Agenda Item/Title: Consonus Pharmacy Services Washington

Date SBAR Communication Prepared: 1/23/2020

Reviewer: Irina Tiginyanu

Link to Action Plan:

- Action
- Information
- Follow-up
- Report only

Situation:

Pharmacy is seeking approval for their technician and assistant AUP

Background:

Assessment:

Pharmacy technicians are performing within their scope of practice:

- Technicians are performing specialized function:
  - sterile compounding
  - IV admixture

Recommendation:

Recommendation to approve the ancillary utilization plan for technicians and assistants, and specialized functions listed in the AUP for technicians

Follow-up Action:
Pharmacy Ancillary Utilization Application

All utilization plans must be submitted 60 days prior to next Pharmacy Commission business meeting. You can find the Commission meeting schedule on the Department of Health website.

Note: Utilization plans for technicians and assistants must accompany this application.

Select One: □ New  ☑ Update

1. Demographic Information

UBI # 602543727  Federal Tax ID (FEIN) # 36-4584871

Legal Owner/Operator Name: Consensus Pharmacy Services Washington

Pharmacy License #: PHAR.CF.00058819

Pharmacy Name: Consensus Pharmacy

Physical Address: 14729 NE 87th St.

City: Redmond  State: WA  Zip Code: 98052  County: King

Facility Phone (enter 10 digit #): 866-6098-5120  Fax (enter 10 digit #): 866-6098-5121

2. Facility Specific Information

Number of Employees:

- Pharmacists: 14
- Technicians: 28
- Assistants: 16

3. Key Individuals

Responsible Pharmacist: Donna Bowser  License #: Ph6066683

Signature: ____________________________  Date: 11/11/19

Signature of Owner/Authorized Representative of Pharmacy: Teva Terreia

Print Name: Print Title: General Manager

Revenue: 0262000000

Ancillary Utilization ......................... Fee
Check the fee page for current fees.
All application fees are nonrefundable
ANCILLARY PERSONNEL UTILIZATION PLAN

ASSISTANTS

While under the immediate supervision of a licensed pharmacist, Assistants assist the pharmacist in performance of all tasks, except those reserved to the pharmacist and pharmacy technician.

A. Maintains assigned work areas and equipment in clean and orderly condition and replenishes supplies.
B. Files and retrieves various pharmacy records as required.
C. Triage - Receives, reviews, and triages all faxes to the appropriate workflow queues.
D. Handles nonprofessional phone calls, when no interpretation is needed to/from:
   a. Calls from physician’s office authorizing refills providing no changes in the prescription are involved. Calls to physician’s office requesting refill authorization:
      i. Refill requests shall be made stating the patient’s name, medication and strength, number of doses and date of prior refills.
      ii. Any additional inquiries by the office concerning the prescription must be referred to a Pharmacist.
   b. Calls for Price information
   c. Calls for Business hours or delivery services
   d. Calls regarding the availability of goods and services – these might require transferring the call to another person
   e. Inquiries from long term care facility staff regarding if prescriptions are refillable or the number of refills left.
   f. Calls dealing with the ordering of drugs and supplies from wholesalers and distributors
E. Processes refill requests only when there is no change in prescription
F. Receives, reviews, and triages all faxes to the appropriate workflow queues
G. Faxes computer generated or electronic refill requests to prescriber
H. Counts, pours and labels for individual prescriptions. This function is performed under the direct supervision of a licensed pharmacist and the accuracy of the prescription contents is checked and verified by a licensed pharmacist.
I. Assists the Pharmacist in the DOSIS replenishment process – stages the medications and cassettes for the Pharmacist who then fulfills the replenishment process which includes barcoding the cassette against stock bottle, loading the cassette and placing the cassette in DOSIS.

J. Manages the replenishment of supplies (cards/bubbles) and maintenance

K. Billing
   A. Intake – sets up billing for new admits
   B. Answers customers billing questions
   C. Interacts with insurance companies to obtain coverage information and non-discretionary overrides
   D. Process e-kit billing

L. Delivery staging
   A. Removing returns from totes to further be sorted by Purchasing
   B. Scanning medications into totes/bags/boxes, printing and placing manifests in the totes, closing totes for delivery
   C. Setting up emergency deliveries with couriers
   D. Delivery of medications to facilities
   E. Cleaning and maintaining IV or CADD pumps
   F. Cleaning and maintaining medication carts

M. Purchasing & Inventory functions including
   A. Places, receives, unpacks and stores drug orders.
   B. Review, remove and process outdated medications
   C. Processes returns from facility per policy
   D. Maintaining drug formulary in pharmacy system
   E. Inventory Control and Maintenance
   F. Pre-package a pre-determined amount of cards of an individual medication or medication(s), print label (non-patient) and affix to card for verification of label and product by a Pharmacist.
TECHNICIANS

While under the immediate supervision of a licensed pharmacist, Technicians assist the pharmacist in performance of all tasks including those of assistants and the addition of the below, except those reserved to the pharmacist.

A. Enters New Prescription data into the computer and monitors label printing. This function is under the direct supervision of a licensed pharmacist and the accuracy of the prescription contents and label is checked and initialed by a licensed pharmacist.

B. Enters allergy and medical conditions into the computer that is provided on the prescription, intake information or discharge information. This function is performed under the direct supervision of a licensed pharmacist and the accuracy is checked and verified by the licensed pharmacist. The technician is not permitted to determine why a medication is being used. This function is reserved for the Pharmacist only.

C. Calls, faxes, records or provides medication data where no interpretation is necessary, ie. Quantity, date last filled, price.

D. Reconstitutes for restoration of original form of medication previously altered for preservation and storage by addition of a specific quantity of distilled water or provided diluents requiring no calculation. In each case, the accuracy of the technician is checked and the work verified by a licensed pharmacist.

E. Performs non-sterile compounding of products using a template which provides the necessary information to compound product including excipients, instructions for mixing and any required equipment needed in the preparation. Compound including calculations, measurements of products and final product are verified and initialed by a licensed pharmacist.

F. Manages e-kit replenishment process
   A. Receives emergency supply (kit) back from facility
   B. Reviews entire contents for any medication/supplies removed
   C. Forwards usage information to billing
   D. Pulls medication/supply based on established min/max
   E. Pharmacist verifies all medications/supplies and quantities before e-kit is locked

G. Manage electronic e-kit replenishment process
   A. Cubex
      i. Receives Cubies back from facility and returns unit dose stock to shelf if in date (outdates to purchasing for processing)
      ii. Pulls medication/supplies based on Cubie Refill Replenishment Process and fills Cubies
      iii. Pharmacist verifies all medications and quantities before placed in tamper proof bag for delivery

H. Pharmacy Technician who is trained in aseptic compounding and passes the didactic reviews and media-fill testing according to USP <797> may prepare compounded sterile
preparations. This includes weighing, measuring, diluting, mixing, purifying, sterilizing, packaging, sealing, labeling, inspecting, and storing the compounded sterile preparations.
## Technician Specialized Function—Program Review Form

### Chapter 246-901 WAC

**Date:** 1/23/2020  
**Responsible Pharmacist:** Danielle Briones  
**Pharmacy Name:** Consonus Pharmacy Services Washington  
**License #:**  
**Pharmacy Address:** 14729 NE 87th St, Redmond WA 98052  
**Phone #:** 866-698-5120

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>Does the Program identify pharmacy technicians who meet the criteria for participation?</td>
<td>☒</td>
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<tr>
<td>Did the responsible pharmacist sign the program proposal?</td>
<td>☒</td>
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<tr>
<td>Training Program at least 8 hours long and specifies the following categories:</td>
<td>☒</td>
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<td>Policies and Procedures provided with description of training</td>
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<tr>
<td>a. Basic skills in health system pharmacy, including goals and requirements of unit-dose medication systems.</td>
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<td>b. Common medication errors and prevention strategies.</td>
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<tr>
<td>c. Mathematical calculations and medical abbreviations.</td>
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<tr>
<td>d. Drug product selection policies and safeguards.</td>
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<tr>
<td>e. A comprehensive examination.</td>
<td>☒</td>
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<tr>
<td>The validation process for individual performance of unit-dose medication checking includes:</td>
<td>☒</td>
<td></td>
<td>Policies and Procedures provided with description of training</td>
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<tr>
<td>a. 1500 doses at several intervals.</td>
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<td>b. Pharmacist supervision.</td>
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<td>c. 99% accuracy for success.</td>
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<tr>
<td>The quality assurance program will annually audit the specialized skills of technicians:</td>
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<td></td>
<td>Policies and Procedures provided with description of training</td>
</tr>
<tr>
<td>a. Random audits of checking accuracy audits performed by a licensed pharmacist.</td>
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<tr>
<td>b. Retention of audit forms and incident reports related to pharmacy technician medication checking.</td>
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<td></td>
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<tr>
<td>Forms used in training, validation and audits are submitted with program?</td>
<td>☒</td>
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<tr>
<td>Utilization plan for specialized pharmacy technician functions is included with the program?</td>
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**Comments:** Approve updated AUP and specialized functions

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### For staff use only

**Review completed on January 23, 2020** by Irina Tiginyanu  
**Agreement type:** □ New ☒ Renewal

**Staff decision:** ☒ Approved □ Revisions needed □ Board agenda  
**Board decision:** □ Approved ☒ Denied □ Notice sent to investigator
Specialized Sterile Compounding Technician

Specialized function reserved for pharmacy technicians who have completed training, initial and ongoing and meet the proficiency criteria set forth by the Commission and USP 797.

A. Technician shall be provided with appropriate training and instruction prior to participating in the aseptic compounding process.

B. Verification of thorough understanding of USP Chapter <797> and aseptic compounding techniques shall be demonstrated prior to participating in the aseptic compounding process by:
   1. Successful completion of written quizzes on each training module
   2. Successful completion of a practical exam and media – fill test procedure.
      i. Appropriate hand-washing, garbing technique, and cleaning of compounding area
      ii. Glove tip sampling x 3 with results no greater than 0 CFU
      iii. PATT II test

C. Competency of compounding technician will be assessed initially and annually and will address the following:
   1. Aseptic technique
   2. Pharmaceutical calculations and terminology
   4. Quality assurance procedures.
   5. Proper gowns and gloving technique
   6. General conduct in the cleanroom area
   7. Cleaning, sanitizing and maintaining the rooms and equipment used.
   8. Container, equipment and closure system.

D. Competency of compounding technicians will be assessed initially and annually by the following methods:
   1. Written testing
   2. Observation of technique
   3. Media Fill Procedures
   4. Assessment of processes for donning cleanroom attire and hand washing, including gloved fingertips sampling.

