Agenda Item/Title: Olympic Memorial Hospital Pharmacy

Date SBAR Communication Prepared: 8/29/2019

Reviewer: Irina Tiginyanu

Link to Action Plan:

☐ Action  ☐ Information  ☐ Follow-up  ☐ Report only

Situation:

Pharmacy is seeking approval for their technician AUP and specialized functions

Background:

Assessment:

Pharmacy technicians are performing within their scope of practice:

-Tech check Tech
-Sterile Compounding

Recommendation:

Recommendation to approve the ancillary utilization plan and specialized functions

Follow-up Action:
Ancillary Personnel Utilization Plan - Pharmacy Technician

GENERAL DESCRIPTION:
Olympic Memorial Hospital (OMH) Pharmacy provides comprehensive inpatient pharmacy services to the Olympic Medical Center Campus including automated dispensing machine (ADM) Support, unit dose dispensing, sterile compounding of IV admixtures compliant with USP 797 Guidelines including limited Chemotherapy agents, Large Volume and Small Volume Parenteral. The OMH pharmacy also distributes medications and provides oversight to Hospital Pharmacy Associated Clinics.

- Pharmacy technicians are scheduled from 0530 am daily until midnight. A pharmacist is scheduled to supervise technician workflow at all times.
- Pharmacy technicians are scheduled to work either 8 or 10 hour shifts.
- Pharmacy technicians are utilized as Pharmacy Buyers in addition to the regular pharmacy technician role.
- All pharmacy technicians work in the main hospital pharmacy except when making deliveries, restocking ADMS or performing unit inspections.
- A licensed pharmacist completes a final quality assurance check on work prior to distribution to patient care areas except when Tech Check Tech is performed.

EDUCATION AND TRAINING:
- Complete a Washington State Pharmacy Quality Assurance Commission approved training program.
- Complete initial didactic training competencies as required by the Sterile Compounding Specialized function and USP 797.
- Training and education for Tech Check Tech certification per approved specialized function.
- Complete ADM competency training per vendor requirements
- Completed EHR training per vendor requirements.
- Other competency assignments based on roles and responsibilities.
- Ongoing competency assignments to support changes in technology and workflows.

RESPONSIBILITIES:
- Maintains license in good standing
- Completes all required continuing education and competencies
- Stays current with Washington state pharmacy regulations relevant to the practice of pharmacy
- Understands and follows hospital and pharmacy policies and procedures
- Maintains a safe work environment and follows all safety requirements.
- Documents all quality variances in the Safety Event Monitoring system.
- Engages in quality improvement initiatives.

DEPARTMENT/JOB SPECIFIC PERFORMANCE EXPECTATIONS:

1. Automated dispensing machines (ADM)
   - Picks the ADM refills daily utilizing barcode scanning technology
   - Delivers ADM refills daily utilizing barcode scanning technology
   - Empties return bins daily
   - Review and files daily/weekly/monthly reports
2. Tech Check Tech Specialized function (see PQAC approved protocol for requirements)
   - Certified "Tech Check Tech" technician Checks ADM refills daily.
3. Unit dose Repackaging
   - Generates batch record including label utilizing electronic record system (Simplifi 797).
   - Utilized CII Safe to generate batch record for controlled substance repackaging.
   - Repackages solid dosage forms in approved packaging.
   - Repackages oral dosage forms in oral syringes or amber bottles.
4. Non-sterile compounding – per batch process record in electronic record system.
   - Follows USP 795 standards for non-sterile compounding.
5. Purchasing – Pharmacy Buyers and pharmacy technicians
   - Place daily order for stock replenishment to drug wholesaler or directly to manufacturers.
   - Receives daily orders and reconciles quantity received with invoice or packing slips.
   - Maintains medication barcodes in electronic health record.
   - Stocks shelves and stock rotation
   - Processes returns
   - Manages backorders
   - Manages recall notices
   - HPAC medication orders
   - Invoice sign off for accounts payable (Pharmacy buyers only)
   - Management of drug shortages – reports to management
6. 340 B program daily management (Pharmacy buyers/340B specialists only)
   - Splits drug orders to 340 B account based on accumulated use.
   - Manages cross walks in third party administrator website.
   - Self-audits for program compliance
7. Controlled substance accountability and distribution
   - Utilize CII safe to account for all controlled substance dispensing
   - Management and filing of all controlled drug administration records not completed through the ADM system.
   - Daily audits for diversion prevention program
8. Restocking kits and trays
   - Bulk charges medications used from kits
   - Daily kit and tray exchanges
9. Non-professional phone calls and Medication Administration Record (MAR) messages
10. Deliveries of patient specific medication to patient care areas
11. Completion of Monthly unit inspections
12. Completion of HPAC inspections
13. Sterile compounding per USP 797 guidelines and PQAC approved specialized function.
   - Documentation of all cleaning tasks in electronic record system (Simplifi 797)
   - Hazardous drugs per USP 797 and USP 800 guidelines and PQAC approved Specialized function
   - Manages trigger fill list for titrating infusions
14. Records retention and archiving
15. Generates PALS sheets from electronic health record for pediatric patients.
16. Charge review and Billing
   - Reviews all high dollar and high quantity dispensing for accuracy.
   - Makes corrections to charges

