October 1, 2014

This working draft is for review and comment through December 31, 2014. Because the changes are considerable, strikeout language is not presented in this draft.

Please compare this draft to the existing rules that the language below would replace once finalized:

- Good Compounding Practices
- Nuclear Pharmacy and Pharmacists
- Parenteral Products for Nonhospitalized Patients

Additionally, Chapter 246-873 Pharmacy-Hospital Standards will be amended to require that hospital pharmacies comply with Chapter 246-878 WAC Compounding Practices when it is finalized.

Chapter 246-878 WAC Compounding Practices

WAC 246-878-001 Purpose.

1) The requirements of this chapter apply to any person or facility that possesses a license under 18.64 RCW that compounds sterile drug preparations. These rules represent minimum good sterile compounding practices for the preparation of drug products for dispensing or administering to humans or animals and are intended to help compounding personnel produce compounded sterile preparations of high quality and reduce the potential for harm to patients.
2) Any pharmacy, pharmacy manufacturer, pharmacy wholesaler or outsourcing facilities licensed under section 503B of the Federal Food, Drug and Cosmetics Act that compounds sterile preparations (including sterile radiopharmaceuticals), repackages or prepackages sterile pharmaceutical products, and distributes those products within or imports them into Washington State shall comply with all requirements of this section and with applicable provisions of state and federal laws, rules and regulations.
3) Any medicinal products that are compounded for patient administration or distribution to a licensed practitioner for patient use or administration shall, at a minimum, meet the standards of the official United States Pharmacopeia (USP) as is applies to nonsterile products and sterile administered products. The minimum standards of USP 797 regarding sterile compounded products shall be met unless requirements listed in the chapter are more stringent.

WAC 246-878-010 Definitions.

The definitions in this section apply throughout this chapter unless the context clearly requires otherwise.

1) "503B Outsourcing Facility" means any facility registered with the Federal Food and Drug Administration as an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act as added by the Drug Quality and Security Act.

2) "ACPE" means the Accreditation Council for Pharmacy Education.
3) "Adverse Event" means an incident in which a compounded sterile product or preparation was suspected or known to have resulted in an undesirable experience for the patient.
4) "Anteroom" means an ISO Class 8 or better room where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling and other high-particulate-generating activities are performed. It is also a transition room that provides assurance that the cascading pressure gradient is constantly maintained so that air flow from cleanest to dirtiest areas and reduces the need for the heating, ventilating, and air conditioning control system to respond to large disturbances.
5) "Aseptic Processing" (see USP <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments) means a mode of processing pharmaceuticals and medical products that involves the separate sterilization of the product and the package (containers-closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.
6) "ASHP" means the American Society of Hospital Pharmacists.
7) "Batch" means any specific quantity greater than one of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced during a single preparation cycle.
8) "Batch preparation compounding" means compounding of batch sterile preparation units, in a single discrete process, by the same individual(s), carried out during one limited time period.
9) "Beyond-Use Date" and "BUD" means the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.
10) "Biological Safety Cabinet" and "BSC" means a ventilated cabinet for CSPs, personnel, product and environmental protection having an open front with inward airflow for personnel protection, downward airflow for personnel protection, downward high-efficiency particulate air HEPA-filtered unidirectional airflow for product protection, and HEPA-filtered exhausted air for environmental protection.
11) "Buffer Area" means an ISO Class 7 or better area within the clean room suite where the primary engineering control is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding sterile preparations.
12) "Chemotherapy Glove" means a medical glove that meets the American Society for Testing and Materials (ASTM) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs 6978-05.
13) "Clean Room Suite" (see USP <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments and also the definition of Buffer Area) means a fully enclosed room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface and personnel gear are not exceeded for a specified cleanliness class.
14) "Closed System Transfer Device" means a drug transfer device that mechanically prohibits the escape of hazardous drug vapor concentrations outside the system.
15) "Commission" means the Washington State Pharmacy Quality Assurance Commission.

16) "Component" means any ingredient intended for use in the compounding of a drug preparation, including those that may not appear in such preparation.
17) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device in accordance with a licensed practitioner's prescription or medication order. Compounding based on a prescription history is bulk compounding and shall comply with 246-895 WAC Pharmacy – Good Manufacturing Practice for Finished Pharmaceuticals.
18) "Compounding Aseptic Isolator" and "CAI" means a form of isolator specifically designed for compounding nonhazardous pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment shall not occur unless the air has first passed through a microbially retentive filter (HEPA minimum). CAIs shall not be used to compound hazardous drugs.
19) "Compounding Aseptic Containment Isolator" and "CACI" means a compounding aseptic isolator (CAI) designed for the compounding of hazardous drugs to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment shall not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. When hazardous drugs are prepared, the exhaust air from the isolator shall be removed by properly designed building ventilation which exhausts air at the roof.
20) "Compounded Sterile Preparation" and "CSP" means a preparation that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber.
21) "Critical Area" means an ISO Class 5 environment.
22) "Critical Site" means a location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination.
23) "Cytotoxic" means a pharmaceutical or other substance that has the capability of killing living cells.
24) "Deactivation" means the treatment of a hazardous drug with another chemical, heat, ultraviolet lights, or other agent or process to create a less hazardous agent.
25) "Decontamination" means the inactivation, neutralization or removal of hazardous drugs, usually by chemical means.
26) "Delayed Activation Device System" means a system or device that separates active components until they are mixed.
27) "Disinfectant" means an agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.
28) "FDA" means the United States Food and Drug Administration.
29) "Goggles" mean tight fitting eye protection that completely covers the eyes, eye sockets, and the facial area that immediately surrounds the eyes and that provides protection from impact, dust and splashes. Some goggles may fit over corrective lenses.

30) "HEPA Filter" means a high-efficiency particulate air filter rated 99.97 percent efficient in capturing 0.3-micron-diameter particles.
31) "Hazardous Drug" means any drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control or any drug that meets at least one of following six criteria.
    a) Carcinogenicity.
    b) Teratogenicity or developmental toxicity.
    c) Reproductive toxicity in humans.
    d) Organ toxicity at low doses in humans or animals.
    e) Genotoxicity.
    f) New drugs that mimic existing hazardous drugs in structure or toxicity.
32) "HVAC" means heating, ventilation and air conditioning.
33) "ISO" means International Organization for Standardization as it relates to airborne particulate cleanliness class. Each specific level of cleanliness is identified by the maximum allowable number of particles per cubic meter of air. For example:
    a) ISO Class 5 is an atmospheric environment that contains less than 3,520 particles 0.5 microns in diameter per cubic meter of air.
    b) ISO Class 7 is an atmospheric environment that contains less than 352,000 particles 0.5 microns in diameter per cubic meter of air.
    c) ISO Class 8 is an atmospheric environment that contains less than 3,520,000 particles 0.5 microns in diameter per cubic meter of air.

ISO Classification of Particulate Matter in Room Air-

Class Name		Particle Count	
ISO Class	U.S. FS 209E	ISO, m^3	FS 209E, ft_3
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

34) "Labeling" means all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.
35) "Laminar Airflow Work Bench" and "LAFW" means a unidirectional airflow device capable of producing ISO Class 5 HEPA filtered air or better, for use in the productions of non-hazardous CSPs.
36) "Manufacture" means the production, preparation, propagation, compounding, or processing of a drug or other substance or device, or the packaging or repackaging of such substance or device, or the labeling or relabeling of the commercial container of such substance or device, but does not include the activities of the practitioner who, as an incident to his or her administration or dispensing such substance or device in the course of his or her professional practice, personally prepares, compounds, packages, or labels such substance or device. Manufacture includes the

distribution of a licensed pharmacy compounded drug product to other state licensed persons or commercial entities for subsequent resale or distribution, unless a specific product item has approval of the commission. The term does not include:

a) the activities of a licensed pharmacy that compounds a product on or in anticipation of an order of a licensed practitioner for use in the course of their professional practice to administer to patients, either personally or under their direct supervision;
b) the practice of a licensed pharmacy when repackaging commercially available medication in small, reasonable quantities for a practitioner legally authorized to prescribe the medication for office use only;
c) the distribution of a drug product that has been compounded by a licensed pharmacy to other appropriately licensed entities under common ownership or control of the facility in which the compounding takes place; or
d) the delivery of finished and appropriately labeled compounded products dispensed pursuant to a valid prescription to alternate delivery locations, other than the patient's residence, when requested by the patient, or the prescriber to administer to the patient, or to another licensed pharmacy to dispense to the patient.

37) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer.
38) "Media-Fill Test" (see USP <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments) means a test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile preparations without microbial contamination. During this test, a microbiological growth medium such as Soybean-Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding. The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.
39) "Negative Pressure Room" means a room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of the air is into the room.
40) "Nuclear Pharmacy" means a licensed pharmacy providing radiopharmaceutical services.
41) "Nuclear Pharmacist" means a licensed pharmacist who has submitted evidence to the commission that he or she meets the requirements of this chapter regarding training, education and experience, and who has been recognized by the commission as qualified to provide radiopharmaceutical services.
42) "Pharmacist-In-Charge" and "PIC" means a licensed pharmacist (also known as the responsible manager) in charge of a pharmacy as designated in WAC 246-869-070.
43) "Pharmacy Bulk Package" means a container of sterile product for parenteral use that contains more than one dose. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes, vials, bags, devices, etc.
44) "Primary Engineering Control" and "PEC" means a device or room that provides an ISO Class 5 environment through the delivery of unidirectional HEPA filtered air for the exposure of critical sites during the compounding of CSPs. Such devices include, but may not be limited to, laminar airflow

workbenches, biological safety cabinets, compounding aseptic isolators and compounding aseptic containment isolators.