E. All functions as outlined in ‘Specialized Sterile Compounding Pharmacy Technician’ Job Description
JOB DESCRIPTION
Specialized Sterile Compounding Pharmacy Technician

REPORTS TO: Pharmacist in Charge of Sterile Compounding & Director of Pharmacy

QUALIFICATIONS:
- Pharmacy technician licensure in WA in good standing
- Successful completion of ‘Sterile Product Staff Competency Training and Assessment’ as outlined in Consonus CSP5-A prior to participating in any sterile compounding in the aseptic compounding process
- Proficient computer skills – typing and excel skills
- Good communication and telephone skills
- Accuracy in work and attention to detail
- Minimal bending and stooping
- Lifting 15-20#s occasionally
- Visual acuity to see and read fine print and operate office equipment
- Ability to stand 6-8 hours per day

RESPONSIBILITIES:
- Performs compounding procedures according to all pertinent local, state and federal regulations and USP 797
- Performs IV pharmaceutical compounding activities under the direct supervision of a pharmacist after completion of initial and yearly competency and other testing as outlined in the CSP P & P manual and then yearly thereafter
- Maintains accurate records of all work order information and all procedures for IV compounding
- Assist in maintaining all aspects of IV infusion patient charts
- Patient safety – report all defects and participate in the action plan and follow up thereof where appropriate
- Performs maintenance and sanitization of clean room and ante-room. Documents all activities on log.
- Maintain and keep pharmacy work area clean
- Performs inventory procedures (drug ordering, receiving of drug orders, supplies and merchandise, shipping or merchandise, stocking supplies)
- Maintains a full level of all supplies within the pharmacy work area and in the clean room complex
- Maintains pump tracking records, including to/from facility, cleaning and QA maintenance records
- Performs billing functions
- Keeps all forms and labels in stock at all times
- Other duties as assigned

______________________________    _______________________
Employee                         Date

______________________________    _______________________
Supervisor                       Date
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POLICY: The patient population of Consonus Pharmacy includes any patient who meets the criteria established for patient acceptance and who resides within the geographic area that is served. Compounded sterile products are prescription items such that this internal P&P manual is considered to be a portion of the general internal pharmacy P&P manual.

1. Consonus Pharmacy compounds products within the low and medium risk categories as defined by USP 797, but does not perform high-risk compounding or compound any items considered hazardous by the latest NIOSH listing.

2. USP 797 defines Low Risk CSP compounding as: Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and two or fewer entries into any container.

3. USP 797 defines Medium Risk CSP compounding as: Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products or more than 2 entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.

4. Consonus does not get involved in medication administration or services to home care patients and does not accept any biological waste for disposal.

5. Infusion therapies provided by the IV pharmacy include, but are not limited to:
   - Parenteral Nutrition
   - Antibiotic Therapy (parenteral)
   - Anti-infective therapy (parenteral/aerosol—e.g. pentamidine)
   - Pain Management (parenteral)
   - Anticoagulant Therapy (parenteral)
   - Catheter Care
   - Immunotherapy
   - Hydration Therapy

   Therapies which are similar to those listed above may also be provided, if appropriate.

6. The pharmacy may prepare other sterile products, but will not compound any sterile products from non-sterile ingredients.

7. Prohibited Compounding: Compounding any drug for human use that the FDA, in its Compliance Policy Guidance has identified as prohibited for compounding or withdrawn or removed from the market for safety reasons is prohibited.
8. Certain medications may need to be compounded at the nursing facility, due to stability concerns or emergent situations. Please see the policy on "Immediate Use Compounding" for more details.

9. The pharmacy is in compliance with United States Pharmacopeia Chapter 797 and has all licenses required by the State Board(s) of Pharmacy for the states to which any products are delivered, including any required Sterile Compounding Permits or has a current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency.
   • Sterile Compounding Permit #____________________

10. The pharmacy has either:
   a) A clean room for the preparation of sterile products that has the following:
      • An ISO class 5 laminar airflow hood within an ISO class 7 buffer area cleanroom.
      • A positive air pressure differential in the clean room that is relative to adjacent areas
      • An ISO class 8 ante room.
      • The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy’s written policies and procedures.
      • The clean room is certified per Consonus P&P at least every 6 months by a reputable agency.
   b) A CAI (Compounding Aseptic Isolator) that meets USP 797 requirements allowing placement in a non ISO-certified space.
      • The preparation of sterile injectable products is conducted in an environment that meets criteria specified in pharmacy’s written policies and procedures.
      • The CAI is certified per Consonus P&P at least every 6 months by a reputable agency.

11. These Policies and Procedures will apply in all Consonus pharmacies unless otherwise noted. It is assumed that references to ante rooms, buffer rooms, laminar flow hoods and isolators only apply in those settings in which those rooms or pieces of equipment are employed in meeting requirements for sterile compounding. Not all locations will employ all rooms or equipment.

12. There are current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.
POLICY: Access to the Sterile Compounding Area

POLICY Number: CSP1-B

REVISED DATES:
11/5/14

Original Date:
4/8/14

POLICY: Access is restricted to those authorized people that are qualified and have tasks and responsibilities in the specific area. This may include cleaning staff and compounding staff.

- Authorized staff will have completed the following:
  - Training per the appropriate portions of the Consonus Policy and Procedure Manual

- In addition, compounding staff will have completed the following:
  - Certification if required by the appropriate state Board of Pharmacy for compounding sterile products
  - Training per the complete Consonus Policy and Procedure Manual
  - Validation of aseptic technique via media fill test
  - Validation of proper handwashing and donning of attire via glove-tip culturing test
POLICY: General Aseptic Area Policy

POLICY NUMBER: CSP2-A

REVISED DATES: 3/5/15, 6/8/16, 6/28/16, 12/30/16, 4/21/17

ORIGINAL DATE: 03/13/2014

POLICY: Procedures for personnel working in the aseptic compounding area must be followed closely to assure a high quality end product. This policy applies to any staff with duties related to aseptic areas, whether that be cleaning or compounding.

Cleaning may be performed by compounding staff or by trained cleaning staff with the exception of cleaning of the laminar flow hoods or isolators which must be done by compounding staff only.

PROCEDURE:

- Traffic flow into the buffer area will be minimized and limited to those authorized and trained personnel that have duties and specific tasks requiring their presence.
- All items will be removed from any carton or packaging material and decontaminated with PeridoxRTU prior to introducing into the buffer area.
- The volume of supplies introduced into the buffer area or isolator will be limited to those necessary for immediate compounding needs or otherwise needed to be close at hand (needles, syringes, alcohol wipes, mini-bags, etc). Non-essential items, especially those that shed fibers (cardboard, paper towels, etc.) will not be brought into the buffer area or isolator.
- Supplies to be introduced into the buffer room may be brought in via a positive pressure "pass through" or through the anteroom. If a pass through is used, there will only be one side opened at a time. Never will both sides of the pass through be open at the same time.
- The anteroom will be divided into "clean" and "dirty" sides by a line of demarcation.
- Carts will not enter the buffer area without first being cleaned and disinfected. For use in bringing supplies into the buffer area, carts will not advance past the line of demarcation in the anteroom. If desired, a "dirty" cart may be used to gather supplies and bring them to the line of demarcation in the anteroom. The supplies will then need to be transferred to the buffer area, either by carrying them (once fully garbed) or by transferring to a "clean" cart on the clean side of the line of demarcation.
- All supplies will be organized to promote efficient compounding activities and to minimize clutter.
- Personnel preparing to enter the buffer area or to use the CAI shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings.
- For cleanrooms, if a tacky mat is used, it will be placed just outside the door into the anteroom from the general pharmacy area.
- Prior to entering the buffer area, staff will follow Consonus procedures for donning the proper garb and for proper hand washing.
- Chewing gum, drinks, candy or other food items will never be introduced into the ante room or buffer area.
POLICY: General Aseptic Procedures Carried Out at a Laminar Air Flow Workbench (LAFW)

POLICY NUMBER: CSP2-B

REVISED DATES: 12/30/16, 8/7/19

ORIGINAL DATE: 03/17/2014

POLICY: Procedures for personnel working in a LAFW must be followed to ensure that product sterility is maintained.

PROCEDURE:

- Before beginning work, scrub and gown according to Consonus standards.
- The hood blower shall be operated continuously if the hood is used on a daily basis. If the hood is not used often, it can remain off, but must be turned on at least 30 minutes prior to use.
- The entire surface of the workbench, including the filter grill (which protects the HEPA filter itself), shall be cleaned/disinfected with a non-linting wipe saturated with PeridoxRTU. Allow a minimum 3 minute wet contact time. If there is any loose material or remnants of a spill, pre-clean the area with a non-linting wipe saturated with sterile water for irrigation. Subsequent daily cleanings shall be accomplished using sterile 70% isopropyl alcohol and need only include the worksurface, unless other areas of the LAFW are visibly soiled.
- Do not spray disinfectant solutions at or on the filter or filter grill.
- Any spills shall be absorbed immediately, and the area washed with sterile water for irrigation followed by disinfectant on a non-linting wipe.
- Plan the work for a certain time period to minimize movement within the hood and in the immediate work area surrounding the hood.
- Before placing in the buffer area or immediate work area, all supplies shall be removed from their outer cartons, boxes, etc. then wiped down with a non-linting wipe saturated with sterile 70% isopropyl alcohol and allowed to dry.
- It is not necessary to wipe down products that are removed from an outer-wrap as they are being introduced into the LAFW. Examples are bags of IV solution or syringes.
- Each vial or ampule to be placed in the LAFW shall be cleaned by wiping the outer surface with sterile 70% isopropyl alcohol.
- Remove all syringes, needles, etc. from their immediate wrapper in the LAFW-filtered air and place them in the LAFW for use as they are needed.
- Only items that are necessary for the immediate preparation shall be placed in the LAFW.
- Organize all materials to enhance efficiency of work and to maintain integrity of the critical sites for all material, in accordance with the flow of air.
- All work must be performed at least six inches within the LAFW.
- Do not touch or place any item upstream of the critical sites of any item, even with gloved hands, as the hands are not sterile.
- Periodically use sterile 70% isopropyl alcohol on the surface of the gloved hands, as necessary.
- Immediately before opening, the necks of all ampules shall be cleaned with a non-linting wipe saturated with sterile 70% alcohol.
- All rubber stoppers of vials and other containers should be cleaned, using a non-linting wipe saturated with sterile 70% alcohol, prior to opening or penetrating with a needle. Allow at least 10 seconds for the alcohol to have its disinfecting effect and to evaporate.
- Filter all solutions removed from glass ampules to remove possible glass particles prior to adding to a vehicle or to another component. A filter needle or filter straw can be used for this purpose.
- During addition of drugs, solutions should be gently swirled or rotated to speed mixing and minimize the occurrence of an incompatibility.
- During preparation, constantly observe the preparation for the formation of a precipitate, cloudiness, gas bubbles, etc.
- After completion, observe the final product for any evidence of incompatibility and visually inspect the container for particulate matter using a lighted white and/or black background.
- Place a tamper-evident cap or seal on the finished product, as appropriate.
- Remove the product from the LAFW, label the product, and place an overwrap, if required and seal. If the overwrap is opaque, it may be advisable to add a duplicate label on the overwrap.
- Remove all empty containers, used syringes and needles, and other materials from the LAFW, minimizing re-entry into the LAFW.
POLICY: General Aseptic Procedures Carried Out in a Containment Aseptic Isolator (CAI)

POLICY NUMBER: CSP2-C

REVISED DATES:
12/30/16, 3/24/17, 4/20/17

ORIGINAL DATE: 07/05/2016

POLICY: Procedures for personnel working in a CAI must be followed to ensure that product sterility is maintained.