Revised 8-26-19 kb
# Technician Specialized Function—Program Review Form

**Chapter 246-901 WAC**

**Date:** 8-26-2019

*Renewal*

**Responsible Pharmacist:** Karen Bright

**Pharmacy Name:** Olympic Memorial Hospital

**License #:** PHAR CF 0200287 Hosp

**Pharmacy Address:** 134 Caroline St., Port Angeles

**Phone #:** 360-417-7165

<table>
<thead>
<tr>
<th>Does the Program identify pharmacy technicians who meet the criteria for participation?</th>
<th>Yes</th>
<th>No</th>
<th>Unclear</th>
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<tbody>
<tr>
<td>Did the responsible pharmacist sign the program proposal?</td>
<td>Yes</td>
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<table>
<thead>
<tr>
<th>Training Program at least 8 hours long and specifies the following categories:</th>
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<tbody>
<tr>
<td>a. Basic skills in health system pharmacy, including goals and requirements of unit-dose medication systems.</td>
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<tr>
<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>
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<tr>
<td>The validation process for individual performance of unit-dose medication checking includes:</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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<tr>
<td>c. 99% accuracy for success.</td>
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<tr>
<th>The quality assurance program will annually audit the specialized skills of technicians:</th>
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<tbody>
<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>
</tr>
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<tr>
<th>Forms used in training, validation and audits are submitted with program?</th>
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<tr>
<th>Utilization plan for specialized pharmacy technician functions is included with the program?</th>
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**Comments**

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**For Staff Use Only**

**Review completed on**

**by**

**Agreement Type:**

**Staff decision:** [ ] Approved  [ ] Revisions Needed  [ ] Board Agenda  [ ] New

**Board decision:** [ ] Approved  [ ] Denied  [ ] Notice sent to investigator  [ ] Renewal

DOH 690-002 (Rev. June 2010)
Pharmacy Technician Specialized Function:
Checking accuracy of medications to be filled into automated drug distribution device

Upon completion of the training program and demonstration of proficiency, selected pharmacy technicians may check the medications pulled by another technician for filling the automated dispensing device.

1. Criteria for selecting pharmacy technicians to check accuracy of medications fills:
   a. Completion pharmacist supervised training program as described in Appendix A
   b. Nationally certified technicians will not be required to take the general exam, but must complete the training program and final exam
   c. Full time (0.6 FTE or greater) with a minimum of 12 months experience

2. Demonstration of proficiency
   a. A Pharmacist will do a third check on the checking technician to verify accuracy
   b. A 99% accuracy rate after checking 100 Pyxis pocket refills will validate proficiency
   c. Training and validation will be tracked and retained in the pharmacy; see Appendix B

3. Quality Assurance
   a. A pharmacist will perform quarterly audits of checking accuracy during the first year; see Appendix C
   b. Random audits of machine fills will be performed at least twice yearly after the first year; see Appendix D
   c. All audits will be documented and retained in the pharmacy
   d. The hospital Safety Risk Management event system will be utilized to report and track automated dispensing device filling errors
   e. These reports will be reviewed by the Pharmacy Director and medication error types will be analyzed as part of the pharmacy performance improvement plan

4. Utilization Plan
   a. Pharmacy technicians will perform the function of checking automated dispensing device medication fills during the day shift when staffing levels permit
   b. The daytime float technician will be assigned the duty to check the fill by the technician assigned to Pyxis duty for that day's shift
c. The technician duties will rotate to ensure that all selected technicians have the opportunity to utilize their checking skills.
d. A pharmacist will check all Pyxis machine fills if insufficient qualified technicians are scheduled on the shift.

