

Pharmacy Board Report
2013

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	January-Sept 2013	Oct-13
Administrative Filings	23	6
Criminal Filing/Felony	3	
Letter of Concern	42	4
PR/Outreach		2
Cases Received	576	79
Case Assigned	549	75
Closed Cases	592	55
Citations Issued	85	10
Pharmacy Inspections	174	13
Pharmacy Alerts	133	27
Dr. Shopper/Law Enforcement Letters	98	12

NOTES:

Oct-13

Lynn Hooper

Investigator Lynn Hooper performed training at the South Town Mall for the Utah Pharmacy Association. The training was on Self Inspection Reports for the Pharmacies and assisted Marv Sims with the Controlled Substance Database Training. Lynn received good reviews from the participants, approximately 100 attendees. Lynn was asked to also do this at the St George training in the Summer at the St George Conference.



KEY:

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Purple Font = Recommendations found in Compounding Sterile Preparations (E. Clyde Buchanan)

		This column includes information that needs to be incorporated into standard operating procedures or policies.	This column lists required practices	This column lists best practices.	This column includes areas where documentation will help prove compliance.			
		<i>Requires procedure/policy</i>	<i>Requires practice</i>	<i>Best practice</i>	<i>Documentation</i>	<i>Documentation</i>	<i>Standard Operating Procedure/policy</i>	<i>Compliance</i>
	personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist and other visible jewelry or piercings that can interfere with the effectiveness of PPE							
B	Standard Operating Procedures shall be created and maintained in written format addressing personnel cleansing and garbing							
	All CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter							
	Compounding personnel are adequately skilled, educated, instructed, and trained to correctly maintain/achieve sterility of CSPs in ISO Class 5 PEC devices and protect personnel and compounding environments from contamination							
	Compounding personnel are adequately skilled, educated, instructed, and trained to correctly identify, weigh and measure ingredients							
	Compounding personnel are adequately skilled, educated, instructed, and trained to correctly manipulate sterile products aseptically, label and quality inspect CSPs							
	Personnel shall be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.							
	Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection or wearing cosmetics shall be excluded from working in ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.							
	Before entering the buffer area/segregated compounding area, compounding personnel shall remove personal outer garments							
	Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.							
	When exiting the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled. Shoe covers, hair & facial covers, face mask and gloves shall be replaced with new one before re-entering the compounding area and proper hand hygiene shall be performed							
TRAINING & COMPETENCY PROCESSES								
B	Standard Operating Procedures shall be created and maintained in written format addressing training of personnel involved in compounding							
	Personnel who prepare CSP shall be trained conscientiously and skillfully by expert personnel and through audio-video multimedia instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulation and in achieving and maintaining ISO Class 5 environmental conditions before they begin to prepare CSPs.							
	Compounding personnel shall perform didactic review and pass written & media-fill testing of aseptic manipulative skills initially and at least annually thereafter. Compounding personnel who fail written tests or whose media-fill test vials results in gross microbial colonization shall be immediately re-instructed & re-evaluated by expert personnel to ensure correction of all aseptic practice deficiencies.							
	Personnel who prepare CSP shall be trained conscientiously and skillfully by expert personnel and through audio-video multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.							
	This training shall be completed and documented before any compounding personnel shall be completed and documented before any compounding personnel begin to prepare CSPs.							

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	<i>Hand Hygiene & Garbing Practices</i>	<i>Required Practices</i>	<i>Best Practices</i>	<i>Documentation</i>	<i>Comments</i>		
	Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing.						
	In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures.						
	After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning & disinfecting procedures conducted by a qualified aseptic compounding expert.						
	Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a form such as Sample Form for Assessing Hand Hygiene & Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sample procedures						
	Sampling of compounding personnel glove fingertips shall be performed. Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene & garbing procedures in addition to educating personnel on proper work practices.						
	All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices						
	Sterile contact agar plates shall be used to sample the gloved fingertips after garbing in order to assess garbing competency and after completing the media-fill preparation in order to assess the adequacy of aseptic work practices prior to being initially allow to prepare CSPs.						
	Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures and it shall be documented and maintained to provide a permanent record and long-term assessment of personnel competency						
	All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure no less than 3 times before initially being allowed to compound. Re-evaluation shall be performed at least annually.						
	Immediately after the compounding employee completes the hand hygiene & garbing procedure, the evaluator will collect a gloved fingertip and thumb sample from both hands of the employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated at 30° to 35° for 48 to 72 hours. Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA.						
	After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs.						
	After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the Media-Fill Test Procedure and subsequent annual or semi-annual Media-Fill Test Procedures. Records of these evaluations will be maintained to provide a permanent record of and long-term assessment of personnel competency						
	When gloved fingertip sample results exceed action levels after proper incubation, review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented. Employee training may be required to correct the source of the problem.						

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	<i>A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site</i>						
	<i>Each person assigned to the aseptic area in preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs</i>						
	<i>Compounding personnel shall design, implement and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections on all personnel to whom such functions and tasks are assigned</i>						
B	<i>Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Training should be documented</i>						
B	<i>Compounding personnel who prepare compounded sterile preparations shall perform didactic review and pass a written and media-filled testing of aseptic manipulative skill initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding</i>						
P	<i>Training records and competence test scores for each employee (e.g. aseptic technique observation, test scores, media fills and fingertip media tests)</i>						
P	<i>The following should be included in the a pharmacy CSP quality assurance program Personnel Records: - orientation check list - didactic training test results - form for assessing hand hygiene and grabbing related practices - form for assessing aseptic technique and related practices - form for assessing cleaning and disinfecting procedures - media fill results - fingertip media testing results - hazardous drug handling training</i>						
MEDIA-FILL TEST PROCESSES							
	<i>This test or an equivalent test is performed at least annually. Process outlining how low, medium and high risk testing will be conducted</i>						
	<i>Media-Fill Challenge Testing may be evaluated using TSB and is used to assess the quality of the aseptic skill of compounding personnel. Media-filled vials are generally incubated at 20° - 25° OR at 30° - 35° for a minimum of 14 days. IF two temperatures are used for incubation, then test filled containers should be incubated at each temperature for at least 7 days. Failure is indicated by visible turbidity in the medium on or before 14 days.</i>						
	<i>Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding.</i>						
	<i>A media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs</i>						
	<i>Compounding personnel who fail written tests or observational audits or whose media-fill test vials have one or more units showing visible microbial contamination shall be re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.</i>						
PRODUCT REQUIREMENTS							
FORMULATION PROCESSES							
	<i>Procedures for measuring, mixing, dilution, purification, sterilization, packaging and labeling conform to the correct sequence and quality established for the specified CSP</i>						