DEFINITION: Compounding Aseptic Isolator (CAI): A form of isolator specifically designed for compounding 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 should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum). CAIs are used to protect the drug and solution from the compounding environment and may not be used to mix hazardous drugs as they do not afford the compounding environment or compounding staff any measure of protection. As used by Consonus, the term CAI only applies to those that are able to meet ISO 5 standards even when set up in a non-certified room and when operated in the absence of Personal Protective Equipment (other than the sleeves/gloves attached to the CAI).

GENERAL PROCEDURES:

• Before beginning work, scrub according to Consonus standards. Note that a second pair of gloves will be used over gloves attached to the gauntlet sleeves.
• Adjust height of the unit
• The blower shall be operated continuously if the CAI is used on a daily basis. If the unit is turned off for any reason, it must run continuously for 10 minutes after cleaning to filter the air inside the cabinet numerous times so an ISO Class 5 condition is met.
• The entire inside surface of the CAI, including the filter grill (which protects the HEPA filter itself), shall be cleaned/disinfected with a non-linting wipe saturated with PeridoxRTU. Subsequent cleaning/disinfecting will be accomplished with sterile 70% isopropyl alcohol. If there is any loose material or remnants of a spill, pre-clean the area with a non-linting wipe saturated with sterile water for irrigation. Cleaning/disinfecting shall be done prior to use, every 30 minutes during use and anytime there is a spill.
• Do not spray disinfectant solutions at or on the filters or filter grills.
• Any spills shall be absorbed immediately and the area washed with sterile water for irrigation followed by disinfec tant on a non-linting wipe.
• Before placing items in the airlock area, all supplies shall be removed from their outer cartons, boxes, etc. then wiped down with a non-linting wipe saturated with PeridoxRTU.
• Each vial or ampule to be placed in the CAI shall be cleaned by wiping the outer surface with sterile 70% isopropyl alcohol.
• It is not necessary to wipe down products that are removed from an outer-wrap as they are being introduced into the CAI. Examples are bags of IV solution or syringes.
• Only items that are necessary for the immediate preparation shall be placed in the CAI.
• Push the Purge airlock button again (red light will illuminate)
• When red light is off open the inner door and slide the tray inside the work area
• Remove items from the tray and slide the tray inside the airlock area. Close and latch inner door
• Begin Preparations
• Organize all materials to enhance efficiency of work and to maintain integrity of the critical sites for all material, in accordance with the flow of air (Top to Bottom).
• All work must be performed at least six inches within the CAI from all edges.
• Do not touch or place any item upstream of the critical sites of any item, even with gloved hands, as the hands are not sterile. Note that the airflow in the CAI is vertical, unlike that of a laminar flow hood or workbench. This will require different hand placement curing compounding.
• Periodically use sterile 70% isopropyl alcohol on the surface of the gloved hands, as necessary.
• Immediately before opening, the necks of all ampules shall be cleaned with a non-linting wipe saturated with sterile 70% alcohol.
• All rubber stoppers of vials and other containers should be cleaned, using a non-linting wipe saturated with sterile 70% alcohol, prior to opening or penetrating with a needle. Allow at least 10 seconds for the alcohol to have its disinfecting effect and to evaporate.
• Filter all solutions removed from glass ampules to remove possible glass particles prior to adding to a vehicle or to another component. A filter needle or filter straw can be used for this purpose.
• During addition of drugs, solutions should be gently swirled or rotated to speed mixing and minimize the occurrence of an incompatibility.
• During preparation, constantly observe the preparation for the formation of a precipitate, cloudiness, gas bubbles, etc.
• After completion, observe the final product for any evidence of incompatibility and visually inspect the container for particulate matter using a lighted white and/or black background.
• Place a tamper-evident cap or seal on the finished product, as appropriate.
• Wipe down all items placed in the air lock using 70% sterile Alcohol, close door
• Discard waste and sharps
• Place completed items in the air lock and remove from outer door.
• Remove the product from the CAI, label the product, and place an overwrap, if required and seal. If the overwrap is opaque, it may be advisable to add a duplicate label on the overwrap.
• Remove all empty containers, used syringes and needles, and other materials from the CAI using the waste and sharps dispensers located within the CAI.

PROCEDURE:

Changing the sleeves and attaching the Gloves

Sleeves are to be changed every 6 months and as needed. Gloves are to be changed daily and as needed.

• Wrap the sleeve around the glove port pulling it to the outer edge.
- Place the "O" ring clamps on the glove ports attaching the sleeve to the glove port on the CAI
- Pull the sleeve out of the CAI so it is in-side-out
- Fold back the sleeve covering the "GOS" ring
- Place an "O" ring clamp covering the sleeve attaching the "GOS" to the sleeve.
- Place the non-latex glove into the sleeve with the thumb facing the upward position
- Roll the cuff of the glove over the sleeve and the "GOS"
- Place the 2nd "O" ring clamp over the glove cuff attaching it to the sleeve and the "GOS"
- Push the sleeve back into the CAI and check for rips or tears so containment is not broken.

PROCEDURE:

Daily cleaning

- Inspect the pre-filter in the frame on top of the unit
- Turn on main blower if not already on. Low pressure alarm will sound until adequate pressure is achieved. (Gloves will push slightly out of the area) – Positive Pressure
- Turn on the work area light and inspect the work area.
- Inspect all gloves and sleeves for tears or holes.
- Clean inside of airlock area using Peridox.
- Place waste and sharps containers in designed areas (attach if needed)
- Clean inside work area from back to front and top to bottom with Peridox
- Clean inside of airlock area using 70% Sterile Alcohol
- Clean inside work area from back to front and top to bottom with 70% Sterile Alcohol
- Push airlock purge button to purge the air in the airlock chamber. Red light will illuminate
- Allow 10 minutes to pass after cleaning to ensure all air inside the work area has been filtered if the unit was off or the cabinet front was opened

PROCEDURE:

Initial cleaning. The daily cleaning procedure above will be completed 3 times in succession prior to initial operation of the CAI, if it is moved and if it has undergone maintenance procedures. Triple cleaning may also be necessary upon failure of any viable microorganism testing.

PROCEDURE:

Changing the gloves that are attached to the sleeves without breaking containment

- Pull out the sleeve out of the CAI so it is in-side-out
- Remove the "O" ring and pull back the cuff to the edge of the "GOS"
- Place the new glove inside the existing glove with the thumb facing in the upward position
- Stretch the new gloves cuff over the old glove to the middle of the "GOS" and place an "O" ring to secure the new glove on the "GOS"
• Push the sleeve back into the CAI
• With the other hand remove the old glove and push the new glove through the sleeve.
• Discard the old glove via the trash port
• Prior to any manipulations within the CAI, don a second set of gloves per procedure.

PROCEDURE:

Changing the sleeves without breaking containment

• Pull out the sleeve out of the CAI so it is in-side-out
• Remove the "O" ring and pull the sleeve to the outer edge of the sleeve port
• Place the new sleeve inside the existing sleeve.
• Stretch the new sleeve over the old sleeve to the outer edge and place an "O" ring to secure
• Push the sleeve back into the CAI
• With the other hand remove the old sleeve and push through the new sleeve.

PROCEDURE:

Changing the prefilter

• The CAI prefilter will be changed quarterly with documentation in Simplifi 797.
POLICY: Prior to entering the buffer area, personnel will don proper attire and will use proper hand-washing procedures. Note that those mixing in a CAI are required to follow the procedure below, but not the garbing portion.

PROCEDURE:
- A hand washing sink with hot and cold running water shall be inside the anteroom in the sterile compounding area. If using a Compounding Aseptic Isolator (CAI), the sink shall be located near the CAI.
- The careful cleansing of hands and arms and the correct donning of PPE (Personal Protective Equipment) by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate of $10^6$ or more per hour, and those skin particles are laden with microorganisms. When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in the cleanroom until their conditions are remedied.
- Before entering the buffer area or approaching the CAI, compounding personnel shall remove all personal electronics such as earbuds and music players, all personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.
- Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless cleaning surfaces above eye level.
- Donning of shoe covers will occur such that the process begins on the "dirty" side of the anteroom line of demarcation and each foot is placed on the "clean" side as soon as the shoe cover is on. Removal of shoe covers is a reverse of this procedure.
- After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by
vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either non-antimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint free disposable towels or an electronic hand dryer.

- After completion of hand washing, a non-shedding gown with sleeves that fit snugly around the wrists and is enclosed at the neck is donned. Sleeves must be long enough that wrists will not be exposed while in the buffer area. Gowns with a thumb hole may be used (or a thumb hole cut) to keep the sleeve extended to the wrist. Gowns designated for buffer area use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.

- Once inside the buffer area or ready to insert hands into CAI sleeves (and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

- If mixing in a CAI, the existing gloves which are attached to the sleeves will be disinfected with sterile isopropyl alcohol, then a new set of sterile gloves will be donned over the gloves which are attached to the sleeves prior to commencing cleaning or mixing. At the completion of use of the CAI, this second set of gloves will be removed.

- Since sterile and sanitized gloves do not remain sterile and clean during compounding activities due to contact with non-sterile surfaces and air, personnel shall intermittently re-sanitize their gloves.

- Should the operator find it necessary to leave the room, it is preferred to don fresh cleanroom garb upon reentry to the buffer or clean area, although the same gown can be worn if during the same work shift and hung in the ante-room between uses.
POLICY: High Risk Medications

POLICY NUMBER: CSP2-E

REVISED DATES:
11/5/14

ORIGINAL DATE:
03/11/2014

POLICY: The pharmacy will consider the following as high risk medications (not high risk compounding) and may require extra levels of review prior to dispensing:

- Concentrated electrolytes with particular emphasis on concentrated KCl
- Opiates and narcotics
- Heparin
- Insulin
- Cardiac Drugs/Antihypertensives
- Oncology Drugs – no sterile compounding is performed on oncology medications or others considered hazardous per NIOSH at Consonus Pharmacy

PROCEDURE:

- Although Consonus Pharmacy Services provides careful review of ALL medications dispensed to our patients in order to minimize medication errors, these high-risk medications warrant special attention based on national documentation of reported serious sentinel events.