45) "Product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the U.S. Food and Drug Administration (FDA). Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.
46) "Positive Pressure Room" means a room that is a higher pressure compared to adjacent spaces and, therefore, the net airflow is out of the room.
47) "Quality Assurance" means the set of activities used to ensure that the process used in the preparation of sterile drug preparations leads to preparations that meet predetermined standards of quality.
48) "Quality Control" means the set of testing activities used to determine that the ingredients, components and final CSPs prepared meet predetermined requirements with respect to identity, purity, potency, non-pyrogenicity, and sterility.
49) "Radiopharmaceutical" means any substance defined as a drug in the federal food, drug and cosmetic act (21 U.S.C. Sec. 201(g)(1)) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
50) "Radiopharmaceutical Service" means the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards and use of radiopharmaceuticals; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operations management and control of a nuclear pharmacy.
51) "Segregated Compounding Area" means a designated room or area within a room that is restricted to preparing non-hazardous, low-risk level CSPs with 12-hour or less BUD. Such rooms shall contain a device that provides unidirectional airflow of ISO Class 5 air quality and shall be void of activities and materials that are extraneous to sterile compounding.
52) "Terminal Sterilization" means the application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a nonsterile unit.
53) "Unidirectional Flow" means an airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.
54) "USP" means the United States Pharmacopeia. All references to USP in this chapter refer to the version USP 37 – NF 32 effective May 1, 2014.
55) "USP/NF" means the United States Pharmacopeia/National Formulary**.** All references to USP/NF in this chapter refer to the version USP 37 – NF 32 effective May 1, 2014.

56) "Wholesaler" means a wholesaler authorized by the commission to possess and sell legend drugs, controlled substances and nonprescription drugs to a licensed pharmacy or other legally licensed or authorized person.

WAC 246-878-015 Licensure requirements.

1) All pharmacists and pharmacy technicians working at resident pharmacies that compound sterile preparations shall be licensed as required by 18.64 RCW. All resident pharmacists and pharmacy technicians must obtain a sterile compounding endorsement to their license in order to perform sterile compounding activities.
2) Pharmacists-in-charge working at non-resident pharmacies that compound sterile preparations to be distributed to Washington State shall be licensed as required by 18.64 RCW. The non-resident pharmacist-in-charge must obtain a sterile compounding endorsement to their license in order to perform sterile compounding activities.
3) Resident and non-resident pharmacies must obtain a sterile compounding endorsement in addition to a license in order to provide sterile compounding services.
4) In addition to obtaining a non-resident pharmacy license all non-resident pharmacies shall participate in the National Association of Boards of Pharmacy (NABP) – Verified Pharmacy Program in order to distribute sterile compounded preparations into Washington State. All non-resident pharmacy inspections for facilities producing sterile compounded preparations shall be conducted by NABP.

WAC 246-878-030 Personnel compounding sterile preparations.

1) Pharmacist-in-charge (PIC). The PIC shall possess the education, training and proficiency as required in Section 2, and complete the required competency training as required in WAC 246-878-160, necessary to properly and safely perform compounding duties undertaken or supervised.
   a) The PIC shall not be in charge of more than one licensed pharmacy at a time. The PIC shall be on site at that pharmacy for a minimum of thirty-two hours per week.
   b) The PIC is responsible for verification of the compounding competency of temporary and permanent pharmacists and technicians.
   c) In addition to their regular duties, the PIC shall manage the development of written standard operating procedures (SOPs) designed to ensure accountability, accuracy, quality, safety and uniformity in the sterile compounding process. The PIC shall ensure that each SOP is followed. At a minimum, the following elements shall be included in the SOP manual.
      i) An organized index.
      ii) Cleaning and disinfecting the direct and contiguous compounding areas.
      iii) Proper maintenance and calibration of primary and secondary engineering controls as well as other equipment used in the compounding process.
      iv) Proper hand hygiene and garbing for non-hazardous and hazardous drug compounding.

v) Compounding procedures including but not limited to the use of automated compounding devices and other specific procedures which are required in sterile compounding.
vi) Education, training, and competency evaluation including continuing education and training.
vii) Verification procedures to ensure appropriate education and training for all regular and relief personnel.
viii) End preparation checks and release test of compounded sterile preparations (CSPs).
ix) CSP compounding methodology and formula information.
x) Determination of beyond-use-dates.
xi) Labeling.
xii) Quality assurance.
xiii) Quality control.
xiv) Adverse event reporting.
xv) CSP recall.
xvi) Drug disposal, including hazardous waste if applicable. Hazardous waste disposal must comply with all federal and state regulations including Washington State Department of Labor and Industries Chapter WAC 296-62 WAC, Part R – Hazardous Drugs and the United States Pharmacopeia. For radiopharmaceutical handling see WAC 246-878-190.
xvii) Procurement, shipping, delivery and storage of pharmaceutical materials including compounded drug preparations, components used in the compounding of sterile preparations and drug delivery devices.
xviii) Patient care and instructions.
xix) Bulk compounding, including the development of master formulas and individual batch compounding worksheets.

2) Pharmacists. All pharmacists who compound sterile preparations shall comply with the following elements.
   a) Possess the education, training and proficiency as required in WAC 246-878-160 to properly and safely perform compounding duties undertaken or supervised.
   b) Successfully complete the required competency training appropriate for the type of compounding performed or supervised by the pharmacist.
   c) Inspect and approve all components, drug preparation containers, closures, labeling, and any other materials involved in the compounding process.
   d) Review all compounding records for accuracy and conduct in-process and final checks to ensure that errors have not occurred in the compounding process.
   e) Ensure proper maintenance, cleanliness, calibration, and use of all equipment used in the compounding process.
3) Pharmacy technicians. All pharmacy technicians who compound sterile preparations shall comply with the following elements.
   a) Possess the education, training and proficiency as required in WAC 246-878-160 to properly and safely perform compounding duties undertaken.
   b) Successfully complete the required competency training appropriate for the type of compounding performed by the pharmacy technician.

c) Conducts in-process and completion checks, and affixes his or her initials to the appropriate quality control records.
d) Ensure proper maintenance, cleanliness, and use of all equipment used in the compounding process.

WAC 246-878-035 Personnel education, training, and testing.

1) All personnel involved in the production, manipulation, validation or supervision of persons producing compounded sterile preparations (CSPs) shall receive a minimum of thirty (30) hours of didactic instruction and forty (40) hours of experiential training. All personnel new to compounding sterile preparations shall complete the required training prior to compounding. Personnel who compound sterile preparations prior to the effective date of this chapter shall complete the required training and testing by June 1, 2016.
2) Initial training courses shall be obtained through:
   a) a structured on-the-job didactic and experiential training program. The training shall be preapproved by the Pharmacy Quality Assurance Commission (commission) or commission designee and shall not be transferred to another pharmacy unless the pharmacies are under common ownership and control, and use a common training program. The required experiential portion of the training programs specified in this section must be supervised by a pharmacist who has already completed the required training; or
   b) completion of a course sponsored by an Accreditation Council for Pharmacy Education (ACPE) accredited provider, which meets the required seventy hours of instruction and experience in the required areas; or
   c) completion of a training program which is accredited by the American Society of Health-System Pharmacists and provides the seventy hours of instruction and training in the required areas.
3) Each training program shall include didactic and experiential training on topics including, but not limited to:
   a) fundamentals of sterile compounding manipulations;
   b) responsibilities of compounding personnel;
   c) purpose and use of policies and procedures;
   d) use of all applicable equipment and supplies (e.g., syringes, needles, vials, ampules, filters);
   e) facility and personnel environmental sampling metrics to include but not limited to: personnel hand hygiene, garbing, gloved fingertip sampling; personnel aseptic media fill; competency evaluation; volumetric air sampling; and surface sampling;
   f) engineering controls to include primary and secondary engineering controls function, use, testing and certification;
   g) assignment of beyond-use-dates;
   h) quality assurance, quality releases and final checks of CSPs;
   i) labeling and packaging control;
   j) batch documentation;
   k) cleaning of controlled environments;

l) filtration and sterility processes; moist and dry-heat sterilization; bacterial endotoxin (pyrogen) testing; and automated compounding devices, if applicable to the risk level of compounding;
m) hazardous drug material handling; and
n) hazardous drug compounding (if applicable) to include hazardous drug health effects, occupational risk and safe handling; hazardous drug garbing, and spill cleanup.

4) In addition to completing the required initial didactic and experiential training, and before initiation of their duties, or responsibilities at a pharmacy all personnel involved in CSP production shall:
   a) have their aseptic technique observed and validated as satisfactory by persons trained in such processes and who are authorized in writing by the pharmacist-in-charge to validate such procedures;
   b) successfully complete a gloved fingertip/thumb sampling procedure on no less than three separate occasions before initially being allowed to compound sterile preparations. This sampling shall:
      i) take place immediately after the hand hygiene and garbing procedure but prior to disinfecting the gloves;
      ii) be performed on all gloved fingertips and thumbs sampled from both hands and onto separate agar plates. The plate shall be incubated for the appropriate time and temperature; and
      iii) be evaluated for colony forming units and production of any colony forming units shall result in a testing failure and a repeat shall be required; and
   c) perform media-fill verification tests. Media-fill testing shall:
      i) be representative of the most difficult types of manipulations, products, risk levels and batch sizes that personnel are likely to encounter;
      ii) be conducted at each pharmacy where individuals compound sterile preparations; and
      iii) be validated successfully in that the media-fill units bear no evidence of turbidity or contamination before the individual is allowed to compound sterile preparations.
   d) All items in WAC 246-878-160 (4) (a-c) shall be documented through written and practical tests and shall be retained pursuant to record requirements in WAC 246-878-170 (5) (b).
5) Personnel who fail any element of WAC 246-878-160 (4) must be reinstructed and re-evaluated by trained compounding personnel prior to starting compounding duties.
6) In addition to training requirements in this section, nuclear pharmacists must comply with WAC 246-878-190, Radiopharmaceuticals.
7) On at least a semi-annual basis the pharmacist-in-charge (PIC) shall ensure continuing competency of pharmacy personnel through in-service education, training, media-fill testing and glove fingertip and surface sample testing performed during the preparation of media-fill units which is in addition to initial required training. Certification of competencies and training shall also be performed whenever:
   a) any increase in difficulty or production of a higher risk level CSP is performed;
   b) the quality assurance program yields an unacceptable outcome; or
   c) unacceptable techniques are observed.
8) Five hours of continuing education pertaining to sterile compounding shall be completed annually for pharmacists and PICs who engage in or supervise sterile compounding activities. The five hours

shall be a part of the fifteen hours of continuing education required annually in WAC 246-861-090 for licensure renewal. The continuing education may be obtained through completion of a course sponsored by an ACPE accredited provider or through training preapproved by the commission or commission designee.