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		<i>for bulk active ingredients</i>	<i>Required Practices</i>	<i>Best Practices</i>	<i>Documentation</i>	<i>Control Measures</i>		
B	bulk active ingredients must be procured from a facility registered with the federal Food and Drug Administration and must not be listed on the federal Food and Drug Administration list of drug products withdrawn or removed from the market for reasons of safety or effectiveness.							
B	A master worksheet shall be developed and approved by the pharmacist for each batch of sterile pharmaceuticals to be prepared. Once approved, a duplicate of the master worksheet shall be used as the preparation worksheet from which each batch is prepared and on which all documentation for that batch occurs.							
B	A master worksheet must contain the following: - formulation name and strength - compounding directions - evaluation and testing requirements - specific equipment used during preparation (specific compounding device) - BUD information - ingredients and quantities - a sample label - sterilization methods (if applicable) - storage requirements							
	A preparation worksheet for each batch of sterile pharmaceuticals shall document the following: - identify all solutions and ingredients - all solution and ingredients corresponding amounts, concentration, or volumes - manufacturer lot number for each component - component manufacturer or suitable identifying number - container specifications (syringe, pump) - unique lot number or control number assigned to batch - expiration date of batch prepared products - date of preparation - name, initials or electronic signature of person(s) involved in preparation - name, initials or electronic signature of responsible pharmacist - end product evaluation and testing specifications (if applicable) - comparison of actual yield to anticipated yield, when appropriate - dosage units compounded - prescription numbers							
B	The compounding records including the master worksheet, preparation worksheet and MSDS files shall be kept for a minimum of 5 years							
B	the facility does not prepare a prescription drug in a dosage form which is regularly and commonly available from a manufacturer in quantities and strength prescribed by a practitioner							
P	Batch compounding records							
P	Master Worksheets							
ASEPTIC TECHNIQUE PROCESSES								
	Access to buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area							
	All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping/spraying them with nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart							
	Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area							

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	<i>Carts used to bring supplies from the storage room cannot be rolled beyond the demarcation line in the ante-area. Carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning</i>	<i>Required Practice/Policy</i>	<i>Required Practice</i>	<i>Best Practice</i>	<i>Documentation</i>	<i>Standard Operating Procedure/Policy</i>	<i>Surfaces</i>
	<i>Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more removable carts. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.</i>						
	<i>Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels and cotton items</i>						
	<i>Essential paper related products shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area</i>						
	<i>Traffic flow in and out of buffer area shall be minimized</i>						
	<i>Chewing gum, drinks, candy or food items shall not be brought into the buffer area or ante-area. Materials exposed in patient car and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present</i>						
	<i>At the beginning of each compounding activity session, and whenever liquid are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe</i>						
	<i>Traffic in the area of the DCA (direct compounding area) is minimized and controlled. Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area</i>						
	<i>All supply items are arranged in the DCA so as to reduce clutter and provide maximum efficiency and order for the flow of work</i>						
	<i>After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the first air from HEPA filters and an exposed critical site</i>						
	<i>All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA</i>						
	<i>All rubber stoppers of vials and bottle and neck of ampules are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs</i>						
	<i>After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects</i>						
	<i>After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace</i>						
B	<i>Standard Operating Procedures shall be created and maintained in written format addressing proper cleaning and maintenance of sterile compounding area and equipment</i>						

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	<i>Packaged compounding supplies and components, such as needles and syringes should be uncapped and wiped down with a disinfectant that does not leave a residue when possible in an ante-area of ISO Class 8 air quality, before being passed into the buffer areas</i>						
	<i>There shall be a demarcation designation that separates the ante-area from the buffer area</i>						
B	<i>USP <797> compounding of sterile preparations is followed</i>						
B	<i>Only authorized personnel are allowed in the immediate vicinity of the drug compounding operations</i>						
B	<i>assurance of sterility in a compounding sterile preparation is mandatory</i>						
RECEIVING PROCESSES							
	<i>Physical inspection of a package of ingredients is necessary in order to detect break in the container, looseness in the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents.</i>						
	<i>The date of the receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient</i>						
	<i>After receipt by the compounding facility, packages of ingredients that lack an expiration date cannot be used after 1 year unless appropriate inspection or testing indicates that the ingredients has retained its purity and quality for use in CSPs</i>						
	<i>Upon receipt of each lot of the bulk drug substance or excipient used for CSPs, the individual compounding the preparation performs a visual inspection of the lot for evidence of deterioration, other types of unacceptable quality, and wrong identification. For bulk drug substances or excipients, visual inspection is performed on a routine basis as described in the written protocol</i>						
PRODUCT VERIFICATION PROCESSES							
B	<i>Standard Operating Procedures shall be created and maintained in written format addressing evaluation and testing requirements</i>						
	<i>Ingredients have their correct identity, quality and purity</i>						
	<i>Before being dispensed or administered, the clarity of solutions are visually confirmed, the identity and amounts of ingredients, procedures to prepare and sterilize and specific release criteria are reviewed to ensure their accuracy and completeness</i>						
	<i>BUDs are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation.</i>						
	<i>Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded</i>						
	<i>Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.</i>						
	<i>Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts and purities of ingredients in CSPs shall be confirmed by review labels on packages, observing and documenting correct measurements with approved and correctly standardized devices and reviewing information in labeling and certificates of analysis provided by suppliers.</i>						
	<i>When correct identity, purity, strength, and sterility of ingredients and components of CSPs CANNOT be confirmed, such ingredients and components shall be discarded immediately.</i>						
	<i>Although not required, a quantitative stability indicating chemical assay is recommended to ensure compounding accuracy of CSPs, especially those that contain drug ingredients with a narrow therapeutic plasma concentration range</i>						