Director of Pharmacy

8-26-19
Date
APPENDIX A – Documented in Simplifi797

Training Schedule of Pharmacy Technician
Pyxis Machine Fill Checking

I. GENERAL EXAM (2 hours)


II. INTRODUCTION (1 hour)

A. Goal: to qualify all eligible technicians to perform the specialized function of checking Pyxis machine fills
B. Purpose: to expand the technician responsibilities/duties to include checking Pyxis machine fills and in doing so allowing pharmacists more time to perform clinical functions
C. Timetable: Selected technicians will have 30 days to complete training and demonstration of proficiency
D. Review of Basic Skills Exam:
   a. Relevant questions will be selected from the Manual for Pharmacy Technicians (4th ed.) self assessment quizzes at the end of each section
   b. A discussion of exam questions will take place after completion to correct information and reinforce ideas

III. GENERAL UNIT DOSE DISTRIBUTION INFORMATION (1 hour)

A. History and purpose of unit-dose distribution systems and automated dispensing devices (Chapter 1 pg 16-17, Chapter 13 pg 320-322)
B. Purpose of Formulary System (Chapter 4, pg58, Chapter 19 pg 482-483)
C. Packaging and Labeling requirements of unit-dose medications

1. Information required on label (Chapter 15)
   a. Differences in packaging requirements for different dosage forms
   b. Physical stability issues
      i. Light protection
      ii. Temperature requirements
      iii. Non-crushable dosage forms
IV. MEDICATION ERRORS (1 hour) (Chapter 17)

A. Most common errors found by the ‘checking person’
B. Most common errors that are missed by the ‘checker’
C. Methods to prevent missing error detection

1. Awareness of error types that occur
2. Decreasing distractions
3. Don’t get rushed by others
4. Remain systematic in your approach to checking

V. MATHEMATICAL CALCULATIONS (1 hour) (chapter 14)

A. Review of Fractions, Percentages, Proportions, etc.
B. Mathematical conversions
   a. Avoirdupois
   b. Apothecary
   c. Metric

VI. PRODUCT SELECTION (1 hour)

A. Generic equivalents
   a. Orange book ratings (Chapter 2 pg 32)
B. Accepted therapeutic equivalents (Chapter 2 pg 32-33)
C. Errors in filling: problem-prone medications (Chapter 19)
   a. Look-alike-sound-alike
   b. High alert medications
   c. Numbers and letters as part of drug name
   d. Product label-marketing strategy
   e. Color coding

VII. MISCELLANEOUS, SUMMARY AND FINAL EXAM (1 hour)

A. Understanding medical abbreviations
B. Questions and Answers
Final Exam (over material presented during sessions)
OLYMPIC
MEDICAL CENTER

APPENDIX B – Documented in Simplifi797

Olympic Medical Center Pyxis Pocket Fill Checking
Pharmacy Technician Training and Validation

Pharmacy Tech: _______________________

Date training started: ________ Final completion by: ________________
Date finished ________________

OBJECTIVE AND TESTS COMPLETED

1. General Unit Dose Distribution information
2. Medication Errors
3. Mathematical Calculations
4. Product Selection
5. Medical abbreviations
6. Exam
7. Validation of 1500 doses

<table>
<thead>
<tr>
<th>OBJECTIVE</th>
<th>DATE</th>
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<tbody>
<tr>
<td>1 General Unit Dose Distribution information</td>
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<tr>
<td>2 Medication Errors</td>
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<td>3 Mathematical Calculations</td>
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<td>4 Product Selection</td>
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<td>5 Medical abbreviations</td>
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<td>6 Exam</td>
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<td>7 Validation of 1500 doses</td>
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VALIDATION

In order to successfully complete this section of the training, it will be necessary to have achieved a 99% accuracy rate (accuracy rate verified by a pharmacist) in checking 100 Pyxis pockets (Greater than or equal to 1500 doses).