- It is Consonus policy that no emergency box contains concentrated potassium chloride (KCl), but rather a large volume premixed solution containing KCL or a minibag of at least 100ml containing this electrolyte. If a facility insists on having concentrated KCl included with the emergency medications, the pharmacy will follow the following requirements.
  - Every effort must be made to convince nursing management at that facility of the documented evidence of fatalities due to the incorrect use of KCL on patient care units. Alternatives such as those discussed above might be suggested as substitutes, which would allow a patient to receive the needed medication safely.
  - If the facility still DEMANDS to have the concentrated form of this drug, a letter outlining the increased liability to the facility and the patients should be drafted and provided to the Director of Nursing and the Administrator as well as the Medical Director. The letter should contain signature lines for all three and copies should then be provided to these individuals with the original retained on file in the pharmacy.
  - Unique storage methods for this drug must then be implemented. Some suggestions include: (1) allowing only one vial of concentrated KCL to be in any emergency IV box, (2) packaging the vial in a heat sealed amber bag with warning labels such as “Must Be Diluted” affixed to the bag, (3) storing the medication in the heat sealed amber bag mentioned above in the narcotic drawer and requiring two nurses to sign when the drug is removed to be administered to a patient.
  - Education regarding infusion parameters must be provided to the facility and this education documented (e.g. inservice sign-in log, individual nurse letters provided at the inservice, etc.). Please remember the following key parameters regarding KCL infusion and at least these MUST be covered in the education provided:
• Administration of potassium chloride via the IV route should ONLY occur when oral replacement is not feasible or when hypokalemia is life threatening.
• Concentrated potassium chloride MUST ALWAYS BE DILUTED.
• If a patient’s serum potassium is below 2 mEq/L, this individual is obviously seriously ill and should be considered for care in an acute care setting. However, if care is not readily available for distance issues, etc., the pharmacy MUST be notified immediately and a safe concentration and infusion rate determined with the pharmacist communicating directly with the patient’s attending physician. If the physician is not the facility medical director and if failure to agree upon a safe dose occurs, the medical director must be notified immediately to provide counsel. If the patient’s physician is the medical director and disagreement occurs between this individual and the pharmacist, the pharmacist will notify the facility administrator and director of nursing to provide counsel as well as his or her immediate pharmacy supervisor. Please remember that any pharmacist who is uncomfortable with a KCl dose is obligated to inform the appropriate individuals of this improper dosing and document his or her conversation clearly indicating to whom he or she has expressed concern.
• If a patient’s serum potassium is above 2 mEq/L, the maximum recommended infusion rate is 10 mEq/hour; the maximum recommended infusion concentration is 40 mEq/liter (in some instances up to 80mEq of KCl has been administered via a central venous catheter only); and the maximum 24-hour dose in the elderly should not exceed 100 mEq’s (in rare instances, up to 120mEq has been administered safely). Any orders for concentrations of KCl above 40 mEq/liter or for an amount greater than 100 mEq to be administered in a 24-hour period must be validated by two pharmacists within the organization and signed by the Director of Pharmacy. In addition, the director of nursing and the medical director at the facility must be informed of the potential for harm in administering KCl above recommend dosage guidelines.

• Particular care must be exercised when the administration of opiate, insulin, narcotic, cardiac drugs like dobutamine, and heparin infusions are provided.
  o Prior to dispensing, calculations involving these drugs, must be checked by two pharmacists, if available.
    • If a pharmacist and a senior technician are on duty, these two individuals may constitute the double pharmacist check process.
    • If the infusion is prepared when only a pharmacist is in the building, all calculations must be well-documented and a self double-check performed with a note in the appropriate area that no additional person was available to provide the double-check.
  o When possible, the infusion device settings will be validated by two pharmacy staff, or a strong suggestion made to the nursing facility that two nurses check the program prior to administration of the drug.
  o Insulin or heparin orders with the abbreviation 'U' rather than the entire word, "units" being provided will be returned to the triage staff for review. An order written using the abbreviation rather than the entire word, "units" will only be accepted in an extreme emergency situation and will be immediately sent for clarification before repeated doses can be administered.
  o The names of nursing facilities which are identified as "repeat offenders" in inappropriately abbreviating instructions for these high risk medications will be forwarded to the consultant pharmacist so that during the next consulting visit, the pharmacist can provide additional reinforcement of the danger in this process.
To minimize the possibility of an error occurring, due to a misunderstanding of the label, all insulin and heparin labels must have the word "units" spelled out completely.

Dosing will be carefully reviewed on oral cardiac drugs, antihypertensives, and other medications with a narrow therapeutic index such as digoxin and phenytoin. Any questions by the dispensing pharmacist regarding these oral medications will be immediately reviewed with the nursing facility and if unresolved, will be discussed with the ordering physician prior to dispensing.
POLICY: Final Product Verification of Compounded Sterile Preparations

POLICY NUMBER: CSP2-F

POLICY: This policy will outline final product verification of compounded sterile preparations. Pharmacists providing any product verification for compounded sterile preparations will have completed all competencies for sterile compounding per the Consonus CSP P&P Manual.

PROCEDURE:

- The aseptic compounding process shall be built on the integration of systematic process controls rather than sole reliance on end product testing.
- The end product shall be evaluated by the verifying pharmacist for:
  - Container integrity
  - Solution cloudiness
  - Phase separation
  - Particulates in solution
  - Appropriate solution color
  - Solution volume
- The verifying pharmacist shall monitor compounding personnel for appropriate aseptic compounding techniques.
- Where possible, while swirling, the end product shall be inspected against lighted white or black background, or both, for evidence of visible particulates or other foreign matter.
- All compounded sterile preparations that are intended to be solutions shall be visually examined for the presence of particulate matter, and not dispensed for administration if such matter is present.
- The verifying pharmacist shall also make the following assessments when inspecting the final CSP:
  - Labeling of product meets company requirements (as described in Labeling policy and procedure)
  - Beyond use dating meets company requirements (as described in Beyond Use Dating policy and procedure)
  - Drug products or ingredients used to prepare the CSP are of correct identity and quantity or volume in accordance with the prescriber’s orders and the compounding record
    - For those ingredients or drug products that are measured with a syringe and are not fully used, the syringe used to measure the product shall be quarantined with the final product until final product verification is complete.
  - Calculations were correctly performed.
  - Ensuring that the drug, dose, and dosage form ordered are appropriate for the patient.
- In case of any unusual observances, the compounded sterile preparation shall be quarantined and reported to the pharmacist-in-charge.
• The pharmacist-in-charge must make a determination to the integrity and quality of the preparation.
• If necessary, the complete disposal of the preparation must be done according to proper procedure and logged accordingly.
• Once the final verification is complete, the pharmacist will assure that the product is stored appropriately prior to delivery.
POLICY: To ensure that compounded sterile preparations are delivered to the patient in a manner such that the product integrity, quality, safety, and efficacy is not compromised and in a fashion that ensures the patient receives the product in a timely manner.

PROCEDURE:

- Drivers (couriers) will receive instruction and evaluations before delivering medication or equipment.
- The personnel responsible for delivery of compounded sterile preparations shall be able to assure that the product is delivered properly to the patient or health care facility without compromising the product integrity, quality, safety, and efficacy.
- The importance of maintaining structural integrity and appropriate temperature conditions for compounded sterile preparations shall be emphasized to delivery personnel as part of their routine training.
- Compounded sterile preparations requiring refrigeration shall be stored in the refrigerator in the pharmacy area until final pharmacist verification. They will then be kept in the refrigerator until just prior to packaging for delivery. The total elapsed time the product may remain unrefrigerated shall not exceed one hour.
- Compounded sterile preparations shall be placed in a plastic zip-locked bag for added protection.
- This bag shall be sealed in an appropriately sized bubble-wrap bag.
- Bubble wrapped container shall be placed in the smallest tote possible.
- Temperature control
  - Products labeled as “refrigerate” shall be packed with ice packs.
  - The number and size of ice packs shall be determined by the size of the tote used and the estimated time in transit, as well as anticipated temperature of the truck during transit time.
- Errors in delivery shall be linked to the company’s internal and external error tracking mechanisms and addressed by the Delivery Manager and the pharmacist-in-charge.
- Drivers will be instructed to refer all clinical questions, or other questions about equipment or procedure that they have not been clearly instructed about to the pharmacy.
- When necessary drivers will only have access to specific non-licensed areas of the building after the licensed area of the pharmacy has been closed.
- All drivers will be instructed in:
  - Appropriate handling of returns (e.g. medications, infusion pumps, etc.)
  - Appropriate handling of CII medications (e.g. delivery and returns)
  - Personal safety of the driver and safety supplies carried (e.g. fire extinguishers, flares, chemotherapy spill kits, etc.).
  - Locking of delivery vehicle
Communicating with the pharmacy while on the delivery route
The driver will understand the importance of maintaining patient and/or resident confidentiality and respecting patient and/or facility property.
The driver must have a signed delivery ticket or manifest by the facility.
Courier services will return delivery validations in timely manner.
Medications needing refrigeration will receive appropriate attention during the shipping process.

- When using a “tote exchange” system, final destination verification will take place in the pharmacy prior to delivery. This will be accomplished via barcode scanning of the order and tote.
- STAT deliveries will be coordinated between triage, PV1 pharmacist, and the delivery department.
- Routine delivery routes and times will be determined by the Delivery Supervisor, Director of Pharmacy, and General Manager.
- Courier service requirements:
  - Management of the courier service must validate that:
    - A mechanism is in place for validating that the right medication has been delivered to the right facility and the mechanism allows for timely communication of this process to the pharmacy.
    - Drivers meet all licensing requirements (current driver’s license).
    - Drivers have been oriented and are competent to make health care deliveries.
    - Others per local process requirements.
    - Drivers will maintain professional appearance and demeanor at all times.
POLICY: All patients will have pharmaceuticals and supplies dispensed safely and accurately by a pharmacist.

PROCEDURE:

- **Routine Dispensing**
  - No sterile product will be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet the criteria specified in these Policies and Procedures.
  - All pharmaceutical products will be dispensed in accordance with a prescription or physician's order from an appropriately licensed prescriber.
  - All compounded sterile products will be prepared in accordance with a written compounding worksheet which will be prepared prior to initiating the compounding of the product.
    - The compounding worksheet will be approved by a pharmacist.
    - Each time a compound is prepared, the ingredients, NDC numbers, quantities, lot numbers and expiration dates as well as appropriate mixing and storage instructions are recorded on a Compounding Record. This record will be initialed by the individuals performing the calculations, doing the compounding and performing the final review (only a pharmacist can perform final review).
  - The prescription will be reviewed and verified with the physician or his or her agent prior to dispensing when necessary.
  - A copy of the prescription will be kept in the patient record, electronically, or in a paper file per state board of pharmacy regulations.
  - All prescription pharmaceuticals will be labeled in accordance with the pharmacy policy and procedure and state board regulations.
  - A delivery ticket will be initiated for each patient or nursing facility delivery according to the pharmacy policy and procedure. The delivery ticket will serve as an additional dispensing record for all pharmaceuticals and supplies in conjunction with the pharmacy operating system reports.
  - Pharmaceuticals and/or supplies may be selected for packaging by either a nurse, pharmacist, or support personnel (e.g. pharmacy technician) as designated by the Director of Pharmacy and placed in a designated area. If pharmaceuticals were selected by personnel other than a pharmacist, they must be checked by a pharmacist prior to dispensing. Supplies should also be checked by a process designated by the Director of Pharmacy.
  - The pharmaceuticals and supplies will be packaged for delivery/shipment as per pharmacy policy and procedure

- **Emergency Dispensing**
- A pharmacist will be on-call 24 hours/day, 7 days/week, as per the pharmacy policy to dispense pharmaceuticals in the event of an emergency.
- When the need arises, the pharmacist will either open the pharmacy or use one of the contracted first-dose pharmacies to perform compounding and/or dispensing functions. If the need is in a nursing facility, instruct the facility staff to use the emergency dispensing system provided by the pharmacy for use in that particular facility.
- If the on-call pharmacist is unable to meet his/her commitment (e.g. illness), it is the responsibility of that individual to arrange for a substitute pharmacist to provide on-call services.
- Proper documentation and accountability of pharmaceutical dispensing will occur in the emergency process as well as in the routine dispensing procedures described above.
POLICY: Consonus collaborates with all long term care facility staff to help assure that medications are administered safely and accurately.