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	All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed						
	Immediately after compounding, and as a condition of release, each CSP unit should be inspected against lighted white or black background for evidence of visible particulates or other foreign matter						
	CSPs with observed defects should be immediately discarded/marked/segregated in a manner that prevents their administration						
	Compounding facilities shall have at least the following written procedures for verifying the correct identity & quality of CSPs before they are dispensed or administered: That there are correct identities, purities and amounts of ingredients by comparing the original written order with the written compounding record for the CSP						
	Compounding facilities shall have at least the following written procedures for verifying the correct identity & quality of CSPs before they are dispensed or administered: That correct fill volumes in CSPs and correct quantities of filled units of CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients						
B	the compounding procedures and sterilization methods for compounded sterile preparations correspond to correctly designated and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining desired accuracy and purity of finished compounded sterile products						
P	Process Validations Records						
P	The following should be included in the a pharmacy CSP quality assurance program Product Verification: -master formula sheets and batch records -CSP orders or prescriptions and corresponding release checks (e.g. accuracy, particulates, closures) and tests (e.g. sterility, non-pyrogenicity)						
PRODUCT RELEASING PROCESSES							
	obtain & evaluate results of testing for identity, strength, purity and sterility before a CSP is dispensed						
	Potential harm from added substances and differences in rate and extent of bioavailability of active ingredients are carefully evaluated before such SCPs are dispense and administered						
	Packaging selected for CSPs is appropriate to preserve the sterility and strength until the BUD						
	compounding manipulations & procedures are separated from post compounding quality inspection & review before CSPs are dispensed.						
	Written procedures for double-checking accuracy shall be followed for every CSP during preparation and immediately prior to release						
	Compounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder.						
	When practical, the accuracy of measurements is confirmed by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate value of density, or specific gravity, of the measured fluid						

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	Correct density or specific gravity values programmed in ACDs, which measure by weight using the quotient of the programmed volume divided by the density or specific gravity, shall be confirmed to be accurate before and after delivering volumes of liquid assigned to each channel or port						
	Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients						
	The compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions						
	The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions						
	Establishing, maintaining and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility						
PRODUCT LABELING PROCESSES							
	Labels on CSPs list the names and amounts/concentrations of active ingredients. Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis, direct chemical analysis, and knowledge or compounding facility storage conditions						
	Compounding facilities shall have at least the following written procedures for verifying the correct identity & quality of CSPs before they are dispensed or administered: Labels of CSPs bear correct names and amounts/concentrations of ingredients, the total volume, the BUD, appropriate route of administration, the storage conditions and other information for safe use						
B	bulk component containers are labeled with appropriate occupational safety and health administration (OSHA) hazard communication labels, and material safety data sheets are available to compounding personnel for all drugs and chemicals used in compounding						
B	The sample label of each batch prepared of sterile pharmaceuticals shall bear at a minimum: -unique lot number assigned to the batch -all solution and ingredient names, amounts, strengths and concentrations -quantity -expiration date and time -appropriate ancillary instructions, such as storage instructions or cautionary statements, including warning labels where appropriate -device-specific instructions (if applicable) -"This is a Compounded Preparation" should be indicated						
B	All prescription labels shall bear at a minimum the following in addition to what is required in UAC 58-17b-602: -unique lot number assigned to the batch -all solution and ingredient names, amounts, strengths and concentrations -quantity -expiration date and time -appropriate ancillary instructions, such as storage instructions or cautionary statements, including warning labels where appropriate -device-specific instructions (if applicable) -"This is a Compounded Preparation" should be indicated						

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P	<p>polices and procedures for labeling should outline the required information for: preparations compounded in batches in anticipation of routine orders, preparation dispensed for administration within the institution, and patient-use preparations</p>						
P	<p>SOPs should indicate where labels are obtained and stored in the pharmacy. They should also require sequestration of batch labels with their preparation batches</p>						
PACKAGING/TRANSPORT PROCESSES							
	<p>Transport, handling and placement into storage may be fulfilled by noncompounding personnel who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has direct interest</p> <p>The critical requirements that are unique to CSPs and that are necessary to ensure CSP quality and packaging integrity shall be addressed in SOPs</p>						
	<p>The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure and stable. The CSPs shall not be redispensed if there is not adequate assurance that preparation quality and packaging integrity were continuously maintained between the time the CSP left and the time they were returned. CSPs shall not be redispensed if redispensing cannot be supported by the originally assigned BUD</p>						
	<p>The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials based on information from product specifications, vendors and experience for compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to recipients</p>						
	<p>Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile and stable condition to recipients</p>						
	<p>It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter to ensure that temperatures during transit will not exceed the warmest temperature specified on the storage temperature range on CSP labels</p>						
	<p>Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported to obtain reasonable assurance of compliance therewith from transporters</p>						
	<p>Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported</p>						
P	<p>SOPs should cover packaging for transport, in transit temperatures, precautions of toxic preparations transport, commercial carrier expectations, evaluation of shipper performance, and in-home conditions.</p>						
P	<p>For CSPs to be used in a patient's home, procedures should include assurance of proper storage capability, written instructions for use and suitability for use and home visitation and inspection</p>						
P	<p>SOPs for shipping CSPs to patients or customers should also define the action to be taken in the event that a patient reports that there has been a deviation from required storage conditions, including environmental sensitive CSPs, prior to point of receipt</p>						

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HAZARDOUS DRUG PROCESSES							
	Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas						
	Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure						
	storage is preferably within a containment area such as a negative pressure room.						
	The storage area should have sufficient general exhaust ventilation, at least 12 air changes per hour to dilute and remove any airborne contaminants.						
	Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration and disposal.						
	Hazardous drugs shall be prepared in an ISO class 5 environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter.						
	Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.						
	All hazardous drugs shall be prepared in a BSC or a CACI that meets or exceeds the standards for CACI in this chapter.						
	When closed-system vial-transfer devices are used, they shall be used within a ISO Class 5 environment of a BSC or CACI.						
	Appropriate personnel protective equipment shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI						
	All personnel who compound hazardous drugs shall be fully trained in the storage, handling and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person annually						
	This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace.						
	Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.						
	The training shall include at least the following: safe aseptic manipulation practices; negative pressure techniques with utilizing a BSC or CACI, correct use of CSTD devices, containment, cleanup, and disposal procedures for breakages and spills; and treatment of personnel contact and inhalation exposure						
	environmental sampling to detect uncontained hazardous drugs should be performed routinely (i.e. initially as a benchmark and at least every 6 months or more often as needed to verify containment).						
	Sampling should include surface wipe sampling of the working area of BSCs and CACIs; counter tops where finished preparations are placed; areas adjacent to BSCs and CACIs, including floor directly under the working area; and patient administration areas.						
	If any measurable contamination is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document and contain the cause of contamination.						
	Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.						