9) Four hours of continuing education pertaining to sterile compounding shall be completed annually for pharmacist technicians who engage in sterile compounding activities. The four hours shall be part of the ten hours of continuing education required annually in WAC 246-901-061 for licensure renewal. The continuing education may be obtained through the completion of a course sponsored by an ACPE accredited provider or through training preapproved by the commission or commission designee.
10) The pharmacy shall maintain a training record on each person, including temporary personnel, who compound sterile preparations. At a minimum, the record shall contain documentation of initial and continuing competency, in-service training, education, and the results of written, practical and media-fill testing. All training and test records are required to be retained pursuant to record requirements in WAC 246-878-170 (5) (b). The record shall contain, at a minimum, the following information:
    a) printed name and signature of the person receiving the training;
    b) name and signature of the person(s) providing the training or validating media-fill testing;
    c) name and signature of the PIC or other pharmacist employed by the pharmacy and designated as responsible for validating the completion of the training program;
    d) general description of the topics covered in sub section (3) of this WAC;
    e) date(s) and results of all elements found in sub section (4) of this WAC; and
    f) all elements found in sub section (5-9) of this WAC.

WAC 246-878-045 Operational standards.

1) Operational activities.
    a) Sterile preparations may be compounded in licensed pharmacies:
        i) upon presentation of a practitioner's prescription or medication order based on a valid pharmacist/patient/prescriber relationship; or
        ii) in anticipation of future valid prescriptions based on a history of receiving valid prescriptions generated solely within an established pharmacist/patient/prescriber relationship, provided that in the pharmacist's professional judgment the quantity prepared meets the beyond-use-date requirements. A valid prescription must be received by the pharmacist prior to dispensing the prescription drug.
        iii) For radiopharmaceutical prescription requirements see WAC 246-878-190.
    b) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:
        i) the commercial product is not reasonably available from normal distribution channels in a timely manner to meet patients' needs; or

ii) the pharmacy maintains documentation that the product is not reasonably available due to drug shortage or unavailability from the manufacturer. The unavailability of such drug product must be documented prior to compounding.

iii) A copy of the United States Food and Drug Administration (FDA) or American Society of Hospital Pharmacists list verifying back-ordered, discontinued, or out-of-stock items shall be sufficient documentation. When the back-ordered, discontinued, or out-of-stock item becomes available again then the pharmacy must resume using the commercially available product.

iv) A pharmacy shall not compound sterile preparations that are essentially copies of commercially available products (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product) unless the prescribing practitioner specifically orders and specifies why the strength or dosage form is needed for the patients.

A) The prescribing practitioner shall provide documentation of a patient's specific medical need and that the preparation produces a clinically significant therapeutic response (e.g., the physician requests an alternate product due to hypersensitivity to excipients or preservative in the FDA-approved product, or the physician requests an effective alternative dosage form) or if the drug product is not commercially available.

v) All documentation must be kept in accordance with WAC 246-878-170 (5) (b).

c) Pharmacists preparing compounded sterile preparations (CSPs) for veterinary patients shall adhere to all applicable federal and state sterile compounding standards set for human medications.

2) Reference materials.

a) In addition to the reference material requirements of the pharmacy's specific license, a pharmacy shall maintain the most recent edition, in hard-copy, electronic format, or electronic subscriber access to each of the following:

i) a reference text on injectable drug preparations, such as the Handbook on Injectable Drugs;

ii) a specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy, (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs); and

iii) the United States Pharmacopeia/National Formulary.

3) Pharmaceutical care services.

a) There shall be a designated physician primarily responsible for the patient's medical care. There shall be a clear understanding between the physician, the patient, and the pharmacist of the responsibilities of each in the areas of the delivery of care, and the monitoring of the patient. This shall be documented in the patient medication record system.

b) The pharmacist-in-charge (PIC) shall develop policies to ensure that the patient and/or patient's agent receives information regarding drugs and their safe and appropriate use, including instructions when applicable, regarding:

i) appropriate storage and disposition of legend drugs, controlled substances, hazardous drugs and ancillary supplies;

ii) proper disposition of controlled substances in the home;

iii) self-administration of drugs, where appropriate; and

iv) emergency procedures, including how to contact an appropriate individual in the event of a problem or emergency related to drug therapy.

c) The PIC shall develop patient monitoring policies to ensure that:
   i) the patient's response to drug therapy is monitored and conveyed to the appropriate health care provider; and
   ii) the first dose of any new drug therapy is administered in the presence of an individual qualified to monitor for and respond to adverse drug reactions.

d) A pharmacist shall be accessible twenty-four hours a day for each pharmacy to respond to patients' and other health professionals' questions and needs.

e) If the patient or patient's agent prepares sterile single-use preparations in the home, the following additional information shall be provided:
   i) safeguards against microbial contamination, including aseptic techniques for compounding intravenous admixtures and aseptic techniques for injecting additives into premixed intravenous solutions;
   ii) appropriate storage methods, including storage durations for sterile pharmaceuticals and expirations of self-mixed products;
   iii) handling and disposition of premixed and self-mixed sterile compounded products;
   iv) proper disposition of compounding supplies such as syringes, vials, ampules, and intravenous solution containers.

f) Written information about the compounded preparation's active ingredient(s) shall be given to the patient at the time of dispensing a prescription drug order. A statement which indicates that the preparation was compounded by the pharmacy shall be included in this written information. If there is no written information available, the patient shall be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate, the prescriber, concerning the drug.

g) No multi-use or bulk preparations shall be provided for home use.

4) Labeling.

a) In addition to the labeling requirements as specified in 246-869 WAC, the label dispensed or distributed pursuant to a sterile compounded prescription drug or medication order shall contain the following:
   i) the generic name(s) or the official name(s) of the principal active ingredient(s) of the CSP;
   ii) for outpatient prescription order only, a statement that the CSP has been compounded by the pharmacy. (An auxiliary label may be used on the container to meet this requirement);
   iii) an appropriate beyond-use-date (BUD).

b) If the sterile pharmaceutical is compounded in a batch, the following shall also be included on the batch label:
   i) unique lot number assigned to the batch;
   ii) quantity;
   iii) appropriate ancillary instructions, such as storage instructions or cautionary statements, including hazardous drug warning labels where appropriate; and
   iv) device-specific instructions, where appropriate.

c) The label of a pharmacy bulk package shall:
   i) state prominently "Pharmacy Bulk Package – Not for Direct Infusion";
   ii) contain or refer to information on proper techniques to help ensure safe use of the preparation; and
   iii) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

5) Records

a) Records for batch compounding.
   i) A master formula work sheet shall be developed and approved by the PIC for preparations prepared in batch. Once approved, a duplicate of the master work sheet shall be used as the preparation work sheet from which each batch is prepared and on which all documentation for that batch occurs. The master work sheet shall contain at a minimum:
      A) the formula;
      B) the components (active and inactive);
      C) beyond-use-dating;
      D) specific, step-by-step compounding directions and double check sign offs where appropriate;
      E) a sample label;
      F) evaluation and testing requirements;
      G) specific equipment used during preparation;
      H) storage requirements; and
      I) batch size.
   ii) In addition to the items required in the master work sheet, the preparation work sheet for each batch of preparations shall document the following:
      A) identity of all solutions and ingredients and their corresponding amounts, concentrations, or volumes;
      B) lot number and expiration date for each component;
      C) component manufacturer/distributor or suitable identifying number;
      D) container specification (e.g., syringe, pump cassette);
      E) unique lot or control number assigned to batch;
      F) BUD of batch-prepared preparations;
      G) time and date of preparation;
      H) sample of label used;
      I) name, initials, or electronic signature of the person(s) involved in the preparation and performing any double checks;
      J) finished preparation evaluation and testing specifications, if applicable;
      K) comparison of actual yield to anticipated or theoretical yield, when appropriate; and
      L) adverse events.

b) Maintenance of records.
   i) Every record required under this chapter must be kept by the compounding pharmacy and be available for at least two years for inspection and copying by an authorized agent of the commission and to other authorized local, state or federal law enforcement agencies. The compounding pharmacy must supply the requested records within seventy-two hours.
   ii) Compounding records for all compounded pharmaceuticals shall be maintained by the pharmacy electronically or manually as part of the prescription drug or medication order, master formula worksheets, preparation worksheets, or compounding log and shall include:
      A) the date of the preparation;
      B) a complete formula, including methodology and necessary equipment which includes the brand name(s) of the raw materials, or if no brand name, the generic name(s) or official name and name(s) of the manufacturer(s) or distributor of the raw materials and the quantities of each;
      C) the quantity in units of finished products or amount of raw materials and components;
      D) signature or initials of the pharmacist or pharmacy technician performing the compounding;

E) signature or initials of the pharmacist responsible for supervising pharmacy technicians and conducting in-process and final checks of compounded pharmaceuticals if pharmacy technicians perform the compounding function;
F) the container and closures used and the number of units prepared; and
G) a reference to the location of the following documentation which may be maintained with other records, such as quality control records:
I) the criteria used to determine the BUD; and
II) the documentation of performance of quality control procedures.

c) Advertising. A compounding pharmacy or pharmacist may advertise or otherwise promote the fact that the pharmacy or pharmacists provides prescription drug compounding services. A compounding pharmacy or pharmacist shall not make a claim, assertion, or inference of professional superiority in the compounding of drug products that cannot be substantiated. Compounding drug price advertising must comply with 246-861 WAC Pharmacy – Prescription Drug Price Advertising.

