

ASHP Self-Assessment Tool for Compounding Sterile Preparations
An Online Primer for Determining Compliance with USP Chapter <797>

Print Version - ASHP Self-Assessment Tool for Compounding Sterile Preparations

Thank you for participating in the ASHP Self-Assessment Tool for determining compliance with USP Chapter <797> requirements. This tool was developed by ASHP in collaboration with Baxter Healthcare Corporation to provide a quick and effective method of identifying and measuring potential gaps or risks in practices as compared to USP <797>. Prior to completing the online self-assessment tool, participants should read the requirements outlined in USP Chapter <797> and the ASHP Discussion Guide for Compounding Sterile Preparations. Also, a workload and risk-level analysis should be completed in preparation for adequately responding to the self-assessment statements. JCAHO will survey for a completed risk assessment (gap analysis) and implementation plan by January 2005. ASHP recommends that managers use the self-assessment tool to perform an initial gap analysis of their sterile compounding practices, prioritize system improvements, and develop an action plan. ASHP also suggests that users periodically reassess their sterile compounding practices as part of an ongoing departmental performance improvement plan in order to monitor and demonstrate progress over time.

Listed below are elements of CSP requirements derived primarily from USP Chapter <797> . The participant should understand that these elements should be included in department training programs, policies and procedures and quality assurance programs.

1.0 Sterile Compounding Personnel	Bibliographic References	Yes	No	N/A	Comments
1.1 Policies, procedures, and operational guidance are maintained, communicated, and adhered to by all personnel responsible for compounding sterile preparations (CSPs), <i>including hazardous drugs</i> , and in packaging and labeling sterile medications.	1.7, 1.19, 1.22, 1.23, 3, 5, 6, 15, 16, 18, 19				
1.2 Pharmacy personnel are oriented, trained, and demonstrate competency in compounding sterile preparations, <i>including hazardous drugs</i> , and in packaging and labeling compounded sterile preparations.	1.6, 1.15, 1.16, 1.19, 5, 6, 7, 8, 19				
1.3 Pharmacy personnel prepare for entering the buffer zone or room by removal of outer lab jackets, makeup and jewelry.	1.5, 1.6, 7, 8				
1.4 Pharmacy personnel thoroughly scrub hands and arms to the elbow with an antimicrobial cleanser and dry hands with air dryer or disposable towels.	1.6, 7, 8				
1.5 Pharmacy personnel select and appropriately don protective gloves, goggles, gowns, masks and hair and shoe covers. Garments must fit properly to prevent contamination as well as particle shedding. Gowns and coveralls should be made of a low-particulate material that protects against bacterial passage and drug permeability, for example Tyvek.	1.5, 7, 8				
1.6 Pharmacists assign the appropriate risk level (<i>low, medium, or high</i>) for each compounding activity based on adequate knowledge and experience in good sterile compounding practices.	1.1, 13				
1.7 Pharmacists check the quality, purity, and identity of all ingredients, and verify amounts and sequence of the additives versus the medication order.	1.2, 1.11, 7, 8, 12				
1.8 Pharmacy personnel who identify, weigh and measure ingredients are adequately trained to measure, mix, dilute, and purify ingredients in the correct sequence and to manipulate sterile preparations aseptically.	1.6, 7, 8				
1.9 Pharmacists select beyond-use dates based on the results of direct stability testing or extrapolation from reliable literature sources.	1.8, 7, 8				
1.10 CSPs are properly packaged to preserve both sterility and concentration until the beyond-use date stated on the preparation's label.	1.11, 7, 8				
1.11 CSPs are properly labeled with the following: names and amounts or concentrations of all ingredients, total volume, beyond-use date, appropriate route(s) of administration, storage conditions and other information for safe use.	1.9, 7, 8				
1.12 CSPs are visually inspected for physical integrity and expected appearance, including final fill amount, after compounding and again during dispensing.	7, 8				
1.13 CSPs are properly stored with refrigeration when the preparation is not immediately dispensed or administered, unless the chemical and physical stability of the CSP are adversely affected by cold temperatures.	1.11, 7, 8				