<table>
<thead>
<tr>
<th>Date</th>
<th># of pockets</th>
<th># of errors</th>
<th>Accuracy rate</th>
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Pharmacist signature _________________________
Olympic Medical Center Quarterly Audit of Pharmacy Tech Check Tech Pyxis Pocket Fills

Pharmacy Technician: ____________________________

<table>
<thead>
<tr>
<th>Date</th>
<th>Correct qty</th>
<th>Incorrect item</th>
<th>Incorrect strength</th>
<th>Incorrect station</th>
<th>Other result</th>
<th>Total items Checked</th>
<th>Accuracy rate</th>
<th>RPH initial</th>
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Accuracy rate: ____________________________ \[100\% - \left(\frac{\text{total errors}}{\text{total pockets}}\right) \times 100\%\]

A 99\% accuracy rate should be achieved while checking the main Pyxis fill of the day
Olympic Medical Center Bi-Annual Random Audit of Pharmacy Tech Check Tech Pyxis Pocket Fills

<table>
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<tr>
<th>Date</th>
<th>Correct</th>
<th>Incorrect qty</th>
<th>Incorrect item</th>
<th>Incorrect strength</th>
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<th>Total items Checked</th>
<th>Accuracy rate</th>
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</tr>
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</table>

Accuracy rate: ____________________  
(100% - [(total errors/total pockets) x 100%])

A 99% accuracy rate should be achieved while checking the main Pyxis fill of the day
Initial Skills Assessment—General

Name: ___________________________________ Date: ___________________________________

Abbreviations
Directions—For questions 1 through 20, match the abbreviations with the correct meaning.

IV Solutions:

1. D5W  a. 5% dextrose in lactated Ringer's
2. NS    b. 0.9% sodium chloride
3. ½NS   c. 5% dextrose in water
4. ¾NS   d. 0.225% sodium chloride
5. D5LR  e. 0.45% normal saline

Prescription Directions:

6. bid    a. four times daily
7. qid    b. three times daily
8. prn    c. twice daily
9. tid    d. immediately
10. stat  e. as needed

Chemical Symbols:

11. Cl    a. sulfate
12. Na    b. potassium
13. Mg    c. chloride
14. K     d. magnesium
15. SO₄  e. sodium
Units of Measure:
- 16. mEq      a. millimole
- 17. mg       b. milliliter
- 18. mcg      c. microgram
- 19. mL       d. milliequivalent
- 20. mmol     e. milligram

Calculations
Directions—Select the best answer for questions 21 through 29. You may use a regular calculator. Do not use a calculator with unit conversion functions.

21. Add 7.25 L and 875 mL. Express the result in milliliters.
   a. 882.25 mL
   b. 1,600 mL
   c. 8,125 mL

22. Add 0.00250 kg, 1,750 mg, 2.25 g, and 825,000 mcg. Express the result in grams.
   a. 5.325 g
   b. 7.325 g
   c. 14.75 g

23. Add 1 pint, 4 fl oz, and 2 tsp. Express the result in milliliters.
   a. 144 mL
   b. 503 mL
   c. 601 mL

24. A patient weighs 149 pounds. How many kg does this patient weigh?
   a. 74.5 kg
   b. 67.7 kg
   c. 29.5 kg

25. How many milligrams does a levothyroxine 75 microgram tablet contain?
   a. 0.075 mg
   b. 0.75 mg
   c. 7.5 mg

26. How many tablets do you need to dispense for the following prescription?
   Prednisone 5 mg tablets
   Take 4 tablets daily for 7 days, then
   Take 2 tablets daily for 5 days, then
   Take 1 tablet daily for 5 days, then
   Take ½ tablet daily for 4 days
   a. 50 tablets
   b. 47 tablets
   c. 45 tablets

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From: ASHP eBooks (digital.ashp.org)
27. A patient has a prescription for metoclopramide syrup 15 mg qid taken 30 minutes before meals and at bedtime for 7 days. The suspension contains 5 mg/5 mL. How many milliliters must be dispensed for a 7-day supply?
   a. 105 mL
   b. 140 mL
   c. 420 mL

28. Naloxone 300 mcg IV has been ordered for a patient. How many milliliters of a 400 mcg/mL solution are needed to prepare this dose?
   a. 0.75 mL
   b. 1 mL
   c. 1.3 mL

29. An order is received for dexamethasone 20 mg IV to be given to a patient prior to a chemotherapy infusion. How many milliliters of a 4 mg/mL solution are needed to prepare this dose?
   a. 0.2 mL
   b. 0.5 mL
   c. 5 mL

Trade and Generic Medication Names

Directions—For questions 30 through 35, choose the best answer.