Procedure:
- By contractual agreement, the pharmacy assists the nursing facility in identifying nursing staff competency to administer both non-intravenous and intravenous medications. Competency may be evaluated by assessment after infusion therapy classes for the staff or by doing medication-pass observations when either the pharmacist, nurse consultant, or the facility nursing administration identifies such a need.
- Current medication reference materials will be suggested to the facility outlining proper medication administration.
- Any possible discrepancies in medication administration should be reviewed by facility nursing administration, internal clinical pharmacy staff, and the consultant pharmacist or nurse as appropriate (e.g. PRN medication frequency and need, administration of medication to the wrong resident, prescription inconsistencies, interruptions in administration of life-sustaining medications e.g. total parenteral nutrition therapy, oral cardiac medications, etc.).
- The pharmacy will take a responsible role in helping the nurse assure the “five rights” of medication administration:
  - Right patient
  - Right drug
  - Right dose
  - Right route
  - Right time
POLICY: Consonus Pharmacy does not perform non-sterile to sterile compounding.
POLICY: Beyond Use Dating (BUD)

DISCUSSION

• The BUD is the date after which a compounded preparation shall not be used and is determined from the date when the preparation is compounded. Because compounded preparations are intended for administration immediately or following short-term storage, their BUDs are assigned on the basis of criteria different from those applied to assigning expiration dates to manufactured drug products. The BUD refers to the time from product preparation to the initiation of infusion on the patient and does not include the timespan during infusion.

PROCEDURE:

• BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:
  o The nature of the drug and its degradation mechanism
  o The dosage form and its components
  o The potential for microbial proliferation in the preparation
  o The container in which it is packaged
  o The expected storage conditions
  o The intended duration of therapy

• BUDs for compounded preparations are usually assigned on the basis of professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations.

• The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction.

• Drug hydrolysis rates increase exponentially with arithmetic temperature increase.

• Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs.

• When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40 degrees for more than 4 hours, such CSPs must be discarded unless direct assay data or appropriate documentation confirms their continued stability.
Because of the uncertainties of determining BUDs, in the absence of data for the specific product in question, USP 797 limits will be followed. USP 797 assigns the following definitions and maximum allowable beyond use dates.

- **Low Risk CSP:** Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container. In the absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at -25 degrees to -10 degrees or colder.

- **Medium Risk CSP:** Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs. In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature and 45 days in solid frozen state at -25 degrees to -10 degrees or colder.

Note that the above USP 797 limits are relative to sterility only. If an item is not stable for that long, it is Consonus policy to use the shorter of the sterility and stability timespans as the BUD. BUDs based on stability will be the shorter of the a) expiration date of any component of the admixture or b) the date obtained by consulting a reference such as Trissel's *Handbook on Injectable Drugs*. 
POLICY: Unused supplies, medications and returns will be properly disposed of.

PROCEDURE:
- The following medication containers and supplies will be disposed of in the pharmacy garbage containers found in the appropriate area:
  - Used medication vials, if empty
  - Used syringes (no needle attached)
  - Packaging materials

- The following items will be disposed of in the sharps containers found in the appropriate area. Sharps containers will be picked up for disposal by a licensed disposal company.
  - Used medication ampules
  - Any glass fragments from broken vials or ampules
  - Used needles (note that these are needles used for compounding sterile products, not needles used to administer medications)

- Compounded sterile products that have been refused or returned to the pharmacy are not typically eligible for credit and so cannot be re-dispensed.
  - If disposed of, they will be opened and poured down the pharmacy sink (fluids/electrolytes) or placed in a biohazard disposal container to be picked up by a licensed disposal company (bags or vials containing medications).
  - If they meet requirements for re-use, they will be re-labeled and re-dispensed.
POLICY: Use of Single Dose and Multidose Containers

POLICY NUMBER: CSP2-M

REVISED DATES: 6/28/16, 5/8/18
ORIGINAL DATE: 2/18/2015

POLICY: Single dose and multidose containers will be stored properly and discarded in keeping with industry standards.

PROCEDURE:
- Single dose containers will be used in the laminar airflow hood or CAI (Compounding Aseptic Isolator) in keeping with the following:
  - Must be used or discarded within 6 hours of opening if a vial or within 6 hours of puncturing the septum if a bag (usually sterile water used for reconstituting a vial of drug)
  - For immediate use only, if an ampule
  - Will not be shared between staff unless labeled with date and time opened and initials of staff person originally opening

- Multidose containers (usually vials) will be used in the laminar airflow hood or CAI in keeping with the following:
  - Will be labeled with date and time opened and initials of person opening
  - Will be stored at refrigerator temperature between uses (unless contraindicated)
  - Will be discarded within 28 days of opening unless manufacturer recommends a shorter expiration date
POLICY: Certain medications may be prepared at the nursing facility when required, due to stability concerns or emergent need for the medication. Preparation at the facility is discouraged; whenever possible, sterile compounds will be prepared in the cleanroom environment at the pharmacy.

PROCEDURE:
- When a medication lacks the stability necessary for the time involved in transportation or is needed more quickly than it can be provided by the Consonus location serving the patient, the following concerns will be considered:
  - Medications prepared at the nursing facility are considered "Immediate Use", due to the lack of a cleanroom environment.
  - Immediate use compounding is to be used only in situations such as stability concerns or need for immediate dosing from an emergency supply.
  - Immediate use compounding will only be performed if the product can be made involving a maximum of 3 commercially manufactured packages of sterile products and not more than 2 entries into any one container.
- The nurse performing the immediate use compounding will:
  - Follow aseptic technique
  - Either administer or witness the administration of the product his/herself or will label it with the name of the patient, the ingredients, the name of the person performing the compounding and the exact 1 hour beyond use date and time.
  - Assure that the administration of the product is either begun before the beyond use date/time or the product is appropriately disposed of.
POLICY: Medication Storage

POLICY NUMBER: CSP3-A

REVISED DATES:

ORIIGINAL DATE: 3/5/2014

POLICY: All medications are stored by a system that will reduce the potential for errors, allow for the appropriate stability requirements of the product to be maintained, and protect staff.

PROCEDURE:
The Director of Pharmacy will establish methods for maintaining and monitoring for:

- Sanitation
- Temperature (refer to Policy CSP3-E and F) for:
  - medication refrigerators
  - licensed areas in which drugs are stored
  - warehouse areas if enterals are stored there
- Light
- Ventilation
- Segregation of products when necessary
- Safety (refer to Policy #064)
- Security (refer to Policy #006)
- Special procedures for storing chemotherapy drugs (refer to Policy #061) and investigational drugs (refer to Policy #020). Note that Consonus does not do sterile compounding of any chemotherapy drugs.
- Regulations developed by the state board of pharmacy, local health department, DEA, and OSHA
- The Assisted Living and Skilled Nursing Facility policy and procedures will have a process that describes medication storage requirements at the facilities.
POLICY: The hood, buffer area and ante-room or the CAI shall be properly cleaned/disinfected and maintained to ensure that compounds prepared in the aseptic environment are not contaminated or adulterated in any manner. Cleaning and maintenance shall follow the following schedule and procedures shall be documented as outlined below.

PROCEDURE (Cleanroom):
- Cleaning/disinfecting the LAFW (Laminar Air Flow Workbench)
  - The horizontal laminar flow hood should be left operating continuously. If the hood is turned off for some reason, it must run for 30 minutes to reestablish laminar air flow and then be cleaned/disinfected prior to use. Only one person should enter the buffer area to turn on and clean the hood.
  - The LAFW will be cleaned/disinfected once daily using PeridoxRTU. When using PeridoxRTU, allow a minimum wet contact time of 3 minutes. Other cleanings will be accomplished with sterile 70% IPA. The minimum wet contact time for sterile IPA is 10 seconds.
  - Before use, all interior working surfaces of the laminar flow hood should be cleaned/disinfected from back to front, starting with the filter grille (never spray anything towards the filter) and moving away from the HEPA filter.
    - If there is any loose material or residue from spills, using lint-free sterile cleaning wipe, clean the hood with sterile water for irrigation (bar, sides, base)
    - Using a new lint-free sterile cleaning wipe, clean/disinfect the hood with Sterile 70% isopropyl alcohol or PeridoxRTU (bar, sides, base)
  - Hoods should be cleaned at the beginning of each compounding activity session, every 30 minutes during compounding operations, after any spills and as needed throughout the shift.
  - Note that it is not necessary to clean the LAFW on days when it is not used.
- Cleaning/disinfecting the buffer or clean area and ante-room
  - Frequency:
    - Daily (on all days that sterile compounding is performed)
    - Floors in all buffer areas and ante-rooms
    - Ante-room sink
    - Counters and other work surfaces in all buffer areas and ante-rooms
    - Seating surfaces, if any
  - All cleaning shall be documented in Simplifi 797 with the date of cleaning and type of germicide used.
• Tear off the top sheet of tacky mat (located outside door from pharmacy into anteroom), if a tacky mat is used

  Monthly
  • Staff performing cleaning duties will always wear goggles or safety glasses when cleaning above eye level.
  • Any hard surfaces such as waste containers, legs and supports for work surfaces, ladders or stools
  • Ante-room area – walls, ceilings and storage shelving
  • Buffer or clean area – walls, ceilings and shelving
  • Replace tacky mat pad, if pharmacy uses one (located outside door from pharmacy into anteroom)

  • At least semi-annually inspect or replace any HEPA pre-filters
  • Clean/disinfect as needed in cases of spills or visible soiling.
  • All cleaning shall be documented in Simplifi 797 with the date of cleaning and type of germicide used.

  O Steps to cleaning.
  • Clean TPN compounding device per TPN maintenance policy and procedure.
  • A wash with sterile water should precede disinfection in cases of loose material or residue from a spill.
  • A non-film forming disinfectant (Peridox RTU) and tightly woven low particle shedding wipe or designated mop shall be used. Allow a minimum wet contact time of 3 minutes, then allow to dry.

  NOTE: Cleaning of the buffer area and ante-room shall be done with a germicide (Peridox).

  • Remove all waste container liners daily.
  • Continue by cleaning the buffer or clean area counter tops, stainless steel cart tops and any other work surfaces after each day's use.
  • Finish daily routine by cleaning floors after each day's use.
  • Mopping shall be done carefully to maximize cleansing. Clean the floor surface with water and/or detergent prior to disinfectant as needed for soiling.

  NOTE: Allowing the surface to stay wet for a short time helps solubilize dried material. Also, mop the buffer or clean area first, and then proceed to the anteroom area. Never perform cleaning processes when aseptic operations are in progress.