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2.0 Clean Rooms and Barrier Isolators	Bibliographic References	Yes	No	N/A	Comments
2.1 Pharmacy personnel compound sterile preparations (CSPs) in ISO Class 5 engineering-controlled environments (<i>previously described as Class 100 hood</i>). For example: horizontal laminar airflow workbench (LAFW), vertical LAFW, Class II or III biological safety cabinet (BSC) or barrier isolator.	1.3, 1.4, 1.10, 1.17, 20, 21				
2.2 The ISO Class 5 LAFW or BSC is located in a buffer zone or buffer room (i.e. cleanroom) that meets ISO Class 8 (formerly Class 100,000) cleanroom standards.	1.17, 20, 21				
2.3 Appropriate HEPA filtered air conditioning and humidity controls are in place for the buffer zone or room.	1.17				
2.4 Only furniture, equipment, supplies, and other goods required for the tasks to be performed are brought into the buffer zone or room.	1.3, 20, 21				
2.5 Surfaces of ceilings, walls, floors, fixtures, carts, shelving, counters and cabinets in the buffer zone or room are smooth, impervious, free from cracks and crevices, nonshedding and resistant to sanitizing agents..	1.17				
2.6 Buffer zone or room contains no sinks or floor drains.	1.17				

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3.0 CSP Environment	Bibliographic References	Yes	No	N/A	Comments
3.1 Pharmacy personnel with access to the buffer zone or room is restricted <i>by frequency and number</i> to minimize contaminants.	13				
3.2 Food and beverages are never introduced into the ante area or buffer zone or room.	13				
3.3 Carts used to bring supplies from storage rooms are not rolled beyond the demarcation line in the ante area or anteroom. Carts used in the buffer zone or buffer room are not rolled out beyond the demarcation line unless cleaned and sanitized before returning.	13				
3.4 Within the ante area or anteroom, supplies for compounding are uncartoned and disinfected. No shipping or other external cartons are taken into the buffer zone or room.	13				
3.5 Hand washing and gowning occur in the ante area or anteroom adjacent to the buffer zone or room.	1.5				
3.6 Objects that shed particles are not brought into the buffer zone or room, including pencils, cardboard cartons, paper towels and cotton items. Only nonshedding paper-related products can be brought into the buffer zone or room.	13				
3.7 Within the LAFW or barrier isolator, supply items are limited to assigned operations and are arranged in a clear, uninterrupted path of HEPA-filtered air, so that the air bathes all critical sites at all times during the procedures. There is no object placed between an exposed critical site and HEPA-filtered air. <i>(The critical site is an opening providing a direct pathway between a CSP and the environment or any surface coming into contact with the CSP or environment)</i>	1.4, 13				
3.8 After compounding sterile preparations, used syringes, bottles, vials, and other supplies are removed from the compounding environment, but with a minimum of exit and re-entry into the LAFW or isolator workspace to avoid introducing contamination.	13				

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4.0 Cleaning and Sanitizing the Workspaces	Bibliographic References	Yes	No	N/A	Comments
4.1 Before compounding, all work surfaces are cleaned of loose materials and residue from spills followed by an application of a residue-free sanitizing agent that is left on for a time sufficient to exert its antimicrobial effect.	13				
4.2 Floors in the buffer zone or room are cleansed by mopping once daily <i>during a time when no aseptic compounding is in progress</i> . Floor cleaning begins in the buffer zone or room and proceeds to the ante area or anteroom.	1.17				
4.3 Only facility-approved cleaning and sanitizing agents are used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues.	1.17				
4.4 Cleaning tools such as wipers, sponges and mops are nonshedding and are used <i>only</i> in the buffer zone or room and are replaced as soon as unsuitable for use.	1.17				
4.5 Cleaning and sanitizing the ante area or anteroom is performed at least <i>weekly</i> , and trash is collected in suitable plastic bags and removed <i>daily</i> with minimal agitation.	1.17				
4.6 Storage shelving is emptied of all supplies and cleaned and sanitized at planned intervals, preferably monthly.	1.17				