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	<i>Respiration Eng/2016</i>	<i>Required Practices</i>	<i>Best Practices</i>	<i>Documentation</i>	<i>Standard Operating Procedure/Policy</i>	<i>Comments</i>
<p>All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.</p>						
<p>RADIOPHARMACEUTICALS PROCESSES</p>						
<p>Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO class 8 or cleaner air environment to permit compliance with special handling, shielding and negative air flow requirements</p>						
<p>Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturer's recommendations.</p>						
<p>Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation</p>						
<p>Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations</p>						
<p>Such generator systems shall be eluted in an ISO Class 8 or cleaner environment to permit special handling, shielding, and air flow requirements.</p>						
<p>To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA</p>						
<p>Radiopharmaceuticals prepared as low-risk level CSPs with 12-hr or less BUD shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established.</p>						
<p>Materials and garb exposed in a patient care and treatment area shall not cross the line of demarcation into the segregated compounding area</p>						
<p>ALLERGEN EXTRACTS PROCESSES</p>						
<p>Allergen extracts as CSPs are single-dose and multiple-dose intradermal or subcutaneous injections that are prepared by specially trained physicians and personnel under their direct supervision</p>						
<p>allergen extracts as CSPs are NOT subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels in this chapter ONLY when ALL of the following criteria are met:</p>						
<p>1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances</p>						
<p>2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter</p>						
<p>3. before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbow for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water</p>						
<p>4. compounding personnel don hair covers, facial hair covers, gowns and face masks.</p>						
<p>5. Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity</p>						

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	<i>Regulatory Procedures/Policies</i>	<i>Regulatory Practices</i>	<i>USP Practices</i>	<i>Documentation</i>	<i>Documentation</i>		
	6. Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations						
	7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts of CSPs						
	8. Ampule necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used in compounding allergen extracts as CSPs						
	9. the aseptic compounding manipulations minimize direct contact contaminations (e.g. from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g. needles, opened ampules vial stoppers).						
	10. the label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer reviewed publications						
	11. Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.						
	Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for CSP Microbial Contamination Risk Levels.						
EQUIPMENT REQUIREMENTS							
EQUIPMENT PROCESSES							
	Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purpose of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.						
B	Standard Operating Procedures shall be created and maintained in written format addressing proper use of equipment						
	Measuring, mixing, sterilizing and purifying devices are clean, appropriately accurate and effective for their intended use						
	Policies and procedures for maintaining and working within the PEC (Primary Engineering Control) area shall be written and followed.						
	PECs shall be located within a restricted access ISO Class 7 buffer area with the following CAI/CACI (Compounding Aseptic Isolator/Compounding Aseptic Containment Isolator) exception below:						
	* Only authorized personnel & materials required for compounding & cleaning shall be permitted in the buffer area						
	* Presterilization procedures for high-risk level CSPs such as weighing & mixing, shall be completed in no worse than an ISO Class 8 environment						
	* PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns						
	When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented & internal procedures developed to ensure adequate recover time is allowed after material transfer before and during compounding operations.						
	If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW (laminar airflow workbench) or BSC (biological safety cabinet) that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous CSP may be prepared and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less						

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	<i>Certification procedures such as those outlined in 'Certification guide for Sterile Compounding Facilities' shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.</i>						
	<i>Certification that each ISO classified area is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI or CACI is relocated or the physical structure of the buffer area or ante-area has been altered</i>						
	<i>Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following: * ISO Class 5: not more than 3520 particles 0.5µm and larger size per cubic meter of air for any LAFW, BSC, CAI and CACI * ISO Class 7: not more than 352,000 particles of 0.5µm size and larger per cubic meter of air for any buffer area.</i>						
	<i>All certification records shall be maintained and reviewed by supervising personnel to ensure that the controlled environments comply with the proper air cleanliness, room pressures and ACPHs</i>						
	<i>Routine maintenance and frequencies of equipment shall be outlined in a SOP</i>						
	<i>Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment</i>						
	<i>Written procedures outlining required calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of equipment and specified time frames for these activities are established and followed.</i>						
	<i>Personnel are prepared through training & experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs</i>						
B	<i>Primary engineering controls shall maintain ISO class 5 or better conditions for 0.5 µm particles while compounding sterile preparations</i>						
B	<i>primary engineering controls shall be located within a restricted access ISO class 7 buffer/ante room</i>						
B	<i>primary engineering controls and secondary (buffer and ante areas) shall be certified following procedures such as those outlined in Certification Guide for Sterile Compounding Facilities and shall be performed by a qualified individual no less than every 6 months and whenever a device or room is relocated or altered or major service to the facility is performed</i>						
P	<i>Certification of laminar-airflow workbenches, biological safety cabinets, compounding isolators and scales or balances</i>						
P	<i>The following should be included in the a pharmacy CPS quality assurance program Equipment: -cleaning logs for the LAFWs, BSCs, CAIs, CACIs, ante area, buffer area, and compounding equipment -equipment calibration logs -primary and secondary engineering control certification reports</i>						
CLEANING REQUIREMENTS							
CLEANING PROCESSES							
	<i>Compounding personnel are responsible for ensuring that the frequency of cleaning is in accordance with the requirements stated in Table 3 and determining the cleaning & disinfecting products to be used.</i>						
	<i>All cleaning & disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.</i>						
	<i>Disinfecting sterile compounding areas shall occur on a regular basis at the interval noted in Table 3 when spills occur, when surfaces are visibly soiled, and when microbial contamination is known/suspected.</i>						

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	<i>Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills. This shall be followed by wiping with a residue free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins</i>						
	<i>Work surfaces in the ISO Class 7 buffer areas and ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 air quality</i>						
	<i>Floors in the buffer area, ante-area and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.</i>						
	<i>All cleaning materials, such as wipers, sponges & mops, shall be nonshedding, preferable synthetic micro fibers and dedicated to use in the buffer/clean area and ante-area and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer area and ante-area, but only in that order.</i>						
	<i>If cleaning materials are reused, procedures shall be developed that ensure that the effectiveness of the cleaning device is maintained & that repeated use does not add to the bioburden of the area being cleaned.</i>						
	<i>Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent and shall be allowed to dry</i>						
	<i>Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampules.</i>						
	<i>Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices</i>						
	<i>No shipping or other external cartons may be taken into the buffer/clean area</i>						
	<i>Surface sampling shall be performed in all ISO classified areas on a periodic basis. Sampling can be accomplished using contact plates or swabs and it shall be done at the conclusion of compounding.</i>						
	<i>Locations to be sampled shall be defined in a sample plan or on a form. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm².</i>						
	<i>Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during changes in cleaning staff, and at the completing of any media-fill test procedure. The visual observation shall be documented using a form and maintained to provide a permanent record and long-term assessment of personnel competency.</i>						