  • The mop utilized for cleaning the buffer or clean area floor must be used for cleaning this area and the anteroom area only. This mop shall never be used for cleaning general pharmacy areas.
  • Begin cleaning the buffer or clean area floor at the corner farthest from the entrance and slowly work toward the entrance.
  • If cleaning tools are reused, their cleanliness shall be maintained by thorough rinsing and sanitization after use or by replacing disposable contact areas and by storing in a clean environment between uses.
NOTE: Ceilings, then storage shelves, walls and all other surfaces (table legs, chair/stool legs, table legs, etc.) shall be cleaned before floors as part of the monthly routine.

- After cleaning and maintenance is complete, all steps shall be documented in Simplifi 797.
- Simplifi 797 records will be retained for at least 3 years.

PROCEDURE (CAI):

- Cleaning/disinfecting inside the CAI (Compounding Aseptic Isolator)
  - The CAI should be left operating continuously. If the CAI is turned off for some reason, it must run for 10 minutes to reestablish laminar air flow and then be cleaned prior to use.
  - The CAI will be cleaned/disinfected once daily (all days on which the airlock door is opened) using PeridoxRTU. When using PeridoxRTU, allow a minimum wet contact time of 3 minutes. Other cleanings will be accomplished with sterile 70% IPA. The minimum wet contact time for sterile IPA is 10 seconds.
  - Before use, all interior working surfaces of CAI should be cleaned from top to bottom and back to front, starting with the filter grille (never spray anything towards the filter) and moving away from the HEPA filter.
    - If there is any loose material or residue from spills, using lint-free sterile cleaning wipe, clean the hood with sterile water for irrigation (bar, sides, base)
    - Using a new lint-free sterile cleaning wipe, clean the hood with Sterile 70% isopropyl alcohol (bar, sides, base)
  - CAI's should be cleaned at the beginning of each compounding activity session, every 30 minutes during compounding operations, after any spills and as needed throughout the shift.
  - For further detail, see CSP2-C General Aseptic Technique-CAI

- Cleaning around the exterior of the CAI (Compounding Aseptic Isolator)
  - Frequency:
    - Daily (on all days that sterile compounding is performed)
      - Floors in close proximity (10 foot perimeter, as possible) to CAI. Move CAI to clean floor underneath
      - Counters and other work surfaces used for sterile compounding components or finished products and in close proximity to CAI
      - Seating surfaces, if any
    - All cleaning shall be documented in Simplifi 797 with the date of cleaning and type of germicide used (Peridox).

- Cleaning the exterior of the CAI (Compounding Aseptic Isolator)
  - The CAI should be left operating continuously. If the CAI is turned off for some reason, it must run for 10 minutes to reestablish laminar air flow and then be cleaned prior to use.
  - The exterior of the CAI shall be cleaned monthly
    - If there is any loose material or residue from spills, using lint-free sterile cleaning wipe, clean the CAI with sterile water for irrigation
    - Using a new lint-free sterile cleaning wipe, clean the CAI with Peridox
  - Be sure to raise the CAI to expose the leg extensions prior to cleaning the exterior
POLICY: Environmental Conditions and Monitoring of the Aseptic Compounding Area

POLICY NUMBER: CSP3-C

REVISED DATES: 11/5/14, 2/18/15, 11/18/15, 6/28/16, 12/30/16, 3/24/17, 6/30/17, 5/17/18

ORIGINAL DATE: 3/28/2014

POLICY: All sterile compounding shall occur in an ISO 5 certified area. This shall be accomplished through the use of a laminar air flow hood placed in an ISO 7 certified area which shall be connected to an ISO 8 certified anteroom or by use of a Compounding Aseptic Isolator (CAI) certified as ISO 5. All ISO certified areas shall be evaluated every 6 months and certified by a reputable company. Additionally, all ISO certified areas will be evaluated and re-certified whenever changes are made to cleanroom configuration or there are repairs to the CAI, LAFW or ceiling mounted HEPA filters. The pharmacy director and cleanroom certification agency will jointly develop a plan for dynamic sampling for particulates in the air and for dynamic sampling of the air and surfaces for any viable organisms. In addition, pressure differentials shall be monitored daily, as appropriate.

PROCEDURE:

• Smoke Studies
  - A qualified environmental engineer or personnel trained in using a smoke generator and in concepts of laminar airflow shall test the critical area (ISO 5 LAFW or CAI) at least once and anytime that the area is re-configured or there is a break in process or a reason to believe that the CAI, LAFW or other cleanroom area air-purification equipment has not been functioning properly.
  - Testing will be completed in a dynamic environment (while personnel are in the area to simulate the airflow at the critical area found during compounding operations).
  - The test results shall be video recorded and documented in the aseptic compounding area cleanroom certification records.

• Particulates
  - A qualified environmental engineer or personnel trained in using a particulate matter counter shall test all ISO certified areas at regularly scheduled intervals, at least every six months and anytime that the area is re-configured or there is a break in process or a reason to believe that the CAI, LAFW or other cleanroom area air-purification equipment has not been functioning properly.
  - Testing will be completed in a dynamic environment (while personnel are in the area to simulate the particulate load found during compounding operations).
  - The test results shall be recorded in the aseptic compounding area cleanroom certification records and documented in Simplifi 797.

• Viable Organisms
  - A qualified environmental engineer or personnel trained in using appropriate sampling techniques shall test all ISO certified areas at regularly scheduled
intervals, at least every six months and anytime that the area is re-configured or there is a break in process, staff technique, or a reason to believe that the CAI, LAFW or other cleanroom area air-purification equipment has not been functioning properly.

- The testing shall include both airborne (volumetric, using impaction methods with an electronic air sampling device) and surface methods of collection and shall be completed while personnel are in the area (dynamic testing).
- The sampling plan will be agreed upon by the certification company and the Pharmacy Director and will include airborne and surface sampling of all ISO certified areas. Surface sampling will include at least the work surface of the ISO 5 equipment (LAFW or CAI), the prep counter in the ISO 7 area and the sink area in the ISO 8 area.
- The test results shall be recorded in the aseptic compounding area cleanroom certification records and documented in Simplifi 797.

- Pressure differentials
  - The buffer area and ante-room will be equipped with a pressure gauge (or continuously recording pressure monitor) or a velocity meter.
  - The pressure gauges should register a higher pressure (0.02 to 0.05 inches of water) in the buffer area than the ante-room and the ante-room will be at a higher pressure (0.02 to 0.05 inches of water) than the general pharmacy area.
  - Pressure gauges will be checked every shift (at least daily) with the LAFW running and shall be recorded in Simplifi 797 or will be monitored and documented by a continuously recording device.
  - The pressure differential will cause a differential airflow, which shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between the buffer area and ante-room.
  - If using a CAI, the pressure will be monitored by use of the gauge on the unit in the range recommended by the manufacturer, which is 0.090-0.125 ml of water column. The reading will be recorded daily in Simplifi 797.
  - Simplifi 797 records will be retained for at least 3 years.
POLICY: Sterile compounding work areas will be airborne and surface tested under dynamic conditions for viable organisms at least every 6 months and anytime the room is altered, there is major service performed to equipment, or identified problems with end products or staff technique. Compounding personnel will be tested on their garb/glove donning techniques prior to compounding sterile products and at least annually per Consonus P&P. Certain microbial contamination levels will cause actions to assess and eliminate the source of the contamination.

PROCEDURE:

- Viable Organisms From Air Sampling
  - Any airborne organisms found, regardless of cfu count will cause an evaluation of cleaning practices and disinfectant solutions used.
  - If any highly pathogenic organisms are found (gram-negative rods, coagulase positive staph, molds, yeasts) or the number of cfu’s exceeds the action level (see chart below), a competent microbiologist, industrial hygienist or infection control professional will be consulted such that the situation will be immediately remedied.

- Gloved Fingertip Sampling
  - When sampling yields cfu counts above the action level (see chart below), the personnel tested will be re-trained in hand hygiene, garbing, glove and surface disinfection procedures then re-tested prior to them undertaking any sterile compounding procedures.
  - Action levels for gloved fingertip sampling relate to the total number of cfu’s for both hands, not per hand.
  - Note that all 3 tests must show no cfu’s on initial testing.

- Surface Microbial Sampling
  - When sampling yields cfu counts above the action level, a re-evaluation of work processes, cleaning procedures and environmental controls (CAI, LAFW and HEPA filters) will be made. The source of the contamination will be identified, the affected area cleaned and re-sampling performed.

### Action Levels for Microbial Contamination

<table>
<thead>
<tr>
<th>ISO Classification</th>
<th>Airborne Sample cfu's (1000 liters/plate)</th>
<th>Initial Gloved Sample cfu's (total-both hands)</th>
<th>Gloved Sample cfu's after media fill for cert or re-cert (total-both hands)</th>
<th>Surface Sample (cfu/plate or other media)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5</td>
<td>&gt;1</td>
<td>&gt;0</td>
<td>&gt;3</td>
<td>&gt;3</td>
</tr>
<tr>
<td>ISO Class 7</td>
<td>&gt;10</td>
<td>N/A</td>
<td>N/A</td>
<td>&gt;5</td>
</tr>
<tr>
<td>ISO Class 8</td>
<td>&gt;100</td>
<td>N/A</td>
<td>N/A</td>
<td>&gt;100</td>
</tr>
</tbody>
</table>
POLICY: All pharmacy temperatures will be monitored continuously according to the following parameters and recorded:

- Compounding area/cleanroom: from 20°C (68°F) to 25°C (77 °F). Excursions are allowed to a range of 15°C (59°F) to 30°C (86°F). For comfort of compounding staff, it is recommended that the compounding area be maintained at 68 to 75 degrees or cooler (required in California).
- Pharmacy: from 20°C (68°F) to 25°C (77 °F). Excursions are allowed to a range of 15°C (59°F) to 30°C (86°F).
- Warehouse: below 80 degrees Fahrenheit
- All refrigerators: between 2°C (36°F) and 8°C (46°F)
- All freezers (if applicable): -25°C (-13°F) to -10°C (+14°F)
- Incubator (if applicable): 30-35 degrees CENTIGRADE or proper temperature as specified by the manufacturer of the media being incubated.

PROCEDURE:
- The Director of Pharmacy will assign appropriate staff to be responsible for monitoring and recording temperatures.

- If any staff member notes that temperatures fall outside of the above parameters at any time, the Director of Pharmacy will be informed immediately, so that measures can be implemented to bring the affected area back into compliance.

- The Director of Pharmacy will periodically review the tracking records for completeness, proper functioning and to assure that the appropriate storage temperatures are consistently maintained.
POLICY: The drug product refrigerator and freezer temperatures shall be maintained to ensure proper storage of chemicals and end products.