30. Mr. Jones has been admitted for a surgical procedure. His doctor has ordered his home medications to be continued as follows: Glipizide 5 mg po daily with the morning meal. Which of the following may be dispensed?
   a. Glucophage
   b. Glyburide
   c. Glucotrol
   d. Glynase

31. Which of the following products contains hydrocodone and acetaminophen?
   a. Vicodin
   b. Percocet
   c. Ultracet
   d. a and c

32. The following order has been received in the pharmacy: Retrovir 100 mg po 30 minutes before meals and at bedtime. Which of the following may be dispensed?
   a. Indinavir
   b. Zidovudine
   c. Ritonavir
   d. Norvir
33. An order has been received in the pharmacy for Sandimmune. The generic name for Sandimmune is

   a. Cycloserine
   b. Octreotide
   c. Sandostatin
   d. Cyclosporine

34. Lomotil contains which of the following ingredients?

   a. Propoxyphene and acetaminophen
   b. Amitriptyline and chlordiazepoxide
   c. Atropine and diphenoxylate
   d. Diphyllyline and guaifenesin

35. Mrs. White has been admitted to the hospital. She has a history of uncontrolled hypertension. Her physician has written the following order: Clonidine 0.1 mg po bid. Which of the following may be dispensed?

   a. Klonopin
   b. Catapres
   c. Clozaril
   d. Clonazepam

Medication Therapy

Directions—For questions 36 through 41, choose the best answer.

36. Which of the following is used for the treatment of high cholesterol?

   a. Atorvastatin
   b. Gemfibrozil
   c. Ezetimibe
   d. All of the above

37. Which of the following medications are examples of anti-infective drugs?

   a. Vancomycin
   b. Adriamycin
   c. Aztreonam
   d. a and c

38. Calcium gluconate, magnesium sulfate, and potassium phosphate are examples of __________.

   a. Trace elements
   b. Heavy metals
   c. Electrolytes
   d. Antioxidants

39. Heparin, enoxaparin, and warfarin are best described as __________.

   a. Anticoagulants
   b. Smooth muscle relaxants
   c. Antineoplastics
   d. Diuretics
40. Which of the following is used in the management of diabetes mellitus?
   a. Glyburide
   b. Chlorpromazine
   c. Rosiglitazone
   d. a and c

41. Which of the following is classified as a diuretic?
   a. Indapamide
   b. Amiodarone
   c. Torsemide
   d. a and c

Competence certified by

Date
CHAPTER 13

Initial Skills Assessment—Pharmacy Technician

Calculations

Directions—Calculate the answers for questions 1 through 5. You may use a regular calculator. Do not use a calculator with unit conversion functions.

1. Digoxin 500 mcg IV has been ordered for a patient. How many milliliters of a 0.25 mg/mL solution are needed to prepare this dose?
   a. 0.5 mL
   b. 2 mL
   c. 20 mL

2. An order is received in the pharmacy for gentamicin 100 mg IV every 12 hours. The pharmacy stocks gentamicin vials containing 40 mg/mL. How many milliliters will be needed to prepare one dose?
   a. 0.4 mL
   b. 2.5 mL
   c. 5 mL

3. An order for an IV admixture calls for 30 mEq of sodium bicarbonate to be added to the solution. How many milliliters of a 50 mEq/50 mL solution are needed to prepare this IV admixture?
   a. 1.7 mL
   b. 3 mL
   c. 30 mL

4. A loading dose of phenytoin 600 mg IV has been ordered for a patient in ICU suffering from seizures. How many milliliters of a 50 mg/mL solution are needed to prepare this dose?
   a. 1.2 mL
   b. 6 mL
   c. 12 mL

5. Erythropoietin 5,400 units IV has been ordered for a patient receiving dialysis. How many milliliters of a 10,000 units/2 mL solution are needed to prepare this dose?
   a. 0.5 mL
   b. 1.1 mL
   c. 1.8 mL
Use the following case report to answer questions 6 through 9.

A medication order has been sent to the pharmacy for normal saline IV solution with potassium chloride 20 mEq/liter to be infused at 80 mL/hr.

6. How many milliliters of fluid is the patient receiving per day?
   a. 480 mL
   b. 1,920 mL
   c. 2,500 mL

7. How many 1-liter bags will be needed per day?
   a. 1 bag
   b. 2 bags
   c. 3 bags

8. Which of the following base solutions should be used to prepare this solution?
   a. 0.225% sodium chloride
   b. 0.45% sodium chloride
   c. 0.9% sodium chloride
   d. 23.4% sodium chloride

Reconstitution

Directions—A new medication, X disodium, comes as a powder that must be reconstituted prior to use. Refer to the label information to answer questions 9 through 14.