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	Requirements/Procedures/Policies	Requirements/Practices	Best Practices	Documentation	Standard Operating Procedures/Policies	Comments	
STORAGE							
MEDICATION STORAGE PROCESSES							
B	Standard Operating Procedures shall be created and maintained in written format addressing storage requirements						
	Opened or partially used packages of ingredients for subsequent use in CSPs are properly stored under restricted access conditions						
	LOW RISK: CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at -25 ° to -10 ° or colder						
	MEDIUM RISK: In absence of passing sterility test, the storage periods cannot exceed the following: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at -25 ° to -10 ° or colder						
	HIGH RISK: In absence of passing sterility test, the storage periods cannot exceed the following: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at -25 ° to -10 ° or colder						
	A written procedure for unit-by-unit physical inspection preparatory to use is followed to ensure that commercially available sterile drug products are sterile, free from defect, and otherwise suitable for their intended use						
	Bulk or unformulated drug substances and added substances or excipients shall be stored in lightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers						
	Personnel who prepare, dispense or administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs						
	When CSPs are exposed to temperatures warmer than permitted or to temperature exceeding 40 ° for more than 4 hours, CSPs should be discarded unless direct assay data or appropriate documentation confirms their continued stability						
DRUG EXPIRATORY / BUD PROCESSES							
B	Standard Operating Procedures shall be created and maintained in written format addressing methods used to determine expiration dates						
	Opened or needle-punctured single-dose containers, such as bags, bottle, syringes, vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 and any remaining contents must be discarded.						
	Single-dose vials exposed to ISO Class 5 or cleaner air may be used up to 6 hours after initial needle puncture.						
	Opened single-dose ampules shall not be stored for any period of time						
	Multiple-dose containers have a BUD after initially entering or opening of 28 days unless specified by manufacturer						
	BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing						
	BUDs for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in Stability Criteria and Beyond-Use Dating under Pharmaceutical Compounding- Nonsterile Preparations <797>						
	When assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions and the intended duration of therapy						

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	<i>The compounding facility should have written policies/procedures governing the determination of the BUDs for all compounded products</i>						
	<i>The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions</i>						
	<i>When manufactured MDVs of sterile ingredients are used in CSPs, the stoppers of the MDVs are inspected for physical integrity and disinfected by wiping with a sterile 70% IPA swab before each penetration with a sterile withdrawal device. When contaminants or abnormal properties are suspected or observed in MDVs, such MDVs shall be discarded</i>						
B	<i>the expiration date assigned shall be based on currently available drug stability information and sterility considerations or appropriate in house or contract service stability testing</i>						
B	<i>methods for establishing expiration dates shall be documented</i>						
B	<i>The facility contains the following sources of drug stability information: -Trissell's -Manufacturer recommendations -Reliable published research</i>						
P	<i>Drug Recall Records</i>						
P	<i>policies and procedure concerning storage should be based on USP or manufacturer specified conditions</i>						
P	<i>SOPs for handling expired drugs and supplies should encompass their removal and quarantine as well as their return or disposal.</i>						
P	<i>Preparation recall procedures should detail notification of recalls, removal from stock and nursing areas, and retrieval from patients.</i>						
ENVIRONMENTAL REQUIREMENTS							
ENVIRONMENTAL MONITORING PROCESSES							
	<i>While being used, the compounding environment maintains the sterility or the presterilization purity</i>						
	<i>Routine disinfection & air quality testing of direct compounding environment to minimize microbial surface contamination and maintain ISO class 5 air quality</i>						
	<i>Placement of devices that are essential to compounding in buffer areas is dictated by their effect on the required environmental quality of air atmosphere and surfaces, which shall be verified by monitoring</i>						
	<i>It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored and verified</i>						
	<i>Compounding facilities are physically designed & environmentally controlled to minimize airborne contamination from contacting critical sites. Facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temp of 20° or cooler</i>						
	<i>The airflow in the PEC shall be unidirectional and because of the particle collection efficiency of the filter, the first air at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination</i>						
	<i>HEPA-filtered air shall be supplied in critical areas at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations.</i>						
	<i>The buffer area shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment and this segregation shall be continuously monitored.</i>						

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	Required Procedure/Policy	Required Practice	Best Practice	Required	Controlled Area	Controlled Operating Procedure/Policy	Comments
	For rooms providing a physical separation through the use of walls, doors and pass throughs, a minimum differential positive pressure of 0.02 to 0.05-inch water column is required.						
	An ISO Class 7 buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30						
	Only the furniture, equipment, supplies and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing and other activities associated with proper maintenance.						
	The surfaces of ceiling, walls, floors, fixtures, shelving, counters and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding. The surfaces shall be resistant to damage by disinfectant agents.						
	Junctures of ceiling to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceiling consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic and they shall be caulked around each perimeter to seal them to the support frame.						
	The buffer area shall not contain sources of water or floor drains						
	Carts should be of stainless steel wire, nonporous plastic or sheet metal construction with good quality, cleanable casters to promote mobility.						
	Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable and disinfectable.						
	A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area						
	Results shall be reviewed & documented on a log at least every work shift or by a continuous recording device.						
	In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer and ante-area						
	An appropriate environmental sampling plan shall be developed for airborne viable particles based on risk assessment of compounding activities performed						
	The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time off day as related to activity in the compounding area and action level.						
	To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage area within the compounding facility						
	Controlled temperature areas in compounding facilities in controlled room temp 20° to 25°						
	Controlled cold temperatures 2° to 8°						
	Controlled freezing temperatures -25° and -10°						
	A controlled temp area shall be monitored at least once daily and the results documented on a temperature log						
	Compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations						
	If using a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly						