WAC 246-878-055 Microbial contamination risk levels and beyond-use-dates.

1) Low-risk level compounded sterile preparations (CSPs).
   a) CSPs under all of the following conditions are at a low risk of contamination.
      i) The CSPs are compounded with aseptic manipulations entirely within International Organization for Standardization (ISO) Class 5 or better air quality using only sterile ingredients, products, components, and devices.
      ii) The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.
      iii) Manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers or other sterile products, or containers for storage and dispensing.
      iv) For a low-risk preparation, in the absence of passing a sterility test (see United States Pharmacopeia (USP) <71> Sterility Tests), the storage periods for each CSP or batch of CSPs shall not exceed the following time periods: before administration, the CSPs shall be properly stored and not be exposed for more than forty-eight hours at controlled room temperatures; for not more than fourteen days at a cold temperature; and for forty-five days in solid frozen state (between -25 to -10 degrees Celsius or -13 to 14 degrees Fahrenheit). For delayed activation device systems, the storage period shall begin when the device is activated.
   b) Examples of low-risk compounding include the following.
      i) Single-volume transfers of sterile dosage forms from ampules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, or other sterile containers. The solution content of ampules shall be passed through a sterile filter to remove any glass particles.
      ii) Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.
   c) Low-risk level CSPs with twelve-hour or less beyond-use-date (BUD).

i) If the primary engineering control (PEC) is a compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI) that does not meet the requirements described in USP 797, Placement of Primary Engineering Controls or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 buffer area, then only low-risk level non-hazardous and radiopharmaceutical CSPs pursuant to a physician's order for a specific patient shall be prepared, and administration of CSPs shall commence within twelve hours of preparation or as recommended in the manufacturer's package insert, whichever is less. Low–risk level CSPs with a twelve-hour or less BUD shall meet all of the following four criteria:
   A) PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified and maintain ISO Class 5 as described in USP 797, Facility Design and Environmental Controls for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.
   B) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation.
   C) Personnel shall follow the procedures described in USP 797, Personnel Cleansing and Garbing and Additional Personnel Requirements prior to compounding. Sinks shall not be located adjacent to the ISO Class 5 PEC. Sinks shall be separated from the immediate area of the ISO Class 5 PEC device by no less than three feet.
   D) The specifications in USP 797, Cleaning and Disinfecting the Sterile Compounding Areas; Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures; and Viable and Nonviable Environmental Sampling Testing shall be followed.

2) Medium-risk level CSPs.
   a) When CSPs are compounded aseptically under low-risk conditions and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.
      i) Multiple individuals or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
      ii) The compounding process includes complex aseptic manipulations other than the single-volume transfer.
      iii) The compounding process requires unusually long duration, such as that required to complete dissolution or homogenous mixing.
      iv) For a medium-risk preparation, in the absence of passing a sterility test (see USP <71> Sterility Tests), the storage periods for each CSP or batch of CSPs shall not exceed the following time periods: before administration, the CSPs shall be properly stored and not exposed for more than thirty hours at controlled room temperature for not more than nine days at a cold temperature, and for forty-five days in solid frozen state between -25 and -10 degrees Celsius or between -13 and 14 degrees Fahrenheit.
      v) The CSPs shall not contain broad spectrum bacteriostatic substances and they are administered over several days (e.g., an externally worn infusion device).
   b) Examples of medium-risk compounding include the following.
      i) Compounding of total parenteral nutrition fluids using a manual or automated device during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

ii) Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.

iii) Filling reservoirs of injection and infusion devices with volumes of sterile drug solutions that will be administered over several days at ambient temperatures between 25 and 40 degrees Celsius or between 77 and 104 degrees Fahrenheit.

iv) Transfer of volumes from multiple ampules or vials into a single, final sterile container or product.

v) Aqueous bronchial and nasal inhalations, solutions, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

3) High-risk level CSPs.
   a) High-risk level CSPs are those compounded under any of the following conditions.
      i) Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral) are incorporated or a nonsterile device is employed before terminal sterilization.
      ii) Nonsterile preparations are exposed to environments less than ISO 5 for more than six hours before being sterilized.
      iii) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.
      iv) For a high-risk preparation, in the absence of passing a sterility test (see USP <71> Sterility Tests), the storage periods shall not exceed the following time periods: before administration, the CSPs shall be properly stored and not exposed more than twenty-four hours at controlled room temperature for not more than three days at a cold temperature, and for forty-five days in solid frozen state between -25 and -10 degrees Celsius or between -13 and 14 degrees Fahrenheit.
      v) All nonsterile measuring, mixing, and purifying equipment shall be rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk compounded sterile aqueous solutions subjected to terminal sterilization shall be passed through a filter with a nominal porosity not larger than 1.2 microns preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile 0.2 micron or .22 micron nominal pore size filter within an ISO Class 5 or superior air quality environment.
   b) Examples of high-risk compounding including the following.
      i) Dissolving nonsterile bulk drug powders and nutrient powders to make solutions which will be terminally sterilized.
      ii) Exposing the sterile ingredients and components use to prepare and package CSPs to room air quality worse than ISO Class 5 for more than one hour.
      iii) Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.
      iv) Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least ninety-five percent by weight of their active chemical moiety and have not been contaminated or adulterated between uses.
4) Immediate-use CSPs.
   a) The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include

cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for low-risk level CSPs subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs shall not be stored for anticipated needs or batch compounded. Immediate-use CSPs shall not be used more than one time or shared. Preparations that are medium-risk level, high-risk level or cytotoxic drugs shall not be prepared as immediate-use CSPs. Immediate-use CSPs are exempt from the requirements described for low-risk level CSPs only when all of the following criteria are met:

i) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile non-hazardous products or diagnostic radiopharmaceutical products from the manufacturer's original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.
ii) Unless required for the preparation, the compounding procedure shall be a continuous a process not to exceed one hour.
iii) During preparation, aseptic technique shall be followed and, if the preparation is not immediately administered, the finished CSP shall be under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
iv) Administration shall begin no later than one hour following the start of the preparation of the CSP.
v) Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact one-hour BUD and time.
vi) If administration has not begun within one hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded. Compounding in worse than ISO Class 5 conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

WAC 246-878-060 Compounding sterile radiopharmaceuticals.

1) Any pharmacist providing radiopharmaceutical services must be a nuclear pharmacist or be under the supervision of a nuclear pharmacist, and act in accordance with all state and federal regulations including Chapter 246-240 WAC Radiation protection – medical use of radioactive material and all other applicable sections of this chapter.
2) In addition to a sterile compounding pharmacist endorsement, a nuclear pharmacist endorsement is required to operate a nuclear pharmacy providing radiopharmaceutical services. The endorsement shall only be issued to a qualified nuclear pharmacist.
3) The nuclear pharmacist shall be responsible for all operations of the licensed area. In emergency situations, in the nuclear pharmacist's absence, he or she may designate one or more qualified, and registered or certified health care personnel to have access to the licensed area. These individuals may obtain radiopharmaceuticals for the immediate emergency and must document such withdrawals as outlined in the facility's policies and procedures.
4) In addition to the training requirements required in this chapter a nuclear pharmacist must:

a) submit to the commission or commission designee certification that he or she has completed a minimum of six months on-the-job training under the supervision of a qualified nuclear pharmacist in a nuclear pharmacy providing radio pharmaceutical services; or
b) submit certification that he or she has completed a nuclear pharmacy training program in an accredited college of pharmacy.

5) Radiopharmaceuticals shall be dispensed only upon a prescription from a practitioner authorized to possess, use and administer radiopharmaceuticals. A nuclear pharmacy may also furnish radiopharmaceuticals for office use to these practitioners.
6) In addition to the records requirements in this chapter, nuclear pharmacies shall maintain records as required by the state radiation control agency and other state and federal agencies.
7) A nuclear pharmacist may transfer to an authorized person radioactive materials not intended for drug use, in accordance with regulations of the state radiation control agency.
8) The immediate outer container of the radiopharmaceutical to be dispensed shall be labeled with:
   a) the standard radiation symbol;
   b) the words "caution-radioactive material";
   c) the name of the pharmaceutical;
   d) the amount of radioactive material contained, in millicuries or microcuries;
   e) if a liquid, the volume in milliliters;
   f) the requested calibration time for the amount of radioactivity contained;
   g) expiration data, if applicable, and beyond-use-date; and
   h) specific concentration of radioactivity.
9) In addition to any applicable labeling requirements in this chapter and WAC 246-869-210 prescription labeling, the immediate container shall be labeled with:
   a) the standard radiation symbol;
   b) the words "caution-radioactive material"; and
   c) the amount of radioactive material contained, in millicuries or microcuries.
10) The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.
11) Nuclear pharmacies may redistribute NDA (new drug application) approved radiopharmaceuticals if the pharmacy does not process the radiopharmaceuticals in any manner or violate the product packaging.
12) In addition to the reference material requirements in WAC 246-878-170 Operational standards, the nuclear pharmacy shall maintain a library commensurate with the level of radiopharmaceutical service to be provided.
13) Production of radio pharmaceuticals for positron emission tomography shall comply with USP Chapter 823 Positron Emission Tomography Drugs for Compounding, Investigational, and Research Uses. All other radiopharmaceuticals shall be compounded as follows.
   a) Radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of one-hundred ml or less for a single-dose injection or not more than thirty ml taken from a multiple-dose container (see USP <1> Injections) shall be designated as, and conform to, the standards for low-risk compounded sterile preparations.
   b) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified International Organization for Standardization (ISO) Class 5 primary engineering control located in an ISO Class 8 or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.
   c) Radiopharmaceutical vials designated for multiple use, compounded with technetium-99, exposed to an ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by the manufacturer's recommendations.

Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

d) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by the manufacturer and applicable state and federal rules. Such generator systems shall be operated in an ISO Class 8 or cleaner air environment to permit special handling, shielding, and air flow requirements. 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.

WAC 246-878-065 Environment.

1) The primary engineering control (PEC) must be located in one of the following:
   a) a segregated compounding area for the preparation of non-hazardous, low-risk less than twelve-hour beyond-use-date (BUD) compounded sterile preparations (CSPs) only; or
   b) a clean room suite for all other low-, medium- and high-risk CSPs.
2) Segregated compounding area.
   a) A pharmacy that prepares low-risk preparations with a less than twelve-hour BUD shall perform these CSP activities in an International Organization for Standardization (ISO) Class 5 PEC. The PEC can be located within a segregated compounding area. The segregated compounding area that is not required to meet any ISO air cleanliness level. This PEC may be a laminar airflow work bench, biological safety cabinet, compounding aseptic isolator, or compounding aseptic containment isolator.
   b) PECs in a segregated compounding area shall be restricted to sterile compounding activities that minimize the risk of CSP contamination.
3) Clean room suite.
   a) A pharmacy that prepares low- and medium-risk preparations shall have a clean room suite for the compounding of sterile preparations that shall be constructed to minimize the opportunities for particulate and microbial contamination. The clean room suite shall:
      i) be clean, well lit, and of sufficient size to support sterile compounding activities;
      ii) be used only for the compounding of sterile preparations;
      iii) be designed such that hand sanitizing and garbing occurs outside the buffer room and allows compounding personnel hands-free access to the buffer room;
      iv) have non-porous and washable floors to enable regular disinfection. Flooring must be monolithic with integral coved base with heat welded or caulked seams; and
      v) be ventilated in a manner to avoid disruption from the heating, ventilation, and air conditioning system and room cross-drafts.
   b) Room segregation and ventilation for clean room suites shall:
      i) provide and maintain room segregation through pressure differentials of at least 0.2 inches water column positive pressure relationship and cascading pressure gradient between each ISO classified space and adjacent spaces (e.g., from the buffer room to the anteroom and from the anteroom to all adjacent spaces);
      ii) for hazardous drug CSPs, provide and maintain not more than 0.02 inches water column negative pressure relationship from the hazardous drug buffer room to the ISO Class 7 anteroom and to all adjacent spaces;
      iii) provide ventilation at a minimum of thirty air changes per hour for the buffer room and twenty air changes per hour for the anteroom;

iv) provide low wall return air and/or exhaust air grills;
v) provide a continuously monitored pressure gauge installed to monitor the required cascading pressure differential for these areas: non-hazardous buffer room to anteroom; anteroom to non-classified space and hazardous drug buffer room to anteroom;
vi) provide high-efficiency particulate (HEPA) filtered air that are certified to meet Type C or Type K per IEST-RP-CC0001.5; and
vii) provide a comfortable working environment, which typically includes a temperature of 68 degrees Fahrenheit or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.

c) Clean room suites shall have walls, ceilings, floors, fixtures, shelving, counters, and cabinets that are smooth, impervious, free from cracks and crevices, non-shedding and resistant to damage by disinfectant agents. This shall include the following:
i) painted walls shall be finished with marine grade epoxy paint or approved equivalent;
ii) ceilings shall be monolithic, impervious, washable acoustic ceiling tile caulked to acoustic ceiling grid, or approved equivalent;
iii) junctures of ceilings shall be coved or caulked;
iv) all penetration through walls and ceiling shall be caulked;
v) caulking shall be of the non-shedding type;
vi) all ceiling lighting fixtures shall have gasketed lenses and be flush with the ceiling;
vii) work surfaces shall be constructed of smooth, impervious washable material, such as stainless steel or molded plastic;
viii) automatic sprinkler heads in the clean room suite shall be of the clean room type that are flush with the ceiling;
ix) have drugs and supplies stored on shelving areas above the floor to permit adequate floor cleaning;
x) provide personnel door access via an anteroom; and
xi) be certified by an independent contractor according to the Controlled Environmental Testing Association Certification Guide for Sterile Compounding Facilities (CAG-003) every six months and whenever the room is altered or major service to the facility is performed.

4) Anteroom.
a) The anteroom shall provide at least ISO Class 8 or better quality air under operational conditions for clean rooms.
b) Anterooms serving hazardous drug clean rooms shall provide at least ISO Class 7 or better quality air under operational conditions for clean rooms.
c) All anterooms shall provide the following:
i) a sink with a non-aerated faucet designed for hands free use;
ii) a closed soap distribution system designed to minimize the risk of extrinsic contamination;
iii) lint free disposable towels;
iv) the sink is to be located on the clean side of the line of demarcation;
v) a line of demarcation shall be present in the anteroom to identify the “dirty” side of the room from the “clean” side of the room. This line may consist of an alternate color of flooring with heat welded or caulked seams, or of marine grade epoxy paint. Tape is not permissible;
vi) a positive pressure relationship to adjacent spaces. Pressure relationships must maintain 0.02 to 0.05 inches water column;
vii) a continuously monitored pressure gauge must be installed to monitor the required pressure relationship;
viii) painted walls shall be coated by marine grade epoxy paint or approved equivalent;

ix) floors must be covered with a monolithic covering with integral coved base. Seams must be heat welded or caulked;
x) anterooms must provide designated storage for cleaning supplies that are dedicated for cleaning of the clean room suite; and
xi) be certified by an independent contractor according to the Controlled Environmental Testing Association Certification Guide for Sterile Compounding Facilities (CAG-003) every six months and whenever the room is altered or major service to the facility is performed.

5) Common elements and general requirements.
   a) The PEC shall:
      i) be located in the buffer room and placed in a manner as to avoid conditions that could adversely affect its operation such as strong air currents from opened doors, personnel traffic, or air streams from the HVAC system;
      ii) be certified under operational conditions by an independent contractor according to the Controlled Environment Testing Association Certification Guide for Sterile Compounding Facilities (CAG-003) and the International Organization for Standardization (ISO) Classification of Particulate Matter in Room Air (ISO-14664-1) for operational efficiency at least every six months and when it is relocated, in accordance with the manufacturer's specifications;
      iii) have pre-filters inspected periodically and replaced as needed, in accordance with written policies and procedures and the manufacturer's specifications, and the inspection and/or replacement date documented; and
      iv) provide a detailed ISO testing certification report to the department of health (DOH) for review as follows:
         A) submit reports to DOH survey when requested by DOH personnel; and
         B) submit reports to DOH Construction Review Services prior to use of spaces newly constructed or renovated.
   b) Whenever test results indicate that the clean room suite or any primary engineering controls do not meet the standards established in this section, the pharmacy shall immediately cease using the clean room suite or PEC that is out of compliance until such time that the clean room suite and/or the PEC meets the requisite standards, unless repair can be made immediately. All out of compliance test results shall be reported in writing to the pharmacist-in-charge or the director of pharmacy, to the risk management officer and the chief operating officer. Test results indicating non-compliance with the requisite standards shall require evaluation of all procedures associated with the production of CSPs in the impacted clean room suite or PEC. The period of time that the clean room suite and/or PEC remained out of compliance shall be documented. See WAC 246-878-170(5)(b) for record retention requirements.
   c) If automated compounding devices are used, the pharmacy shall have a method to calibrate and verify the accuracy of automated compounding devices used in aseptic processing. The calibration and verification shall be based on the manufacturer's recommendations. Written documentation of the measurements shall be kept on file and made available for inspection upon request per record retention requirements in WAC 246-878-170(5)(b).
   d) All drugs shall be stored at the proper temperature and conditions, as defined in the United States Pharmacopeia/National Formulary.
   e) Beyond-use-dates.
      i) Unless sterility testing is performed for the CSP, the BUD of the preparation shall not exceed the limits in the following table:

Risk Level	Room Temperature	Refrigeration	Freezer
Low	48 hours	14 days	45 days

Medium	30 hours	7 days	45 days
High	24 hours	3 days	45 days

ii) If sterility testing is performed according to USP <71> Sterility Tests, the CSP can be assigned BUD based on the maximum chemical stability of the drug in solution as permitted by valid references. BUDs in excess of forty-five days are strongly discouraged.

iii) Documentation of the criteria used to determine the stability and microbial contamination risk level for the anticipated shelf time for all products must be maintained and available for inspection per record retention requirements in WAC 246-878-170(5)(b).

WAC 246-878-075 Hazardous drugs.

1) Hazardous Drugs – General
   a) Hazardous drugs shall be prepared for administration only under conditions that protect pharmacy personnel in the preparation and storage areas.
   b) Hazardous drugs shall be stored separately from other inventory in a manner to prevent breakage, contamination, and personnel exposure. Hazardous drugs shall not be stored, unpacked, compounded, or otherwise manipulated in an area that is positive pressure relative to the surrounding area.
   c) Hazardous drugs shall be stored at or below eye level in containers that minimize the risk of breakage and leakage, and shall not be stored on the floor.
   d) Access to areas where hazardous drugs are stored and prepared shall be restricted to authorized staff to protect persons not involved in hazardous drug handling.
   e) Hazardous drugs shall be handled with caution at all times using chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation, administration and disposal.
   f) Hazardous drugs shall not be removed from their white plastic-coated cardboard until they are in the area where they are to be stored.
   g) Hazardous drugs shall be prepared in negative pressure biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI) and follow aseptic practices specified in this section.
   h) Hazardous drug compounding activities shall comply with all federal regulations and Washington State Department of Labor and Industries Chapter WAC 290-62 General Occupational Health Standards and United States Pharmacopeia.
2) All personnel involved in the compounding of hazardous drugs shall wear appropriate personal protective equipment (PPE) at all times regardless of the PEC used. PPE includes gowns made of polyethylene or other material which prevents saturation with liquids, face masks, hair covers, shoe covers or dedicated shoes, and two pairs of chemotherapy gloves. Eye protection in the form of goggles shall be worn during activities where there is danger of eye exposure to hazardous drugs such as during cleaning of a PEC used for hazardous drug compounding.
3) Equipment used in the manipulation and compounding of hazardous drugs shall be used only with hazardous drugs.
   a) Appropriate safety and containment techniques for compounding of hazardous drugs shall be used only with hazardous drugs.
   b) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements.
   c) Prepared doses of hazardous drugs must be dispensed, labeled with proper precautions inside and outside, and distributed in a manner to minimize patient contact with hazardous agents. Hazardous drugs shall be dispensed with appropriate packaging and labeling in compliance with

the requirements and recommendations established by applicable federal, state, and local agencies including, but not limited to the commission, Occupational Safety and Health Administration (OSHA), National Institutes for Occupational Safety and Health (NIOSH) and Environmental Protection Agency (EPA).