PROCEDURE:

• Refrigerator
  o A refrigerator/freezer thermometer shall be positioned in the middle of one of the drug product refrigerator shelves for each refrigerator.
  o Optimal temperature range for the pharmacy drug product refrigerator is 2 - 8 °C.
  o Continuous readings shall be recorded in the SensoScientific software.
  o If the temperature of the drug product refrigerator falls out of the optimal temperature range, drug products must be removed immediately and placed in an alternate drug products refrigerator.
  o Any products determined to be damaged by the variation in temperature shall be discarded.
  o Calibration:
    ▪ A buffered refrigerator/freezer thermometer shall be positioned in the refrigerator on one of the shelves. Allow one hour for the thermometer to equilibrate with the environment.
    ▪ At the end of the hour, read the thermometer. If the reading does not agree with the temperature desired, adjust the refrigerator temperature control accordingly.
    ▪ Allow one hour for the refrigerator to adjust to the new setting and the thermometer to equilibrate with the environment.
    ▪ At the end of the hour, read the thermometer. Repeat this process until the desired temperature is achieved.

• Freezer
  o A buffered refrigerator/freezer thermometer shall be positioned on one of the drug product freezer shelves for each freezer.
  o Optimal temperature range for the drug product freezer is -25 to -10 °C.
  o Daily readings shall be recorded by the SensoScientific system.
  o If the temperature of the drug product freezer falls out of the optimal temperature range, drug products must be removed immediately and placed in an alternate drug products freezer.
  o Any products determined to be damaged by the variation in temperature shall be discarded.
POLICY: The Company directs the pharmacist-in-charge to establish an up to-date reference library that is readily available for the staff of the aseptic compounding laboratory.

PROCEDURE:
- A compounded sterile preparations reference library will be available in printed or online format for aseptic compounding personnel so they may access critical information in a timely manner.
- The reference library shall include, but not be limited to, the following:
  - Handbook on Injectable Drugs (Trissel)
  - A general pharmacy reference such as Micromedex, Facts and Comparisons or LexiComp
- Other potential references:
  - Principles of Sterile Product Preparation (ASHP)
  - Remington: The Science and Practice of Pharmacy
  - Martindale: The Extra Pharmacopeia
POLICY: Labeling of Compounded Sterile Preparations

POLICY NUMBER: CSP4-A

POLICY: This policy will outline the minimum labeling requirements for a compounded sterile preparation.

PROCEDURE:
- All compounded sterile preparations shall meet labeling requirements set forth by the appropriate State Board of Pharmacy.
- A compounded preparation shall be labeled properly to include:
  - Pharmacy name, address and phone number
  - Patient name
  - Date
  - Identifying number
  - Prescriber name
  - Name, quantity and concentration of all ingredients contained in product, including primary solution
  - Volume
  - Dosing instructions, including rate of infusion if appropriate
  - Route of administration
  - Storage requirements or conditions as applicable
  - Beyond-use date
  - Auxiliary labeling as appropriate. In California, this will include a statement that the prescription has been compounded by the pharmacy
  - Handwritten initials of pharmacist who verified accuracy of the completed product
POLICY: All staff with duties in the cleanroom or using the Compounding Aseptic Isolator (CAI) or those performing final verification will receive training and an assessment of competency prior to performing those duties at Consonus. The assessment will be repeated annually.

PROCEDURE:
There are two potential groups of staff with cleanroom access. Compounding personnel are those that are involved in the aseptic compounding of products within the ISO 5 LAFW or CAI and/or those that perform final verification. These personnel will be trained in all aspects of CSP preparation and in cleanroom/CAI cleaning and maintenance. Only compounding staff will use or clean the LAFW or CAI. Staff or contractors involved only in cleanroom cleaning will undergo training in proper hand hygiene, garbing and cleaning and disinfection procedures and will demonstrate these procedures back to the trainer.

- Prior to performing any infusion compounding or final verification, the technician or pharmacist will summarize their previous training and experience to the Director of Pharmacy or designee. Those with limited background will receive additional training from the Director of Pharmacy, a designee or from an outside source.
- Anyone performing aseptic compounding or final verification will first read and become familiar with this Policy and Procedure Manual.
- Competency of compounding personnel will be assessed initially and annually and will address the following:
  - Aseptic technique.
  - Pharmaceutical calculations and terminology.
  - Sterile product compounding documentation.
  - Quality assurance procedures.
  - Aseptic preparation procedures.
  - Proper gowning and gloving technique.
  - General conduct in the cleanroom area.
  - Cleaning, sanitizing and maintaining the rooms and equipment used.
  - Container, equipment and closure system.
- Competency of compounding personnel will be assessed initially and annually by the following methods:
  - Written testing. The Director of Pharmacy or designee will administer a written test covering a broad selection of infusion basics.
  - Observation of technique. The Director of Pharmacy or designee will observe the staff person while they simulate compounding various admixtures. A check sheet will be used to document the competencies demonstrated.
  - Media Fill procedure.
  - Assessment of processes for donning cleanroom attire and handwashing, including gloved fingertip sampling.
Records of training and demonstrated competence shall be available for each individual and shall be retained for at least 3 years beyond the last day of employment.
POLICY: This policy will outline training requirements, initial and on-going, and process validation for employees engaged in aseptic compounding.

PROCEDURE:

- All personnel who prepare or perform final verification of compounded sterile preparations shall be provided with appropriate training and instruction to perform their tasks prior to participating in the aseptic compounding process.
- Such training shall include, but not necessarily be limited to:
  - Orientation to the aseptic compounding area and equipment in use at the location.
  - Review of company policy and procedures as they apply to sterile compounding.
  - Simplifi 797/Critical Point modules as assigned by the Pharmacist-In-Charge.
- Verification of thorough understanding of USP Chapter <797> and aseptic compounding techniques shall be demonstrated prior to participating in the aseptic compounding process by:
  - Successful completion of written/online quizzes on each training module
  - Successful completion of a practical exam and media-fill test procedure:
    - Appropriate hand-washing, garbing technique (not required for CAI), and cleaning of compounding area
    - Glove fingertip sampling
    - PATT II test (Media Fill)
- Practical exam, media-fill test and glove fingertip sampling procedures shall be repeated annually by each aseptic compounding staff member.
- Employees shall review USP Chapter <797> and company policies and procedures as updates or changes are made to these documents at the prompting of the Pharmacist-In-Charge, whose responsibility it is to be aware of current trends and guidelines in the field.
- Process validation shall be repeated when the quality assurance program yields an unacceptable result and whenever unacceptable techniques are observed.
- Personnel who fail a test, or whose glove tip sampling or media-fill test results in gross microbial colonization must be immediately reinstructed and reevaluated by a designated aseptic compounding technician or pharmacist to assure correction of all aseptic practice deficiencies.
  - In these cases, personnel will also review training documents again, and successfully complete all practical assessments prior to beginning or resuming aseptic compounding duties.
POLICY: Personnel Cleansing and Garbing

POLICY NUMBER: CSP5-C

REVISED DATES: 6/28/16, 12/30/16, 3/24/17, 4/20/17

ORIGINAL DATE: 4/10/2014

POLICY: This policy will outline items that need to be removed prior to engaging in sterile compounding and proper processes for donning protective gear and handwashing.

PROCEDURE - Cleanroom:
- Items that must be removed before entering the ante-room:
  - Personal outer garments (hats, jackets, scarves, etc.),
  - All cosmetics (due to particle shedding),
  - All hand, wrist and other visible jewelry and piercings,
  - Headphones, earbuds, and any personal electronic devices,
  - Artificial nails or extensions are not allowed. Natural nails will be kept short and neatly trimmed
- Before entering the buffer room, personnel shall don protective gear in an order from dirtiest to cleanest:
  - Don dedicated cleanroom shoes or shoe covers
  - Head and facial hair covers (beard covers are required as appropriate)
  - Face masks and eye shields (eye shields are optional unless performing cleaning procedures at or above eye level)
- After the above, but prior to entering the buffer room:
  - Remove debris from under fingernails using a nail cleaner under running warm water
  - Wash hands and forearms to the elbow vigorously for at least 30 seconds using soap and water. The use of scrub brushes is not recommended due to irritation and skin damage
  - Dry thoroughly using a lint free disposable towel or electronic hand dryer
  - Don disposable non-shedding gown designed for buffer area use, enclosed at the neck and with tight-fitting wrists
- Once in the buffer room:
  - Perform aseptic hand cleansing with a waterless alcohol-based surgical hand scrub with persistent activity per manufacturer’s recommendations
  - Allow hands to dry completely
  - Don sterile non-powdered gloves
  - Since gloves will become contaminated while performing compounding, routinely wipe them down or rub with sterile 70% IPA. Gloves should be ones tested for this use
  - Routinely inspect gloves for holes and tears. Replace as necessary
- Upon exiting the buffer area:
  - Remove and discard gloves in the ante-room
  - Remove gown (retain for use later in that shift as appropriate)
  - All other disposable garb shall not be re-used
PROCEDURE – Compounding Aseptic Isolator (CAI):

- Items that must be removed before entering the CAI area:
  - Personal outer garments (hats, jackets, scarves, etc.),
  - All hand, wrist and arm jewelry and piercings,
  - Artificial nails or extensions are not allowed. Natural nails will be kept short and neatly trimmed

- After the above, but prior to use of the CAI:
  - Remove debris from under fingernails using a nail cleaner under running warm water
  - Wash hands and forearms to the elbow vigorously for at least 30 seconds using soap and water. The use of scrub brushes is not recommended due to irritation and skin damage
  - Dry thoroughly using a lint free disposable towel or electronic hand dryer
  - Perform aseptic hand cleansing with a waterless alcohol-based surgical hand scrub with persistent activity per manufacturer's recommendations
  - Allow hands to dry completely
  - Insert arms/hands into sleeve/glove assembly. Note that gloves should have already been attached to sleeves. See procedure for attaching gloves to sleeves.
  - Prior to performing CAI cleaning or any admixing, attach a second set of sterile gloves over the gloves which are attached to the sleeves. This should be accomplished by introducing a package of sterile gloves into the CAI via the airlock, disinfecting the gloves attached to the sleeves with sterile IPA, and aseptically donning the second set of gloves.
  - Since gloves will become contaminated while performing compounding, routinely wipe them down or rub with sterile 70% IPA. Gloves should be one tested for this use
  - Routinely inspect sleeves and gloves for holes and tears. Replace as necessary
POLICY: Compounding Staff Gloved Fingertip Sampling

POLICY NUMBER: CSP5-D

REVISED DATES:
11/5/14, 7/5/16, 3/24/17, 8/4/17

ORIGINAL DATE:
3/27/2014

POLICY: All staff with compounding duties will receive training and an assessment of competency prior to performing those duties at Consonus. The assessment will be repeated annually. A part of this assessment will be testing the staff’s gloved fingertips for viable microorganisms. New compounders must successfully complete this test (donning garb/handwashing/gloving then gloved fingertip sampling) three times before being allowed to prepare CSPs for human use. Note that those using a CAI are not required to don garb. For the initial and annual re-certification, gloved fingertip sampling will be performed at least once after the media fill procedure. Note that incubation time will add days until the time that a new staff person can prepare CSPs, so plan staffing accordingly. Check the Consonus P&P on Microbial Contamination Action Levels for acceptable cfu numbers.