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	<i>The compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur (fridge door left open)</i>						
	<i>The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared.</i>						
B	<i>the facility supplies potable water for hand and equipment washing. Purified water must also be used for rinsing equipment and utensils</i>						
B	<i>Compounding facilities are physically designed & environmentally controlled to minimize airborne contamination from contacting critical sites</i>						
B	<i>A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.</i>						
P	<i>Refrigerator and freezer temperature logs or charts</i>						
F	<i>written procedures are needed for temperature monitoring of refrigerators and freezers, light, ventilation, and humidity standards; stock rotation and inspection; and locations of quarantined preparations (both ingredients and end preparations)</i>						
P	<i>The following should be included in the a pharmacy CPS quality assurance program Environmental Monitoring: -refrigerator and freezer temperature logs -compounding area and drug storage room temperature logs -air pressure differentials, air velocities, and air changes per hour -surface microbial testing logs -hazardous drug surface contamination logs</i>						
AIR SAMPLING PROCESSES							
	<i>The ES program shall provide information to staff and leadership to demonstrate that the PEC is maintaining an environment within the compounding area that consistently ensures acceptably low viable & nonviable particle levels.</i>						
	<i>Environmental sampling shall occur as a part of a comprehensive quality management program and shall occur minimally under any of the following conditions:</i>						
	<i>* Part of the commissioning & certification of new facilities & equipment</i>						
	<i>* Following any servicing of facilities & equipment</i>						
	<i>* As part of the re-certification of facilities and equipment (q6months)</i>						
	<i>* in response to identified problems with end products or staff technique</i>						
	<i>* in response to issue with CSPs, observed compounding personnel work practices, or patient-related infections</i>						
	<i>Evolution of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels</i>						
	<i>Impaction shall be the preferred method of volumetric air sampling</i>						
	<i>For low-, medium-, high-level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning</i>						
	<i>Locations shall include zones of air backwash turbulence within the LAFW and other areas where air backwash turbulence may enter the compounding area</i>						

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		<i>Regular Air Sampling/Rolls</i>	<i>Regular Air Tests</i>	<i>Best Practices</i>	<i>Documentation</i>	<i>Control Logs</i>	<i>Standard Operating Procedures/Rolls</i>												
	A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity.																		
	Air sampling shall be performed at least semiannually as part of the re-certification of facilities and equipment.																		
	At the end of designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers are secured, and they are inverted and incubated at a temp and for a time period conducive to multiplication of microorganisms. TSA should be incubated at 30° to 35° for 48 to 72 hours. Malt extract agar should be incubated 26° to 30° for 5 to 7 days. The number of discrete colonies of microorganisms are counted and reported as cfu and documented on an environmental sampling form.																		
	Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If any activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.																		
	Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures and air filtration efficiency within a aseptic compounding location. An investigation into the source of contamination shall be conducted. The source of the problem shall be eliminated, the affected area cleaned and resampling performed.																		
	<p>Table 2. Recommended Action Levels for Microbial Contamination (cfu per cubic meter [1000 liters] of air per plate)</p> <table border="1"> <thead> <tr> <th>Classification</th> <th>Air Sample?</th> </tr> </thead> <tbody> <tr> <td>ISO Class 5</td> <td>≤ 1</td> </tr> <tr> <td>ISO Class 7</td> <td>≤ 10</td> </tr> <tr> <td>ISO Class 8 and beyond</td> <td>≤ 100</td> </tr> </tbody> </table> <p><small>Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing, Current Good Manufacturing Practices (USP <797>), FDA, September 2004</small></p>	Classification	Air Sample?	ISO Class 5	≤ 1	ISO Class 7	≤ 10	ISO Class 8 and beyond	≤ 100										
Classification	Air Sample?																		
ISO Class 5	≤ 1																		
ISO Class 7	≤ 10																		
ISO Class 8 and beyond	≤ 100																		
	To sample surfaces using a contact plate, gently touch the sample area with the agar surface and roll the plate across the surface. If an area is sampled via the swab method, collection of the sample is processed by using appropriate procedures that will result in the surface location equivalent to that of a contact plate.																		
	Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.																		
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Classification	Finger tip Sample	Surface Sample (Contact Plate)																	
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KEY:

Black Font = Stated in USP <797> Pharmaceutical Compounding — Sterile Preparations
Blue Font = Stated in the State of Utah Pharmacy Compounding Inspection Report
Purple Font = Recommendations found in Compounding Sterile Preparations (E. Clyde Buchanan)

	This column includes information that needs to be incorporated into standard operating procedures or policies.	This column lists required practices	This column lists best practices.	This column includes areas where documentation will help prove compliance.			
	Required Practices/Policy	Required Practices	Best Practices	Documentation	Required M/M	Standard Operating Procedure/Policy	Comments
	Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered by an appropriate credentialed laboratory of any microbial bioburden captured as cfu using an impact air sampler.						
	Highly pathogenic microorganisms can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional or industrial hygienist.						
STERILIZATION REQUIREMENTS							
STERILIZATION PROCEDURE							
	Determine that the selected sterilization method both sterilizes and maintains the strength, purity, quality and packaging integrity of CSPs.						
	The sterilization process is obtained from experience and appropriate information sources (USP 1211) and preferably, verified whenever possible to achieve sterility in particular CSPs.						
	General Guidelines for matching CSPs and components to appropriate sterilization methods						
	1. CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method						
	2. Glass & metal devices may be covered tightly w/aluminum foil, then exposed to dry heat in an oven at a mean temp of 250° for 30 minutes to achieve sterility and depyrogenation. Such items are either used immediately or stored until use in an environment suitable for compounding Low/Medium-Risk level CSPs						
	3. Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically & physically compatible with the CSP						
	Environmental sampling test results						
QUALITY ASSURANCE REQUIREMENTS							
QUALITY ASSURANCE PROCESSES							
B	Standard Operating Procedures shall be created and maintained in written format addressing formal QA program intended to provide a mechanism for monitoring, evaluating, correcting and improving the activities and processes						
	Deficiencies in compounding, labeling, packaging and quality testing & inspection can be rapidly identified and corrected						
	A written quality assurance procedure includes the following in-process check that are applied, as appropriate, to specific CSPs:						
	1. Accuracy & precision of measuring and weighing						
	2. The requirement for sterility						
	3. Methods of sterilization & purification						
	4. Safe limits & ranges for strength of ingredients, bacterial endotoxins and particulate matter						
	5. pH						
	6. Labeling accuracy and completeness						
	7. BUD assignments						
	8. Packaging and storage requirements						
	A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting and improving the activities performed at the compounding facility						

