be created that indicates plans to re-evaluate.

Quarterly Trends Noted per TCRX5-E



Plan of Corrective Action

PLAN OF CORRECTION

Plan of Correction

PI Activity Audit: Mislabeling errors Date: 5/29/14

Threshold/Goal: 0 mislabeled rxs per month Actual Result: 5/month

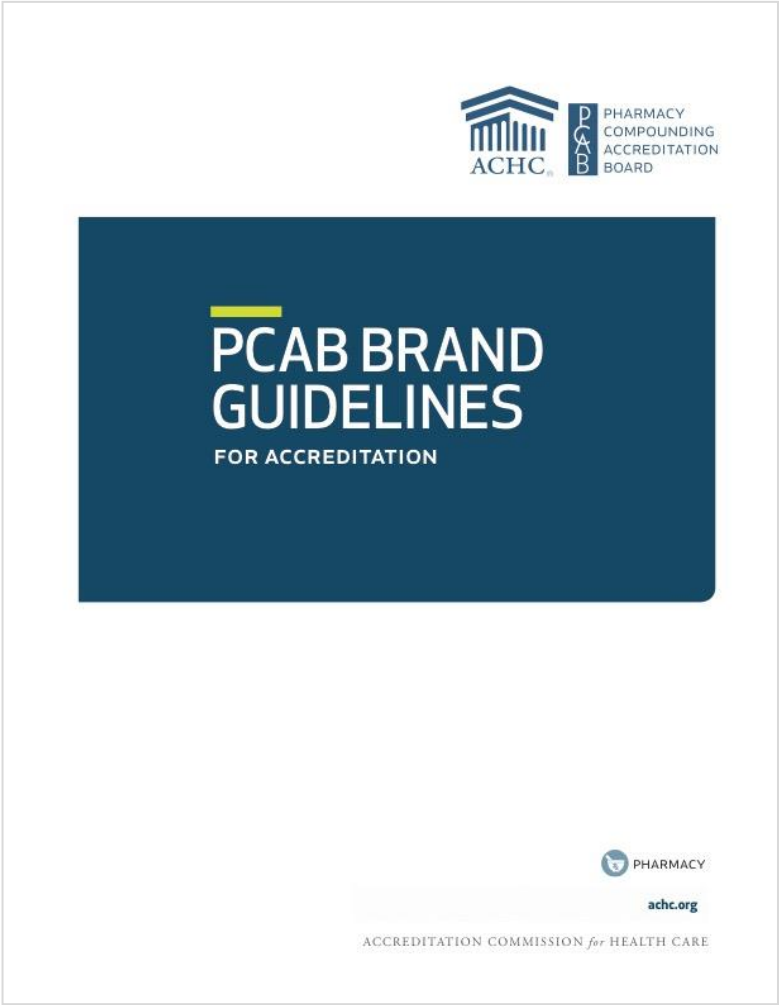
Possible Reasons Goal Not Met:
90% of the errors were a result of selecting similarly labeled and sized vials adjacent to each other in the refrigerator. Errors due to mispicks.

Corrective Plan of Action:
(List any policy & procedure changes, re-education, form changes, etc.)

ACTION ITEM	RESPONSIBLE PERSON
Conduct inservice on standard triple check	PIC
Separated similar vials in refrigerator and	
Labeled each with a different color	Chief Tech

Marketing Tools

- ACHC provides the tools to leverage your accredited status
- All PCAB-accredited organizations receive the PCAB Branding Kit
  - Brand Guidelines
  - PCAB Accredited Logos
  - Sample Press Release Template
  - Window Cling



Branding Elements

- PCAB Accredited Logos
  - Represents compliance with the most stringent national standards

Branding Elements

- PCAB Accredited Secondary Logo
  - Available for applications with limited space

Promoting Your PCAB Accredited Status

- A few basic places to promote PCAB accredited status include:
  - Website — Home page or dedicated landing page
  - Marketing Materials — Any marketing piece that is seen by the public
  - Press Releases — In the “boilerplate” of the press release, or the background information normally found toward the bottom of a press release
  - Social Media — Home page, banner image, or profile image
  - Promotional Items — Trade show displays, giveaways, binders, or folders
  - Email — Email signature
  - Voicemail — Voicemail message

ACHC Resources

- ACHC's Marketing Department is available to help with your marketing needs.
- Feel free to contact them at marketing@achc.org or (855) 937-2242.