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5.0 Environmental Monitoring	Bibliographic References	Yes	No	N/A	Comments
5.1 Certification for proper function and air quality requirement (ISO Class 5) of each LAFW and barrier isolator is performed by a qualified operator using current, state-of-the-art electronic air sampling at least every six months and whenever the LAFW or barrier isolator is relocated.	1.18, 14, 17				
5.2 Air quality of the buffer zone or room and the ante area or anteroom is evaluated by a qualified operator for conformance to ISO Class 8 requirements at least every six months and when renovations occur.	1.18, 17				

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6.0 Equipment	Bibliographic References	Yes	No	N/A	Comments
6.1 Equipment, apparatus and devices used to compound CSPs are consistently capable of operating properly and within acceptable tolerance limits.	1.3, 1.17				
6.2 Manufacturer recommendations are followed for equipment calibration, maintenance, monitoring for proper function, and controlled procedures for use of the equipment. Written procedures specify a time frame for CSP-related equipment maintenance activities.	1.3				

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7.0 Verification of Automated Compounding Devices for Parenteral Nutrition Compounding	Bibliographic References	Yes	No	N/A	Comments
7.1 Automated compounding device (ACD) is tested initially for its volume and weight accuracy.	4, 9				
7.2 Additional tests of accuracy for ACDs are employed to determine the content of certain ingredients in the final volume of the parenteral nutrition admixture (e.g. dextrose content, calcium gluconate, magnesium sulfate, potassium chloride). Additional tests might include analytical measurements, density measurements, and refractive index.	1.21, 4, 9				

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8.0 Low-Risk and Medium-Risk Level Compounding Requirements	Bibliographic References	Yes	No	N/A	Comments
8.1 Evaluation of airborne microorganisms (such as <i>centrifugal air sampling</i>) is performed at least monthly for sterile compounding areas used for low and medium-risk preparations.	1.18, 14, 20, 21				
8.2 Critical area work surfaces (<i>the surface that comes into contact with previously sterilized preparations or closures</i>) is cleaned between batches.	1.13, 13				
8.3 In the absence of sterility testing, storage for Low-Risk Level CSPs does not exceed: 48 hours at room temperature or 14 days at cold (refrigerated) temperature or 45 days in a frozen state at -20° C or colder.	13				
8.4 In the absence of sterility testing, storage for Medium-Risk Level CSP's does not exceed: 30 hours at room temperature or 7 days at cold (refrigerated) temperature or 45 days in a frozen state at -20° C or colder.	13				
8.5 Compounding personnel perform didactic review and pass written and medial-fill validation testing of aseptic manipulative skills <i>initially and at least annually thereafter</i> for low-risk and medium-risk level compounding.	1.16, 1.20, 20, 21				

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9.0 High-Risk Level Compounding Requirements Participants who have determined that no high-risk level compounding is performed should mark each question in this section as N/A.	Bibliographic References	Yes	No	N/A	Comments
9.1 High-risk level quality controls are utilized when any nonsterile components, devices or ingredients are used to prepare CSPs.	1.1, 1.2, 13				
9.2 During high-risk level compounding, the anteroom is a separate room and is appropriately cleaned and disinfected weekly.	1.17				
9.3 Evaluation of airborne microorganisms (<i>such as centrifugal air sampling</i>) is performed at least weekly for sterile compounding areas used to compound high-risk sterile preparations.	1.18, 14, 20, 21				
9.4 Pharmacists verify that components meet USP standards for identity, purity, and endotoxin levels when any nonsterile components are used.	1.2, 12				
9.5 When non-official ingredients are used, they are accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality and purity in relation to the intended use in the particular CSP.	1.2, 12				
9.6 Sterilization methods are based on specific properties of the compounded preparation and maintenance of integrity throughout the beyond-use dating period.	1.13, 1.14, 20, 21				
9.7 Bulk substances are stored in tightly closed containers with appropriate temperature, humidity, and lighting conditions as indicated in official monographs.	1.2				
9.8 In the absence of sterility testing, storage periods before administration do not exceed: 24 hours at room temperature, 3 days at 2° to 8° C or 45 days at -20° C.	13				
9.9 High-risk level CSPs are tested for sterility, pyrogens and potency <i>before</i> release.	1.21, 10, 11, 20, 21				
9.10 High-risk CSPs for administration by injection into the vascular or central nervous systems when prepared in groups of > 25 identical individual single-dose packages (ampuls, bags, syringes, or vials) , <i>or</i> in multiple-dose vials for administration to multiple patients, <i>or</i> are exposed longer than 12 hr at 2° C to 8° C <i>or</i> longer than 6 hours at warmer than 8° C before they are sterilized are tested for sterility and the presence of excessive bacterial endotoxin (pyrogens) .	1.21				
9.11 Filter integrity is determined by testing and documented with each CSP when filtration is used to sterilize high-risk CSP's.	1.21				
9.12 End Product Sterility testing is performed <i>daily</i> for open-system transfer preparations (batched TPN) or preparations compounded using nonsterile ingredients (concentrated morphine solutions prepared using powdered ingredients).	1.21, 20, 21				
9.13 Compounding personnel perform didactic review and pass written and media-fill testing of aseptic manipulative skills <i>initially and at least semiannually thereafter</i> for high-risk level compounding.	1.20, 20, 21				