4) Hazardous drugs – primary engineering control device.
   a) Hazardous drugs shall be prepared in a Class II (Type A2 or B2) or III vertical flow biological safety cabinet or compounding aseptic containment isolator located in an International Organization for Standardization (ISO) Class 7 area that is physically separated by doors and walls from other preparation areas. The area for preparation of sterile chemotherapeutic preparation shall:
      i) not have less than 0.01 inches water column negative pressure to the adjacent positive pressure ISO Class 7 or better anteroom;
      ii) have a pressure indicator that shall be calibrated yearly and monitored throughout the day for correct room pressurization; and
      iii) have a minimum of twelve air changes per hour of HEPA supplied filtered air.
   b) All BSCs or CACIs shall be externally vented to the outside air terminating at the roof through HEPA filtration.
5) Hazardous drugs- personal protective equipment (PPE).
   a) Appropriate PPE shall be worn when handling hazardous drugs. The garbing and glove requirements listed in this section shall be used for compounding sterile hazardous drugs in any setting.
   b) When performing a task when engineering controls are not available, such as cleaning a spill, additional PPE may be required.
   c) Garbing requirements – gloves.
      i) Gloves used shall be labeled chemotherapy gloves.
      ii) Gloves shall be powder free.
      iii) Two pairs of chemotherapy gloves shall be worn when compounding, administering, managing a spill, or disposing of hazardous drugs.
      iv) The outer glove shall be sterile. The inner glove shall be worn under the gown cuff and the outer glove over the cuff.
   d) Garbing requirements – gowns.
      i) Gowns that have been tested to resist permeability to liquids shall be worn when handling hazardous drugs. Selection of gowns shall be based on the hazardous drugs used.
      ii) Gowns shall close in the back, have long sleeves, and have closed cuffs, which shall be either elastic or knit.
      iii) Gowns shall not have seams or closures that could allow drug permeation.
      iv) Gowns shall be secured at all times when handling hazardous drugs.
      v) Gowns shall not be worn outside the compounding area if they have been worn in the hazardous drug compounding area.
      vi) The time limit that the manufacturer lists for permeation of the gown shall be followed. If no permeation data is available the gown shall be changed every two hours or immediately after a spill or splash.
      vii) Gowns used for hazardous drug compounding will not be reused.
   e) Garbing requirements – head, hair, shoe and sleeve covers.
      i) Head, beard, and moustache (if applicable), and shoe covers shall be worn in hazardous compounding areas.
      ii) Shoe covers shall not be worn outside the hazardous compounding areas.

iii) Sleeve covers, if used, shall be constructed of coated materials to provide additional protection for the arms.
iv) Sleeve covers shall be discarded after a single use.

f) Garbing requirements – eye and face protection.
i) Appropriate eye and face protections shall be worn when handling hazardous drugs outside of any engineer control and when opening PECs for cleaning.
ii) Goggles shall be used when eye protection is needed. Eyeglasses alone or safety glasses with side shields do not provide adequate protection.
iii) Eye and face protection shall be worn when manipulating a hazardous drug outside of the primary engineering control, working at or above eye level, cleaning the primary engineering control, or cleaning a spill.
iv) Face shields alone do not provide full eye and face protections and must be worn with goggles.

g) Garbing requirements – respiratory protection.
i) Surgical or procedures masks do not provide respiratory protection from drug exposure and shall not be used to compound or administer hazardous drugs.
ii) For most activities a NIOSH-certified N95 or better protective respirator is sufficient.
iii) An appropriate full-face piece, chemical cartridge-type respirator shall be worn when attending to hazardous drug spills larger than what can be contained with a spill kit, or when there is known or suspected airborne exposure to powders or vapors.

6) Hazardous drugs – cleaning: deactivation, decontamination, cleaning and disinfection.
a) Work practices for environmental cleaning/decontamination services shall include:
i) wearing two pairs of ASTM-tested chemotherapy gloves that are chemically resistant to the decontamination of cleaning agents used;
ii) wearing eye protection;
iii) wearing face shields if splashing is possible; and
iv) wearing a full face respirator for protection against vapors which may be generated during the decontamination/deactivation phase of cleaning.

b) Cleaning hazardous drug areas shall be consistent with this chapter and the recommendations of the primary engineering control manufacturer.

c) Cleaning of the primary engineering control, devices, equipment, and areas used for compounding hazardous drugs shall include:
i) Deactivation. Chemical deactivation of hazardous drugs is preferred, but no single process has been found to deactivate all currently available hazardous drugs.
A) Deactivation shall occur when an appropriate agent is identified.
ii) Decontamination. Decontamination occurs by removing hazardous residue from surfaces and transferring them to a low lint wipe.
A) Final CSPs shall be decontaminated before being placed in their protective bag for delivery.
B) The agent used for wiping vials must not alter the product label.
C) The primary engineering control shall be decontaminated on a weekly basis at a minimum, any time a spill occurs, before and after certification, voluntary interruption, or if the ventilation is moved.
iii) Cleaning and disinfecting shall follow general sterile compounding rules and occur after decontamination is completed.

7) Hazardous drugs – spill control.
a) Spills shall be contained and cleaned immediately by appropriately trained personnel.
b) Signs shall be available to restrict access to the spill area.

c) All personnel who may be required to clean up a hazardous drug spill shall receive appropriate training in spill management and in the use of PPE including NIOSH certified respirators.
d) Written policies and procedures shall be developed to prevent spills and address cleaning of hazardous drug spills. Written policies and procedures shall include the following elements.
    i) Listing the name of the person who is responsible for spill management to address the size and scope of the spill.
    ii) Assure that personnel cleaning up the hazardous spill are trained in handling hazardous spill clean-up.
    iii) Description of PPE required for various spill sizes, the possible spreading of material, restricted access to hazardous spills, and signs to be posted.
    iv) Use of an appropriate full face piece, chemical cartridge type respirator for spills that exceed the capacity of the spill kit, such as when an IV bag breaks or a line disconnects and leaks, or where there is known or suspected airborne exposure to vapors and gases.
    v) Spill kits containing all of the materials needed to clean hazardous spills shall be available in all areas where hazardous drugs are routinely handled.
    vi) Spill handling shall be documented. This documentation shall be maintained on site and be available for review at inspection.

8) Transport.
    a) Policies shall be established pertaining to packaging, transport, and handling of hazardous drugs.
    b) Policies shall address at a minimum prevention of accidental exposures, spills, personnel training to respond to exposure, and use of a spill kit.
    c) All hazardous drugs shall be clearly labeled at all times during their transport and use.
    d) Hazardous drugs shall be transported in closed containers that minimize the risk of breakage or leakage and maintain appropriate temperatures.
    e) Transport containers shall be selected that maintain physical integrity, stability, and sterility of hazardous drugs during transport.
9) Environmental quality control.
    a) Environmental sampling to detect uncontained hazardous drugs shall be performed initially as a benchmark, then every six months at a minimum to verify containment.
    b) Sampling shall include:
        i) surface sampling of the primary engineering controls;
        ii) surface sampling of the countertop where finished preparations are placed;
        iii) surface sampling areas adjacent to the primary engineering controls including the floor directly under the working area; and
        iv) patient administration areas.
    c) Any measurable contamination found shall identify, document, and contain the cause of contamination. Appropriate cleaning and documentation procedures of contamination shall occur immediately upon discovery.
10) Medical surveillance.
    a) Employers shall ensure that healthcare workers who are exposed to hazardous drugs are routinely monitored as part of a medical surveillance program.
    b) The surveillance program shall include all personnel who directly handle hazardous drugs.
    c) Elements of medical surveillance program shall include:
        i) development of an organized plan to identify workers who are potentially exposed to hazardous drugs;
        ii) design of medical surveillance program that is appropriate to the exposure;
        iii) a baseline assessment of workers health and occupational history to include an estimate of drug identity, drug quantity, and dosage forms handled;

iv) hours spent handling these drugs per week;
v) the number of preparations and administration per week;
vi) future monitoring for any changes that may result from exposure to hazardous drugs to include periodic and routine physical examinations and reproductive and general health questionnaires, exposure histories, tracking of current exposure;
vii) monitoring of data to identify prevention failure leading to disease; and
viii) development of a follow-up plan for workers who have shown health changes suggesting toxicity or who have experienced accidental exposure.

11) Follow-up plan.
   a) The occurrence of exposure related disease or health changes shall prompt immediate evaluation of the primary preventative measures to include at a minimum, engineering controls, PPE, and standard operating procedures related to hazardous drugs.
   b) Post exposure examinations shall be tailored to the type of exposure. The assessment of the exposure is maintained on an incident report.
   c) Treatment and laboratory studies shall follow as indicated and should be guided by emergency protocols.
   d) Verify and document that all controls are in proper operating condition.
   e) Verify and document that the personnel complied with existing policies. Review use of PPE and employee compliance with PPE use and policies.
   f) Review availability of appropriate PPE.
   g) Develop and document an action plan that will prevent additional personnel exposure.
   h) Ensure confidential notification of any adverse health effect to an exposed worker.