PROCEDURE - LAFW:

1. EnviroTest #ET1000 and #ET3000 are "Media Paddles" used by Consonus to collect samples from fingertips and work surfaces. For sampling gloved fingertips, one paddle will be used for each hand (all digits). Your evaluator will open the EnviroTest package and provide you with the paddles to touch. Both sides of the paddle are covered with media. Touch the paddle such that all your fingers are on one side of the paddle and your thumb is on the other.

2. Using EnviroTest #ET1000 or #ET3000, collect gloved fingertip and thumb samples from all digits of both hands after completing the hand hygiene and garbing procedure. The hand hygiene and garbing procedure, followed by the collection of samples must be performed a total of four times for new compounding staff (three times before and once after the media fill test) and once (after media fill test) for annual re-certification. If doing the initial certification, the garbing is completed, then the hand hygiene and the gloved fingertip testing procedures are done 3 times, new gloves are donned and the media-fill test procedure is done. Immediately following the media-fill testing procedure (and without disinfecting the gloves), the fourth gloved fingertip testing procedure is completed.

3. Using EnviroTest #ET1000 or #ET3000, collect gloved fingertip and thumb samples from both hands immediately after completing the media-fill test procedure (re-certifying staff). Do not disinfect gloves prior to sampling.

4. After inoculation, carefully place the paddle in the vial and close tightly. Label with sample source and date.

5. Incubate #ET1000 at 30-35°C for 48 to 72 hours. Incubate #ET3000 at 26-30°C for 120 to 168 hours. Carefully remove the paddle from the vial and visually examine under good lighting. Count the number of discrete colonies present, if any and report as colony forming
units (cfu's). Record results in log, including which hand the sample came from. Address as indicated by Consonus Action Level P&P.

PROCEDURE – CAI:

1. As above for LAFW, however, your evaluator will be unable to assist you inside the CAI. When performing the gloved fingertip test in a CAI, a set of sterile gloves will be introduced into the CAI via the airlock and donned over the gloves that are attached to the sleeves prior to sampling for microorganisms. Do not disinfect this second set of sterile gloves prior to testing. Once the testing is complete, this second set of gloves should be removed and discarded as it will have growth media on it and replaced with another set of sterile gloves.
POLICY: Compounding Staff Media-Fill Testing

POLICY NUMBER: CSP5-E

REVISED DATES: 3/24/17

ORIGINAL DATE: 3/27/2014

POLICY: All staff with compounding duties in the cleanroom or Compounding Aseptic Isolator (CAI) will receive training and an assessment of competency prior to performing those duties at Consonus. The assessment will be repeated annually. A part of this assessment will be testing the staff's technique through a media-fill test. This is sometimes called “PATT” which stands for Personal Aseptic Technique Test. Note that incubation time will add days until the time that a new staff person can prepare CSPs, so plan staffing accordingly.

PROCEDURE:

Note: GroMed #GM7030 is a kit used by Consonus to assess the staff person's technique.

1. Wipe all supplies with sterile 70% Isopropyl Alcohol (IPA) and place in cleanroom or CAI.
2. Perform standard Consonus Hand Hygiene and Garbing Procedure. The media-fill test may be performed directly after performing the gloved fingertip sampling procedure for initial certification.
3. Sanitize work area using standard procedures.
4. Select 1 GroMed ampule, 1 GroMed partially filled minibag and 1 GroMed 20ml vial, each containing Trypticase Soy Broth (TSB) growth medium. Wipe the ampule and injection ports of the bag and vial with a wipe saturated with IPA. Place all materials at least 6 inches within the LAFW or CAI work area.
5. Select 20 sterile 19G x 1" needles and one sterile 3, 5 or 6cc syringe. Remove the syringe from its pouch or protective cover and place within the work area.
6. Aseptically attach a needle to the syringe.
7. Draw up the contents of the ampule and inject into the GroMed vial. Shake to mix indicator dye.
8. Withdraw 1ml of TSB from the vial and inject into the minibag. Change the needle.
9. Repeat step #8 19 more times. Replace the needle each time, but use the same syringe, vial and minibag.
10. Place foil closure over minibag port.
11. Immediately inspect the minibag for particulates, corings and fibers. These particles should not be recorded as microbial growth. They may occur due to entering the vial and minibag ports so many times. Proceed to gloved fingertip sampling as needed (do not clean gloves with IPA or other disinfectant between media-fill test and gloved fingertip sampling).
12. Label the minibag with date and staff name.
13. Perform gloved fingertip testing procedure without消毒ing gloves.
14. Incubate PATT test media at room temperature or at 30-35°C for 14 days. Inspect the minibag daily for turbidity. If turbidity occurs (signifies growth and a failed test), re-train staff person and re-test. There is no need to wait the full 14 days unless the test is negative (no turbidity).
15. Record results.
POLICY: Compounded sterile preparations are often dispensed in devices that are unfamiliar to nurses and/or caregivers. Nurses and/or caregivers shall be counseled thoroughly to ensure they comply with therapy and understand how to use the compounded sterile preparation.

PROCEDURE:
- Nurses and caregivers, with a new prescription for a compounded sterile preparation shall have access to pharmacist consultation on the appropriate use of the compound, any adverse effects that they should be aware of, and any additional information relevant to the compounded preparation via the 24-hour pharmacy triage line.
# IV Admixture Checklist Evaluation of Sterile Technique

## IV ADMIXTURE EVALUATION CHECKLIST

**Name:** ____________________________  **Date:** ______________

<table>
<thead>
<tr>
<th>STANDARDS</th>
<th>STANDARDS MET</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removes jewelry</td>
<td>YES</td>
</tr>
<tr>
<td>Ties long hair back</td>
<td>YES</td>
</tr>
<tr>
<td>Dons mask and facial hair cover (if needed)</td>
<td>YES</td>
</tr>
<tr>
<td>Washes hands to elbows</td>
<td>YES</td>
</tr>
<tr>
<td>Gowns appropriately (sleeves)</td>
<td>YES</td>
</tr>
<tr>
<td>Dons sterile gloves appropriately</td>
<td>YES</td>
</tr>
<tr>
<td>Cleans hood (back to front, sterile 70% alcohol)</td>
<td>YES</td>
</tr>
<tr>
<td>Performs calculations prior to admixture</td>
<td>YES</td>
</tr>
<tr>
<td>Aseptically places items in hood</td>
<td>YES</td>
</tr>
<tr>
<td>Works well within hood (6&quot;)</td>
<td>YES</td>
</tr>
<tr>
<td>Alcohol swipes all points of entry</td>
<td>YES</td>
</tr>
<tr>
<td>Prepares IV aseptically</td>
<td>YES</td>
</tr>
<tr>
<td>Places only hands and arms in hood</td>
<td>YES</td>
</tr>
<tr>
<td>Uses filter needle</td>
<td>YES</td>
</tr>
<tr>
<td>Caps vials with aluminum seal (multiple dose vials only)</td>
<td>YES</td>
</tr>
<tr>
<td>Checks label prior to and after compounding</td>
<td>YES</td>
</tr>
<tr>
<td>Inspects for incompatibilities, cores, particulate matter</td>
<td>YES</td>
</tr>
<tr>
<td>Correctly labels product</td>
<td>YES</td>
</tr>
<tr>
<td>Places proper expiration date on label</td>
<td>YES</td>
</tr>
<tr>
<td>Addresses storage requirements</td>
<td>YES</td>
</tr>
<tr>
<td>Initials final product(s)</td>
<td>YES</td>
</tr>
</tbody>
</table>

**EVALUATOR:** ____________________________

**COMMENTS**

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________

_____________________________________________________________________
Personnel Training, Evaluation and Recertification

New pharmacists and technicians are trained by the Director of Pharmacy, Lead IV Technician or designee. New employee training includes the following:

1. Tour and orientation to IV area and layout.
2. Review Consonus IV admixture policies and procedures.
3. Read applicable IV admixture job descriptions.
4. Watch a technique video series, related to quality assurance, LAF hoods, attire, hand washing and manipulation of compounded sterile products (CSP's).
5. Read a Compounding Manual that parallels the videos. Go over key points of the manual with the trainer.
6. Take a 30-question test, grade and review.
7. Complete the IV Admixture Checklist Evaluation of Sterile Technique.
8. Complete the donning of protective gear, handwashing and gloved fingertip sampling process 3 times (twice prior to PATTI and once after per P&P).
9. Complete the media-fill testing PATT II (Personal Aseptic Technique Training) of aseptic manipulative skills.
10. Complete the IV room orientation/observation, including all computer system training.
11. Review with the IV pharmacist and proceed to train on all IV room equipment.
12. Train with a pharmacist or lead technician on the daily tasks and work into independent operation.
13. Receive final discussion, evaluation, and certification from the trainer. Compounding personnel who fail written, didactic or media-fill tests must be re instructed and reevaluated immediately. Copies of all documentation are included in the employee’s performance evaluation. Recertification then occurs every year during the employee's birth month.

The annual recertification procedure includes:
1. Review applicable IV admixture policies and procedures.
2. Watch the technique video relating to quality assurance, hoods, attire, hand washing and manipulation of CSP's.
3. Read the Compounding Manual. Go over key points of the book with the trainer.
4. Take 30-question test, grade and review.
5. Complete the IV Admixture Checklist Evaluation of Sterile Technique.
6. Complete the PATT II (Personal Aseptic Technique) media-fill testing of aseptic manipulative skills.
7. Complete the assessment of gloving techniques, including the culturing of glove fingertips (after PATTII).

Compounding personnel who fail written, didactic or media-fill tests must be re instructed and reevaluated immediately. Copies of all documentation are included in the employee's personnel file.
# Pharmacy Calculations

**Curriculum:** Pharmacy  
**Target Audience:** Pharmacists and Pharmacy Technicians

| Authors            | Philip Trapskin, PharmD  
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Rebecca Reagan, RPh</td>
</tr>
<tr>
<td></td>
<td>Kimberley Hite, MS, PharmD</td>
</tr>
<tr>
<td><strong>Service Area:</strong></td>
<td>Pharmacy Services</td>
</tr>
<tr>
<td><strong>Phone:</strong></td>
<td>(859) 257-8414</td>
</tr>
<tr>
<td><strong>Email:</strong></td>
<td><a href="mailto:khite2@email.uky.edu">khite2@email.uky.edu</a></td>
</tr>
<tr>
<td><strong>Date Developed Or Revised:</strong></td>
<td>April, 2005</td>
</tr>
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Supplies needed for this CBL

- Please have a calculator, pencil and paper available to complete this CBL.

University of Kentucky / NetLearning CBL
Objectives
Basic Mathematics
Units of Measure
Ratios and Proportions
Intravenous flow (drip) rate calculations
Common Abbreviations
Objectives

- Review basic mathematics
- Review units of measure
- Review ratios and proportions
- Review concentration and dilution
- Review intravenous flow (drip) rate calculations
- Provide sample problems and solutions
Basic Mathematics

• Numerals
  – A numeral is a word or a sign, or a group of words or signs that expresses a number.
    • Arabic (0, 1, 2, 3, 4...)
    • Roman (I, X, L, D, C, M...)

• Numbers
  – A number is a total quantity or amount that is made of one or more numerals.