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10.0 Storage and Beyond-Use Dating	Bibliographic References	Yes	No	N/A	Comments
10.1 Solutions, medications, supplies, and equipment are stored according to manufacturer or USP requirements and are inspected for proper conditions of light, temperature, moisture, and ventilation.	1.2, 1.11, 12				
10.2 Refrigerator, freezer and incubator temperatures are checked daily and recorded and equipment problems are addressed promptly.	1.11				
10.3 Pharmacists assume responsibility for the proper packaging, handling, transport, and storage of all CSPs dispensed, including appropriate education and training of nonpharmacy personnel.	1.12				
10.4 Packing materials are selected to maintain physical integrity, sterility, and stability of CSPs during transit and written instructions for safely opening containers are provided to patients or recipients. When shipped outside the premises, CSPs are packaged for maintaining physical and chemical integrity, and are labeled with beyond-use dates, storage instructions, and disposal instructions as appropriate.	1.12				
10.5 Multiple-dose parenteral medication vials (MDV's), when used, are refrigerated after opening unless otherwise specified by the manufacturer. Beyond-use dating <i>unless otherwise referenced in the package insert</i> does not exceed 30 days once the vial has been opened.	1.11				

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11.0 Maintaining Product Quality and Control after the CSP leaves the Pharmacy	Bibliographic References	Yes	No	N/A	Comments
11.1 Pharmacy personnel assist in adequately training <i>nonpharmacy</i> personnel who are responsible for carrying out any aspect of packaging, handling, transport and storage of CSPs after leaving the pharmacy.	1.12				
11.2 Pharmacy personnel evaluate the effectiveness of methods used for packaging, handling, transport and storage of CSPs outside the pharmacy. Evaluation should be <i>continuous</i> , including a system to report problems to the pharmacy.	1.12				
11.3 Outdated and unused CSPs are returned to the pharmacy for disposal or possible reuse.	1.12				
11.4 Drug storage refrigerators have <i>daily</i> monitoring and documentation of temperatures to ensure that temperatures remain between 2° and 8° C.	1.12				
11.5 Pharmacy personnel inspect all drug storage areas <i>monthly</i> to ensure compliance with appropriate storage conditions, separation of drugs and food, and proper use of multiple-dose containers and the avoidance of using single-dose products as multiple-dose containers..	1.12				
11.6 Pharmacy personnel determine whether a CSP <i>not administered as originally intended</i> can be used for an alternate patient or under alternate conditions.	1.11				

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12.0 Packing and Transporting Compounded Sterile Preparations	Bibliographic References	Yes	No	Not Applicable	Comments
12.1 Compounding personnel select packing containers and materials appropriate to maintain physical integrity, sterility and stability of CSPs during transit when CSPs are transported outside the premises. For example, the use of styrofoam containers, ice packs, and foam or bubble wrap.	1.12				
12.2 Compounding personnel select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients when CSPs are transported outside the premises	1.12				
12.3 Compounding personnel periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.	22				
12.4 Compounding facilities that ship CSPs outside the premises verify that labels and accessory labeling for CSPs have clearly readable beyond-use dates, storage instructions, and disposal instructions.	1.12				
12.5 Compounding facilities that ship CSPs outside the premises verify that each patient or other recipient is able to store the CSPs properly. (including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage)	1.12				