WAC 246-878-080 Equipment and supplies.

1) Pharmacies compounding sterile preparations shall have the following equipment and supplies:
   a) a calibrated system or device to continuously monitor the temperature to ensure that proper storage requirements are met, if sterile pharmaceuticals are stored in the refrigerator;
   b) a calibrated system or device to continuously monitor the temperature where bulk chemicals are stored;
   c) if applicable, a Class A prescription balance, or analytical balance and weights. Such balance shall be properly calibrated and maintained, and subject to periodic inspection by the Washington State Pharmacy Quality Assurance Commission;
   d) equipment and utensils necessary for the proper compounding and monitoring of sterile preparations and environment. Such equipment and utensils used in the compounding process shall be:
      i) of appropriate design, appropriate capacity, and be operated within designed operational limits;
      ii) of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the drug preparation beyond the desired result;
      iii) cleaned and sanitized daily at the end of each day or more often, if required; and
      iv) routinely inspected, calibrated (if necessary), or checked to ensure proper performance.
   e) appropriate packaging or delivery containers to maintain proper storage conditions for sterile preparations;
   f) infusion devices, if applicable; and
   g) all necessary supplies, including but not limited to:
      i) disposable needles, syringes, and other supplies for aseptic mixing;

ii) disinfectant cleaning solutions;
iii) hand washing agents with bactericidal action;
iv) disposable, lint free towels or wipes;
v) appropriate filters and filtration equipment;
vi) cytotoxic spill kits, if applicable; and
vii) masks, caps, coveralls or gowns with tight cuffs, shoe covers, and sterile gloves, as applicable.

2) Maintenance logs must be kept in accordance with WAC 246-878-170(5)(b) on all equipment that is required to be inspected and calibrated.

WAC 246-878-090 Drug components and materials used in sterile compounding.

1) Drugs used in sterile compounding shall be a United States Pharmacopeia/National Formulary (USP/NF) grade substances manufactured in a Food and Drug Administration (FDA)-registered facility.
2) If USP/NF grade substances are not available they shall be of a chemical grade in one of the following categories:
   a) Chemically Pure (CP);
   b) Analytical Reagent (AR);
   c) American Chemical Society (ACS); or
   d) Food Chemical Codex.
3) All drugs, components and materials shall be manufactured in an FDA-registered facility or the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier. The pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis. All drugs, components and materials shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.
4) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity of the compounded drug preparation beyond the desired result.
5) Components, drug preparation containers, and closures shall be rotated so that the oldest stock is used first.
6) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the compounded drug preparation.
7) A pharmacy shall not compound a preparation that contains ingredients appearing on a federal food and drug administration list of drug products withdrawn or removed from the market for safety reasons.
8) Opened or needle-punctured, single-dose containers, such as bags, bottles, syringes, and vials of sterile products and compounded sterile preparations shall be used within one hour if opened in worse than International Organization for Standardization (ISO) Class 5 air quality (see WAC 246-878-180(4)), and any remaining contents shall be discarded.
9) Single-dose vials and pharmacy bulk packages exposed to and maintained in ISO Class 5 or cleaner air may be used up to six hours after initial needle puncture. Opened single-dose ampules shall not be stored for any time period.
10) The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers shall not exceed twenty-eight days (see USP <51> Antimicrobial Effectiveness Testing) unless otherwise specified by the manufacturer.
11) A closed system drug transfer device shall not be used to extend the BUD requirements.

12) When a container is used as a pharmacy bulk package, the closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a certified primary engineering control within a clean room compliant with WAC 246-878-200.

WAC 246-878-093 Compounding process requirements.

1) All significant procedures performed in the compounding area shall be covered by written standard operating procedures designed to ensure accountability, accuracy, quality, safety, and uniformity in the compounding process.
2) Any compounded formulation with an official monograph in the United States Pharmacopeia/National Formulary (USP/NF) shall be compounded, labeled, and packaged in conformity with the USP/NF monograph for the drug.
3) At each step of the compounding process, the pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate to conform to the formula being prepared.
4) Only one batch shall be prepared by each of the compounding staff members at a time.
5) Any person with an apparent illness or open lesion that may adversely affect the safety or quality of the drug preparation being compounded shall be excluded from the contiguous compounding area including the buffer area, anteroom and the primary engineering control.
6) Before entering the clean area, compounding personnel must remove the following:
   a) personal outer garments (e.g., bandanas, coats, hats, jackets, scarves, sweaters, vests);
   b) all cosmetics; and
   c) all hand, wrist and other body jewelry.
7) Gum chewing, food or drink shall not be allowed in the clean areas.
8) Personal electronic devices or accessories shall not be allowed in the clean areas.
9) Particle shedding items shall not be allowed in an International Organization for Standardization (ISO) 5 environment (e.g., labels and worksheets).
10) Wearing artificial nails or extenders shall not be allowed while working in the sterile compounding environment. Natural nails shall be kept under one-quarter inch in length from the tip of the finger.
11) Personnel shall don personal protective equipment and perform hand hygiene in an order that proceeds from the dirtiest to the cleanest activities as follows:
   a) Activities considered the dirtiest include head and facial hair covers (e.g., beard covers in addition to face masks), face mask/eye shield, and donning dedicated shoes or shoe covers. Eye shields are optional but strongly suggested when there is a likelihood of splashing of germicidal detergents or sporicidal agents during cleaning solution preparation and cleaning the ceiling and areas overhead. Shoe covers or dedicated shoes shall not touch the floor on the dirty side of the line of demarcation.
   b) After donning head and facial hair covers, face masks, and dedicated shoes or shoe covers, personnel shall perform hand hygiene procedure by wetting hands and elbows with water and either antimicrobial or non-antimicrobial soap, removing debris from underneath the fingernails using a disposable nail cleaner followed by vigorous hand washing that generates lather. Personnel shall begin washing arms at the hands and continue washing to elbows for at least thirty seconds. Scrub brushes shall not be used.
   c) Non-shedding towels shall be used to dry hands and arms.

d) After completion of hand washing, personnel shall don clean non-shedding gowns with sleeves that fit snugly around the wrists. The gown shall be secured with snaps or ties and close up to the neck. All bare skin on arms and legs is to be covered when appropriately garbed.
e) Prior to donning sterile gloves, antiseptic hand cleaning shall be performed with persistent activity following manufacturers' recommendations. The hands shall be allowed to dry prior to donning sterile gloves.
f) Sterile gloves that form a continuous barrier with the gown shall be the last item donned before compounding begins and can occur in either the anteroom or buffer room.
g) Routine application of sterile seventy percent isopropyl alcohol shall occur between individual batches, when re-entering an ISO 5 environment, and every thirty minutes during continuous compounding or whenever nonsterile surfaces are touched.
h) Gloves on hands shall be inspected throughout the compounding process and replaced immediately if a hole, puncture, or tear occurs.
i) Gloved fingertip and thumb sampling procedures shall be conducted randomly for all personnel while conducting compounding procedures under operational conditions. Random testing shall occur at least every three months for each person under operational conditions.
j) When compounding personnel must temporarily exit the non-hazardous buffer room environment during a work shift, the exterior gown, if not visibly soiled, may be removed, hung, and retained in the ISO Class 8 anteroom, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face mask/eye shield, and sterile gloves are single-use items and must be replaced with new ones before re-entering the buffer room environment. Proper hand hygiene technique must be performed again.

WAC 246-878-097 Operational standards – sanitation.

1) The following cleaning and disinfecting practices and frequencies apply to all direct and contiguous compounding areas, which include International Organization for Standardization (ISO) Class 5 compounding areas as well as clean rooms, buffer rooms and anterooms. The pharmacist-in-charge is responsible for developing a standard operating procedure related to schedules and methods for cleaning and disinfecting the direct and contiguous compounding areas including intermittent use of sporicidal agent to augment the use of the daily germicidal detergent, maintaining cleaning documentation, and assuring the procedures are followed. Procedures shall address at a minimum:
   a) Cleaning records that include, at a minimum, a cleaning solution preparation log which includes dilution of cleaner, the number of containers prepared, the preparer's initials and date of preparation.
   b) The cleaning logs shall include a daily cleaning log for the ISO 5 areas, and a daily and monthly cleaning log for the ISO 7 and 8 areas both non-hazardous and hazardous. Cleaning records shall specify all areas to be cleaned.
   c) Training of all pharmacy and non-pharmacy personnel who perform cleaning functions and successful completion of competencies in hand hygiene and garbing, as well as cleaning and disinfecting shall be completed on an annual basis. Documentation of training shall be maintained for a period of two years pursuant to record requirements in WAC 246-878-170(5)(b). Training shall include at a minimum:
      i) particulate control in the primary and secondary engineering controls;
      ii) dilution of cleaning agents;
      iii) cleanroom asepsis;
      iv) specific areas to be cleaned;
      v) use of personal protection equipment and safety precautions;

vi) cleaning agents and type of water used to dilute;
vii) mechanics and frequency of cleaning;
viii) documentation;
ix) environmental sampling for quality control; and
x) hazardous drug handling (if applicable).

