



ITEMS NEEDED FOR ON-SITE SURVEY

CUSTOMIZED FOR PHARMACY COMPOUNDING ACCREDITATION BOARD (PCAB)



Below are items that the Surveyor will review during your on-site survey. Please have these items available for your Surveyor prior to his or her arrival to expedite the process. If you have any questions, please contact your Account Advisor.

- Policy and procedure manual and crosswalk if applicable
- Personnel list with title, discipline and start date (including contract personnel)
- Personnel files with all items required by standard (see below)
- Any previous survey results from the past year (i.e., board of pharmacy, Food and Drug Administration (FDA), Drug Enforcement Agency (DEA), and fire department)
- Personnel meeting minutes for the past 12 months
- Sample prescription labels
- Records of formulas for the past three months
- Prescription logs for the past three months
- Potency test results
- Quality Related Events (QRE) documentation
- Equipment logs
- Client/patient advisory leaflets

ACHC Standard	Required Item	Located
Multiple	Access to policy and procedure manual with the following policies flagged: <ul style="list-style-type: none"> • TCRX5-E Handling incidents • TCRX5-G Quality control for finished preparations • TCRX6-O Cleaning, disinfecting, monitoring of controlled air environment(s) • TCRX6-P Assigning Beyond Use Dates(BUDs) (non- sterile) • TCRX6-Q Assigning BUDs (sterile) • TCRX6-R Sterility requirements and endotoxin limits 	
TCRX1-A	Copy of current applicable licenses or permits and if applicable, pharmacy licenses for those states preparations are shipped into	
TCRX2-A	Grievance/complaint log** (or plan to enact this standard once accredited)	
TCRX3-A,B&H	Competency evaluation** and/or training materials (if applicable) (CFNS, CFST), didactic training/testing,, gloved fingertip testing, media fills, etc.,** cleaning/disinfecting procedures, and hand hygiene/garbing (CFST)	
TCRX3-C	Staff education** on operating, cleaning, maintenance, and calibration of compounding equipment	
TCRX3-D	Staff education on routine cleaning and maintenance of equipment used in the client's/patient's home (CFST)	
TCRX3-E	<ul style="list-style-type: none"> • Staff education on identification, storage, handling, and disposal of hazardous drugs • Hazardous drug waivers for employees of reproductive capacity 	

ACHC Standard	Required Item	Located
TCRX3-G	Pharmacist license for other states in which medications are dispensed	
TCRX3-J	On-call/after- hours schedules, if applicable	
TCRX3-K	Reference library	
TCRX4-A & B	Client/patient medication profiles, Omnibus Budget Reconciliation Act (OBRA) counseling, and tracking of shipped preparations	
TCRX5A-K	Performance Improvement (PI) Program, data collection tools,** and plans of correction**	
TCRX5-E,	Incident log**	
TCRX5-G	Finished preparation quality control records	
TCRX5-L	PI annual report** (if PI Program has been in place >1 year)	
TCRX6-B	Recall records and compounding records	
TCCR6-3C	Temperature/humidity and cleaning logs	
TCRX6-D	Shipping/delivery container temperature testing records	
TCRX6-E	<ul style="list-style-type: none"> • Manufacturer's service manuals/guidelines for equipment used for preparing, dispensing, labeling, and shipping of preparations • Calibration, maintenance, and cleaning logs 	
TCRX6-F	Certificates of analysis (CofAs)	
TCRX6-G	Master Formulation Records (MFRs)	
TCRX6-H	Compounding records	
TCRX6-J	Class I Biological Safety Cabinet (BSC) environment certifications	
TCRX6-K	Compounding environment cleaning records (CFNS)	
TCRX6-O	Quality control records (cleaning and disinfecting), primary and secondary engineering control certifications, monitoring of the controlled-air environment, air pressure differential logs, viable/non-viable air sampling records, and surface sampling records (CFST)	
TCRX6-P&Q	BUD references for any extended BUDs	
TCRX6-R	Sterility and endotoxin tests (CFST)	
TCRX6-U	Labels for compounded preparations	

** Provide for the past three years if a renewal