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13.0 Patient or Caregiver Training for Home Environment Participants who do not dispense CSPs for home use should mark each question in this section as N/A.	Bibliographic References	Yes	No	N/A	Comments
13.1 A formal hands-on training program is provided for home care patients and caregivers to learn and demonstrate knowledge of the following. Patient or caregiver training is documented.	22				
13.2 Patients or caregivers are instructed to inspect all CSPs, devices, equipment, and supplies upon receipt to ensure proper temperatures during transport and no evidence of damage.	22				
13.3 Patients or caregivers are instructed on proper handling, storage, and monitoring of drugs, equipment and supplies in the home setting.	22				
13.4 Patients or caregivers are instructed on how to perform a visual inspection of CSPs at the time of administration for leakage, precipitates, discoloration, or other problems.	22				
13.5 Patients or caregivers are instructed on how to check CSP labels for verification of the correct medication name, dose, patient, and time of administration.	22				
13.6 Patients or caregivers are instructed on how to clean the in-home preparation area, proper handwashing, proper aseptic technique, and aseptic manipulation of CSPs, supplies, and equipment.	22				
13.7 Patients or caregivers are instructed on proper technique for catheter and dressing care.	22				
13.8 Patients or caregivers are instructed to follow procedures to ensure product quality for special devices such as in-line filters, automated infusion control devices and the replenishment of drug products into the reservoirs of implantable or portable infusion pumps.	22				
13.9 Patients or caregivers are instructed on monitoring for complications such as infection, phlebitis, electrolyte imbalance, and catheter potency.	22				
13.10 Patients or caregivers are instructed on how to receive Immediate response to an emergency or critical situation such as catheter displacement, clot formation, or equipment malfunction.	22				
13.11 Patients or caregivers are instructed to seek professional emergency services if needed.	22				
13.12 Patients or caregivers are instructed on proper handling of hazardous medications and waste, such as chemotherapy preparations, needles, syringes, and infectious substances.	1.7, 1.12				

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14.0 Patient Monitoring and Adverse Event Reporting	Bibliographic References	Yes	No	N/A	Comments
14.1 Clinical monitoring is performed routinely according to accepted standards of safe medication management.	22, 23, 24, 25				
14.2 Pharmacists are available for patients to ask questions regarding CSPs or administration devices and to report any concerns.	22				
14.3 Information regarding suspected ADRs and errors involving CSPs is reported to the pharmacy for complete data collection, analysis, and reporting.	22, 26				

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15.0 Quality Assessment Program	Bibliographic References	Yes	No	N/A	Comments
15.1 There is an ongoing, systematic program for quality assessment and improvement that provides a mechanism for monitoring, evaluating, correcting, and improving all activities associated with CSPs.	1.11, 2				
15.2 The pharmacy reviews system-wide documentation on medication errors involving CSPs to analyze and aggregate data, identify trends, and develop methods for improving quality in compounding sterile preparations.	1.11, 2				