Questions?

Now what?

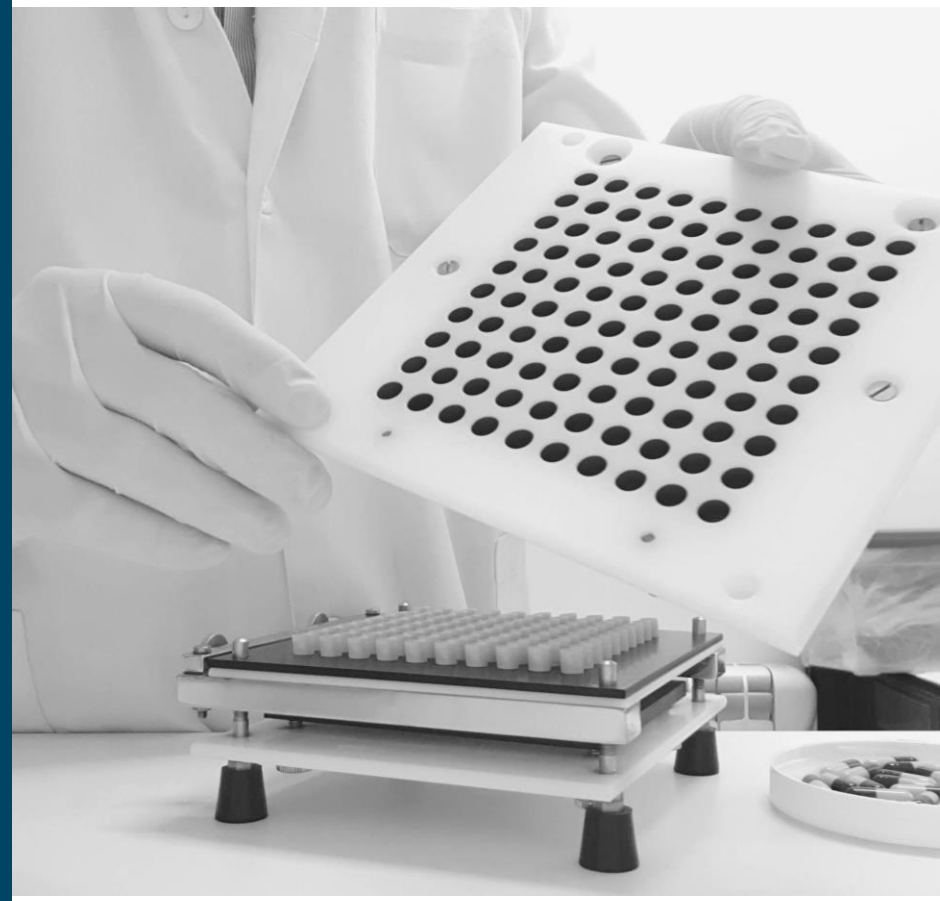
- Analysis
- You have spent today with ideas running through your head
  - Only you know where you are and where you fall short
  - Develop a team approach to determine areas of need
  - Prioritize those items most critical to patient and staff safety
- Audits
- Be the Surveyor; perform your own survey
- Use the audit tools provided
- Corrective Action and Preventative Action (CAPA)
- Develop and document corrective and preventative actions
- Monitor areas of concern or high risk in your PI Program

Workshop Evaluation

- Please help us know what we can do better
- What additional education or resources would be helpful?
- Would additional workshops would be helpful?
- Would on-site or pre-survey audits be helpful?
- How would you like us to communicate updates or changes?

ACHC U®
EDUCATIONAL RESOURCES

PHARMACY



THANK YOU

Accreditation Commission for Health Care
139 Weston Oaks Ct., Cary, NC 27513
(855) 937-2242