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	This column includes information that needs to be incorporated into standard operating procedures or policies	This column lists required practices	This column lists best practices	This column includes areas where documentation will help prove compliance			
	Required Practice/Policy	Required Practice	Best Practice	Document	Method	Standard Operating Procedure/Policy	Comments
	<p>Characteristics of a QA program include the following:</p> <ol style="list-style-type: none"> 1. Formalization in writing 2. Consideration of all aspects of preparation and dispensing of products as described, including environmental testing & verification results 3. Description of specific monitoring and evaluation activities 4. Specification of how results are to be reported and evaluated 5. Identification and appropriate follow-up mechanisms when action limits or thresholds are exceeded 6. Delineation of individuals responsible for each aspect of the QA program <p>The selection of indicators and the effectiveness of the overall QA program is reassessed on an annual basis</p> <p>Quality assurance procedures for high-risk level CSPs include all those for low-level CSPs.</p>						
B	all significant procedures performed in the compounding area should be covered by written standard operating procedures. Procedures should be developed for the facility, equipment, personnel, preparation, packaging, and storage of compounding preparations to ensure accountability, accuracy, quality, safety and uniformity in compounding.						
B	the facility maintains documentation regarding an ongoing quality control program that monitors and evaluates personnel performance, equipment and facility's compliance with following USP NF chapters 795 and 797 standards						
P	Product problem reports to manufacturers and USP						
P	Adverse drug reaction reports to manufacturers and the Food and Drug Administration						
P	Patient complains and problem handling and outcome reports						
P	The following should be included in the a pharmacy CPS quality assurance program: -annual policy and procedure review statement -annual review of effectiveness of QA program						
Patient/Caregiver Requirements							
Patient or Caregiver Training Processes							
P	<p>policies and procedures for patient or caregiver training must be formalized and include:</p> <ul style="list-style-type: none"> -understanding of therapy provided -handling and storage of the sterile preparations -appropriate administration techniques -use and maintenance of any infusion device used -use of printed material -appropriate post-training verbal counseling 						
P	the pharmacy should have written policies and procedures for monitoring, evaluating, correcting and improving sterile preparation activities and processes. The QA program should refer to those on training and education, competency evaluation, preparation compounding, sterilization methods, media fill testing, and end-preparation evaluation.						
P	<p>the program must delineate individual responsibilities for each aspect of the program. Specific responsibilities should include:</p> <ul style="list-style-type: none"> -formalization in writing -consideration of all aspects of the preparation and dispensing of product as described in USP 797 -description of specific monitoring and evaluation activities -specification of how results are reported and evaluated -identification of appropriate follow-up mechanisms when action levels are exceeded -delineation of the individuals responsible for each aspect of the QA program 						

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Pharmacy Practice Act
58-17b-613. Patient counseling.

- (1) Every pharmacy facility shall orally offer to counsel a patient or a patient's agent in a personal face-to-face discussion with respect to each prescription drug dispensed, if the patient or patient's agent:
 - (a) delivers the prescription in person to the pharmacist or pharmacy intern; or
 - (b) receives the drug in person at the time it is dispensed at the pharmacy facility.

- (2) A pharmacist or pharmacy intern shall provide counseling to each patient, and shall provide the patient with a toll-free telephone number by which the patient may contact a pharmacist at the dispensing pharmacy during normal business hours and receive oral counseling, with respect to each prescription drug dispensed if the patient provides or the prescription is otherwise provided to the pharmacy facility by a means other than personal delivery, and the dispensed prescription drug is mailed or otherwise delivered to the patient outside of the pharmacy facility.

- (3)
 - (a) The provisions of Subsections (1) and (2) do not apply to incarcerated patients or persons otherwise under the jurisdiction of the Utah Department of Corrections or a county detention facility.
 - (b) A written communication with a person described in ~~Subsection~~ (3)(a) shall be used by a pharmacist or pharmacy intern in lieu of a face to face or telephonic communication for the purpose of counseling the patient.

R156-17b-610. Operating Standards - Patient Counseling.

In accordance with Subsection 58-17b-601(1), guidelines for providing patient counseling established in Section 58-17b-613 include the following:

- (1) Based upon the pharmacist's or pharmacy intern's professional judgment, patient counseling may be discussed to include the following elements:
 - (a) the name and description of the prescription drug;
 - (b) the dosage form, dose, route of administration and duration of drug therapy;
 - (c) intended use of the drug, when known, and expected action;
 - (d) special directions and precautions for preparation, administration and use by the patient;
 - (e) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - (f) techniques for self-monitoring drug therapy;
 - (g) proper storage;
 - (h) prescription refill information;
 - (i) action to be taken in the event of a missed dose;
 - (j) pharmacist comments relevant to the individual's drug therapy, including any other information specific to the patient or drug; and
 - (k) the date after which the prescription should not be taken or used, or the beyond use date.

(2) Patient counseling shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to administer the drugs.

(3) A pharmacist shall not be required to counsel a patient or patient's agent when the patient or patient's agent refuses such consultation.

(4) The offer to counsel shall be documented and said documentation shall be available to the Division. These records shall be maintained for a period of five years and be available for inspection within 7-10 business days.

(5) Counseling shall be:

- (a) provided with each new prescription drug order, once yearly on maintenance medications, and if the pharmacist deems appropriate with prescription drug refills;
- (b) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent; and
- (c) communicated verbally in person unless the patient or the patient's agent is not at the pharmacy or a specific communication barrier prohibits such verbal communication.

(6) Only a pharmacist or pharmacy intern may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs.