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<p align="center">16.0 Hazardous Drug Handling</p> <p>The following statements concern compounding hazardous drugs and are recommended for compliance with Chapter <797> requirements.</p>	Bibliographic References	Yes	No	N/A	Comments
<p>16.1 Policies, procedures, and operational guidance appropriately describe the requirements for handling hazardous drugs to prevent contamination of the work environment and to protect personnel, patients, or family members from exposure to hazardous drugs during preparation, packaging, distribution, administration and disposal.</p>	1.7, 1.22, 5, 6, 18				
<p>16.2 Pharmacy personnel are oriented, trained, and demonstrate competency in the accurate and safe preparation of hazardous drugs. Protective gowns or coveralls with fitting elastic or knit cuffs, masks, eye protection, bouffants, and 2 pairs of gloves are worn during compounding, with the outer glove covering the gown's cuff.</p>	1.7, 1.15, 1.16, 5, 6, 18				
<p>16.3 Hazardous drugs are compounded and packaged in one of the following: a properly vented and certified <i>vertical</i> LAFW, or Class II or Class III biological safety cabinet or barrier isolator. Equipment is designed to minimize sprayback of hazardous droplets. Exhaust should be HEPA-filtered and whenever feasible exhausted to the outdoors. A horizontal LAFW should not be used because the airflow directs particles and aerosolized drug at the preparer.</p>	1.7, 1.17, 5, 6, 18				
<p>16.4 Pharmacy personnel demonstrate knowledge of appropriate procedures to be followed in case of accidental skin or eye contact with hazardous drugs (such as a designated eyewash station, eyewash irrigant solution or emergency showers).</p>	1.7, 5, 6, 18				
<p>16.5 Hazardous drugs are labeled with a warning label stating the need for special handling and disposal.</p>	1.7, 1.9, 5, 6, 18				
<p>16.6 Sufficient information, including Material Safety Data Sheets, is maintained on the safe use and disposal of all hazardous products.</p>	1.7, 5, 6, 18				
<p>16.7 Standardized guidelines are readily available for reconstituting, diluting, preparing, and administering commonly used antineoplastics.</p>					
<p>16.8 Appropriate safeguards such as sealed plastic bags and cautionary labeling are utilized for packaging and handling chemotoxic and other hazardous CSPs when transported outside the pharmacy.</p>	1.7, 1.12, 5, 6, 18				
<p>17.0 NIOSH - The following self-assessment statements are included as an introduction to the recently issued NIOSH alert <i>Preventing Occupational Exposures to Antineoplastic and other Hazardous Drugs in Healthcare Settings</i>. For complete information, access the NIOSH alert found at http://www.cdc.gov/niosh/docs/2004-HazDrugAlert/pdfs/2004-HazDrugAlert.pdf (June 7, 2004) Compliance with NIOSH recommendations is recommended to provide employees with protection from health risks posed by working with hazardous drugs.</p>	Bibliographic References	Yes	No	N/A	Comments
<p>17.1 National Institute for Occupational Safety and Health (NIOSH) recommendations for protection procedures and equipment when handling hazardous drugs are reviewed and implemented. Pharmacy managers should review NIOSH recommendations prior to any structural modifications of pharmacy areas where CSPs are prepared.</p>	19				
<p>17.2 Pharmacy managers perform a regular assessment of the total working environment and equipment and physical layout, <i>with input from employees and other potentially exposed workers</i>, as well as the type of drugs being handled, the volume, frequency and form, maintenance of equipment, decontamination, and cleaning and handling of waste.</p>	19				
<p>17.3 Exposure to blood borne pathogens and chemicals used to deactivate hazardous drugs or clean surfaces is evaluated and addressed. Hazardous waste is handled separately from other trash and in compliance with EPA regulations for handling, storing, and transporting hazardous waste.</p>	19				
<p>17.4 A written <i>workplace safe handling program</i>, including an inventory of hazardous materials, labeling, storage, personnel issues such as pregnancy, and spill control is implemented and reviewed annually, based on the workplace evaluation.</p>	19				
<p>17.5 Workplace procedures address the use and maintenance of biological safety cabinets, containment or barrier isolators, closed-system drug transfer devices, needle-less systems, and personal protective equipment (PPE). PPE includes chemotherapy gloves, low-lint, low-permeability disposable gowns and sleeve covers, and eye and face protection. An example of a closed-system transfer device designed for chemotherapy is PhaSeal™. Work areas are decontaminated before and after each activity with hazardous drugs and at the end of each shift.</p>	19				

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17.6 Work practices address drug manipulation techniques, general hygiene practices, and safety training for the handling of hazardous drugs, patient wastes, contaminated materials, and operation of equipment. Syringes and intravenous administration sets with luer-lock fittings are encouraged. Closed system, drug-transfer devices and needle-less systems should be considered to protect nursing personnel during drug administration.	19				
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