2) Personnel competency shall be evaluated:
   a) during orientation and training prior to the regular performance of those tasks;
   b) whenever the quality assurance program yields an unacceptable result; or
   c) whenever unacceptable techniques are observed.
3) Cleaning and disinfecting must not occur while compounding is occurring and shall occur from cleanest to dirtiest areas, from top to bottom, unidirectionally. Dedicated utensils and supplies shall be used and stored appropriately in the anteroom.
   a) The daily cleaning sequence shall be to remove all trash, clean the primary engineering controls and any equipment that resides in the primary engineering control (PEC), all easily cleanable horizontal surfaces in the buffer area including the counter of any pass-through that exists or horizontal surfaces of furniture that resides in the pass-through, all easily cleanable horizontal surfaces in the anteroom; any door handles/knobs, telephones, intercoms; the sink proper, its handles and an exposed plumbing on top of the sink; the floor of the buffer area as well as the floor of any existing full-height pass-throughs, and then the floor of the anteroom allowing surfaces to dry prior to use.
   b) The monthly cleaning sequence includes all daily cleaning activities and shall begin with cleaning the ceiling of the buffer area, the walls of the buffer area including all interior surfaces of any pass-throughs, doorknobs, telephones, intercoms; all outside surfaces of the primary engineering controls. Inside the surfaces of the PEC and any equipment that resides in the PEC, all surfaces of any carts, shelving and bins. Progress to the anteroom cleaning in a similar fashion from the ceiling, walls and all surfaces of carts, shelving and bins, then the floor of the anteroom allowing surfaces to dry prior to use.
   c) Mops shall be a reusable microfiber or disposable variety and must be non-shedding. Handles must be constructed of nonporous easily cleanable materials. If reusable mop heads are used they must be rinsed and sanitized thoroughly prior to storage. Reusable mop heads require dedicated handles and shall be used only for cleaning ceilings and walls, with a separate dedicated mop head and handle for floor cleaning. Mops are to be hung to dry.
   d) Bucketless cleaning systems are required. Sprayers shall be used to apply cleaning agents.
   e) Dedicated cleaning equipment shall be used in sterile compounding areas and stored in the anteroom. All equipment shall be clearly labeled for its area of use.
4) The primary engineering control shall be disinfected with sterile seventy percent isopropyl alcohol prior to and after each work shift (at a minimum of every twelve hours while the pharmacy is open), approximately every thirty minutes during continuous compounding, between batches, when visibly soiled or when surface contamination is suspected.
5) All surfaces of the PEC must be cleaned each day with a germicidal detergent solution followed by disinfection with sterile seventy percent isopropyl alcohol.
6) It is preferred that daily cleaning of the primary and secondary engineering controls occur at the end of the compounding day for pharmacies that do not operate twenty-four hours a day or at a designated time each day for those pharmacies in continuous operation.
7) During the daily cleaning of the PEC, all items shall be removed from the primary engineering control and all surfaces shall be cleaned of loose material and residue from spills with sterile water. Follow with an application of germicidal detergent prior to the application of sterile residue-free disinfecting agent such as sterile seventy percent isopropyl alcohol. The germicidal cleaning agent

shall be allowed to dry before applying the disinfecting agent. The disinfecting agent shall be left to dry or wiped with non-shedding wipes. Germicidal detergents shall be prepared with sterile water.

8) Once a week, a sporicidal agent will be used to clean in lieu of the germicidal detergent.
9) Horizontal or easily cleanable work surfaces in the buffer area and clean area shall be cleaned of loose material and residue from spills with a germicidal cleaning agent daily.
    a) Floors in the buffer and anteroom shall be cleaned by mopping with a germicidal cleaning agent using a non-shedding mop at least once daily by appropriately trained personnel when no aseptic operations are in progress, proceeding from the buffer or clean room suite to the anteroom.
    b) The walls, ceiling, doors, non-horizontal surfaces of the furniture, shelving and bins, and trash cans, shall be cleaned at least monthly in the buffer room and anteroom with a germicidal agent.
    c) Door handles, telephones, intercoms and other surfaces that are touches often must be cleaned daily with a germicidal agent.
    d) Supplies and equipment removed from shipping cartons shall be wiped with a disinfecting agent, preferably a sporicidal agent, prior to entering the anteroom. However, if supplies are received in sealed sterile pouches, the pouches may be removed as the supplies are introduced into the buffer or clean area without the need to disinfect the individual supply items. No shipping or other external cartons shall be taken into the buffer or clean area. No particle shedding items shall be taken into the buffer or clean area. All items will be wiped down a second time with sterile seventy percent isopropyl alcohol immediately prior to the introduction to the ISO Class 5 area.

WAC 246-878-100 Operational standards – quality assurance and control.

1) Quality Assurance - Prior to routine compounding sterile preparations (CSPs), a pharmacy shall conduct an evaluation that shows the pharmacy is capable of compounding a preparation that is sterile and that contains the stated amount of active ingredient(s).
2) Low-risk preparations.
    a) Quality assurance practices include, but are not limited to the following:
        i) routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain International Organization for Standardization (ISO) Class 5 air quality;
        ii) visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments and goggles;
        iii) review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded;
        iv) visual inspection of CSPs against a light background and then against a dark background to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags; and
        v) review of label for accuracy and thoroughness.
    b) Example of a Low-Risk Media-fill Test Procedure. This test or an equivalent test shall be performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during the compounding of low-risk level CSPs. Once begun, this test shall be completed without interruption. Example of test procedure: within an ISO Class 5 air quality environment, three sets of four 5-mL aliquots of sterile Soybean-Casein Digest Medium (also known as trypticase soy broth or trypticase soy agar) are transferred with the same sterile 10-

mL syringe and vented needle combination into separate sealed, empty, sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of the three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20 to 25 degrees Celsius or at 30 to 35 degrees Celsius; or at 68 to 77 degrees Fahrenheit or 86 to 95 degrees Fahrenheit for a minimum of fourteen days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least seven days at each temperature (see United States Pharmacopeia (USP) <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments). Inspect for microbial growth over fourteen days as described USP 797, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfections Procedures.

3) Medium-risk preparations.
   a) Quality assurance procedures for medium-risk level CSPs shall include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually, or more frequently.
   b) Example of a medium-risk Media-Fill Test Procedure. This test or an equivalent test shall be performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test shall be completed without interruption. Example of test procedure: within an ISO Class 5 air quality environment, six 100-mL aliquots of sterile Soybean-Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10- mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for ten seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20 to 25 degrees Celsius or at 30 to 35 degrees Celsius; or at 68 to 77 degrees Fahrenheit or 86 to 95 degrees Fahrenheit for a minimum of fourteen days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least seven days at each temperature (see USP <1116> Microbiological Evaluation of Clean Rooms and Other Controlled Environments). Inspect for microbial growth over fourteen days as described in USP 797, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfections Procedures. The media-fill test shall include a positive-control sample.

4) High-risk preparations.
   a) Procedures for high-risk level CSPs shall include all those for low and medium-risk level CSPs. In addition, a media-fill test that represents high-risk level compounding shall be performed every six months by each person authorized to compound high-risk level CSPs.
   b) Example of a high-risk Media-Fill Test Procedure for CSPs Sterilized by Filtration. This test, or an equivalent test, is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. This test is completed without interruption in the following sequence:
      i) Dissolve three grams of nonsterile commercially available Soybean-Casein Digest Medium in 100 milliliters of non-bacteriostatic water to make a three percent nonsterile solution.
      ii) Draw twenty-five milliliters of the medium into each of the three 30-milliliter sterile syringes. Transfer five milliliters from each syringe into separate sterile 10-milliliter vials.

These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.

iii) Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-micron porosity filter unit and a 20-gauge needle to each syringe. Inject the next ten milliliters from each syringe into three separate 10-milliliter sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20-35 degrees Celsius (68-95 degrees Fahrenheit). Inspect for microbial growth over fourteen days as described in Chapter 797 Pharmaceutical Compounding – Sterile Preparations, of the USP/NF.

5) Finished preparation release checks and tests for all sterile compounded preparations.
   a) All high-risk level CSPs that are prepared in identical individual single-dose packages (such as ampules, bags, syringes, and vials), or in multiple dose vials for administration to multiple patients, or are exposed longer than twelve hours at 2-8 degrees Celsius (36-46 degrees Fahrenheit) and longer than six hours at warmer than 8 degrees Celsius (46 degrees Fahrenheit) before they are sterilized shall be tested to ensure they are sterile and do not contain excessive bacterial endotoxins as specified in USP <71> Sterility Tests.
   b) All CSPs that are intended to be solutions shall be visually examined against a light background and then against a dark background for the presence of particulate matter and shall not administered or dispensed when such matter is observed.
   c) The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels shall be inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.
   d) All sterile compounded batch preparations which are transferred to another pharmacy under common ownership shall be tested by the central compounding pharmacy for sterility prior to release.
6) Quality control.
   a) The pharmacist-in-charge shall develop and the pharmacy shall follow quality control procedures to monitor the compounding environment and quality of compounded drug preparations for conformity with the quality indicators established for the preparation. When developing these procedures, the pharmacist-in-charge shall consider the provisions of USP Chapter 797, Pharmaceutical Compounding – Sterile Preparations, and USP Chapter 1160, Pharmaceutical Calculations in Prescription Compounding. Such procedures shall be documented and be available for inspection. See WAC 246-878-170(5)(b) for record retention requirements.
   b) The pharmacist-in-charge shall establish an adverse event reporting process. The process shall include procedures for investigating, determining cause, correcting failures or problems and reporting in the compounding process, testing, or in the CSP. Any adverse event shall be reported by the pharmacist-in-charge to MedWatch: The United States Food and Drug Administration Safety Information and Adverse Event Reporting Program within forty-eight hours of becoming aware of the adverse event.
   c) The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing 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) If the correct identity, purity, strength and sterility of ingredients and components of CSPs cannot be confirmed, such ingredients and components shall be discarded immediately.

ii) Individual ingredients such as bulk drug substances that are not labeled with expiration dates shall require testing to determine the correct amount to weigh for accurate content of active chemical moieties in CSPs. Components that do not have expiration dates assigned by the manufacturer or supplier, shall be labeled on the container with the date of receipt and shall be assigned an expiration date not to exceed three years after receipt of the component.