(7) In addition to the requirements of Subsections (1) through (6) of this section, if a prescription drug order is delivered to the patient at the pharmacy, a filled prescription may not be delivered to a patient unless a pharmacist is in the pharmacy. However, an agent of the pharmacist may deliver a prescription drug order to the patient or the patient's agent if the pharmacist is absent for ten minutes or less and provided a record of the delivery is maintained and contains the following information:

- (a) date of the delivery;

- (b) unique identification number of the prescription drug order;
 - (c) patient's name;
 - (d) patient's phone number or the phone number of the person picking up the prescription; and
 - (e) signature of the person picking up the prescription.
- (8) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:
- (a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;
 - (b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and
 - (c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

- (c) patient's name;
 - (d) patient's phone number or the phone number of the person picking up the prescription; and
 - (e) signature of the person picking up the prescription.
- (8) If a prescription drug order is delivered to the patient or the patient's agent at the patient's or other designated location, the following is applicable:
- (a) the information specified in Subsection (1) of this section shall be delivered with the dispensed prescription in writing;
 - (b) if prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container, the telephone number of the pharmacy and the statement "Written information about this prescription has been provided for you. Please read this information before you take this medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions."; and
 - (c) written information provided in Subsection (8)(b) of this section shall be in the form of patient information leaflets similar to USP-NF patient information monographs or equivalent information.

R156-17b-606. Operating Standards - Approved Preceptor.

In accordance with Subsection 58-17b-601(1), the operating standards for a pharmacist acting as a preceptor include:

- (1) meeting the following criteria:
 - (a) hold a Utah pharmacist license that is active and in good standing;
 - (b) document engaging in active practice as a licensed pharmacist for not less than two years in any jurisdiction;
 - (c) not be under any sanction which, when considered by the Division and Board, would be of such a nature that the best interests of the intern and the public would not be served;
 - (d) provide direct, on-site supervision to:
 - (i) no more than two pharmacy interns during a working shift except as provided in Subsection (ii); [and]
 - (ii) up to five pharmacy interns at public-health outreach programs such as a informational health fairs, chronic disease state screening and education, and immunization clinics, provided it is:
 - (A) deemed appropriate in the professional judgment of the preceptor; and
 - (B) has written approval from the pharmacy interns' schools of pharmacy; and
 - (e) refer to the intern training guidelines as outlined in the Pharmacy Coordinating Council of Utah Internship Competencies, October 12, 2004, as information about a range of best practices for training interns;
 - (2) maintaining adequate records to document the number of internship hours completed by the intern and evaluating the quality of the intern's performance during the internship;
 - (3) completing the preceptor section of a Utah Pharmacy Intern Experience Affidavit found in the application packet at the conclusion of the preceptor/intern relationship regardless of the time or circumstances under which that relationship is concluded; and
 - (4) being responsible for the intern's actions related to the practice of pharmacy while practicing as a pharmacy intern under supervision.

58-17b-623. Disposal of unused prescription drugs.

- (1) A pharmacy may accept unused prescription drugs for disposal in accordance with administrative rules adopted by the division.
- (2) The division shall adopt administrative rules regarding a pharmacy accepting unused prescription drugs for disposal as permitted by federal law and regulation relating to the disposal of unused prescription drugs.

R156-37-606. Disposal of Controlled Substances.

- (1) Any disposal of controlled substances by licensees shall:
 - (a) be consistent with the provisions of 1307.21 of the Code of Federal Regulations; or
 - (b) require the authorization of the Division after submission to the Division to the attention of Chief Investigator of a detailed listing of the controlled substances and the quantity of each. Disposal shall be conducted in the presence of one of its investigators or a Division authorized agent as is specifically instructed by the Division in its written authorization.
- (2) Records of disposal of controlled substances shall be maintained and made available on request to the Division or its agents for inspection for a period of five years.

distributors for those distribution activities, and subject to the pharmacy requirements for its pharmacy activities. To obtain a DEA chemical distributor registration, a pharmacy may complete the DEA Form 510 online at www.DEAdiversion.usdoj.gov. A paper version may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

SECTION IV – TRANSFER OR DISPOSAL OF CONTROLLED SUBSTANCES

Transfer of Controlled Substances

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

Transfer to a Pharmacy

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA. The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

Transfer to the Original Supplier or Original Manufacturer

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with the DEA. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.

The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances.

Disposal of Controlled Substances

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office (**Appendix K**) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

Reverse Distributors Authorized to Dispose Controlled Substances

A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (**Registrants Inventory of Drugs Surrendered**) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should not be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

Disposal of Controlled Substances by Persons Not Registered with DEA

On January 21, 2009, DEA published in the Federal Register an Advance Notice of Proposed Rulemaking (ANPRM), *Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration*. This ANPRM sought comments on how to address the issue of disposal of dispensed controlled substances held by DEA nonregistrants (i.e., ultimate users, long term care facilities). DEA was interested in the possible options that would enable nonregistrants to dispose of unwanted controlled substances, while also protecting public health and public safety, and minimizing the possibility of diversion. The public comment period for this ANPRM ended on March 23, 2009.

SECTION V – SECURITY REQUIREMENTS

Requests for Employment Waivers for Certain Pharmacy Employees

Under 21 C.F.R. § 1301.76(a), a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, 21 C.F.R. § 1307.03 does permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances. A waiver request should be sent by the employer to the following address:

Drug Enforcement Administration
Attn: Administrator
8701 Morrisette Drive
Springfield, Virginia 22152

A registrant that applies for such a waiver should understand that the following factors will be considered by the DEA in the approval process and should provide details relevant to each factor as part of the waiver request submitted, since a waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur:

1. A detailed description of the nature and extent of the individual's past controlled substances violations, including all pertinent documentation;
2. Current status of the individual's state licensure;
3. Extent of individual's proposed access to controlled substances. "Access" is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant's proposed physical and professional safeguards to prevent diversion by the individual;

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R156-17b-614a. Operating Standards - Operating Standards, Class A and B Pharmacy.

(1) In accordance with Subsection 58-17b-601(1), standards for the operations for a Class A and Class B pharmacy include:

- (a) shall be well lighted, well ventilated, clean and sanitary;
- (b) the dispensing area, if any, shall have a sink with hot and cold culinary water separate and apart from any restroom facilities. This does not apply to clean rooms where sterile products are prepared. Clean rooms should not have sinks or floor drains that expose the area to an open sewer. All required equipment shall be clean and in good operating condition;
- (c) be equipped to permit the orderly storage of prescription drugs and durable medical equipment in a manner to permit clear identification, separation and easy retrieval of products and an environment necessary to maintain the integrity of the product inventory;
- (d) be equipped to permit practice within the standards and ethics of the profession as dictated by the usual and ordinary scope of practice to be conducted within that facility;
- (e) be stocked with the quality and quantity of product necessary for the facility to meet its scope of practice in a manner consistent with the public health, safety and welfare; and
- (f) be equipped with a security system to permit detection of entry at all times when the facility is closed.