X disodium
Equivalent to 6 g of X
For IV or IM use

For IV use: Add 24 mL of Sterile Water for Injection, USP. Each 2.5 mL of the resulting solution contains 500 mg of X. Prior to administration, dilute further to desired volume with an appropriate IV solution. For IM use: Add 12 mL of Sterile Water for Injection, USP or 1% lidocaine HCl solution (without epinephrine). Each 2.5 mL of the resulting solution contains 1 g of X. Solutions stored at room temperature must be discarded after 24 hours or after 72 hours if stored under refrigeration.

9. How much diluent is added to the vial to prepare the drug for IM use?
   a. 12 mL
   b. 6 mL
   c. 24 mL
   d. 72 mL

10. Which of the following solutions may be used as the diluent for IM use?
    a. Sterile Water for Injection
    b. 1% lidocaine
    c. 1% lidocaine with epinephrine
    d. a or b
11. Which of the following concentrations may be used to describe the prepared IM solution?
   a. 1 g/2.5 mL
   b. 400 mg/mL
   c. 2 g/5 mL
   d. All of the above

12. If the order is for 1 g IM, what volume must you give?
   a. 1 mL
   b. 2.5 mL
   c. 5 mL
   d. 0.25 mL

13. How long will the reconstituted solution retain its potency at room temperature?
   a. 24 hours
   b. Until the expiration date on the original vial
   c. 72 hours
   d. The reconstituted solution must be used immediately

14. If you reconstitute the medication at 8:00 a.m. on October 23rd, what expiration information (date/time) will you print on the label if the medication is to be refrigerated?
   a. 10/25, 0800
   b. 10/25, 2400
   c. 10/26, 0800
   d. The expiration date on the original vial

Trade and Generic Medication Names

Directions—For questions 15 through 22, choose the best answer.

15. Mrs. Green has been admitted to the obstetric unit. Her physician has ordered a Pitocin IV drip. Which of the following products may be used to prepare this drip?
   a. Pitressin
   b. Oxytocin
   c. Vasopressin
   d. a or b

16. A medication order for carboplatin is received in the pharmacy. Which of the following may be dispensed?
   a. Platinol
   b. Paraplatin
   c. Cisplatin
   d. a or b
_17. An order has been received in the pharmacy as follows: Doxorubicin 75 mg IV push today. Which of the following products may be used to prepare this injection?
   a. Adriamycin
   b. Doxil
   c. Daunorubicin
   d. a or b

_18. The following medication order is received in the pharmacy: Rifampin 300 mg po daily. Which of the following may be dispensed?
   a. Rifadin
   b. Rifabutin
   c. Rifamate
   d. Rifaximin

_19. Mr. Martin is experiencing severe pain and his physician has ordered hydromorphone 4 mg IM every 4 to 6 hours prn severe pain. Which of the following products may be administered?
   a. Morphine
   b. Demerol
   c. Fentanyl
   d. Dilaudid

_20. The following medication order is received in the pharmacy: Docetaxel 160 mg IV infused over 3 hours. Which of the following products may be used to prepare this infusion?
   a. Paclitaxel
   b. Taxol
   c. Taxotere
   d. Paxil

_21. A medication order for celecoxib is received in the pharmacy. Which of the following may be used to fill this order?
   a. Celexa
   b. Cerebyx
   c. Celebrex
   d. Celestone

_22. A medication order for rosvastatin is received in the pharmacy. Which of the following may be used to fill this order?
   a. Zocor
   b. Mevacor
   c. Lipitor
   d. Crestor
Medication Therapy

Directions—For questions 23 through 30, choose the best answer.

23. Which of the following is used for the treatment of hypertension and cardiac arrhythmias?
   a. Digoxin
   b. Diltiazem
   c. Norepinephrine
   d. Procainamide

24. Metadata CD is classified as a(n) __________.
   a. Sustained-release methylphenidate product
   b. Biphasic-release methylphenidate product
   c. Immediate-release methylphenidate product
   d. None of the above

25. Which of the following medications is an example of a chemotherapy agent?
   a. Mitomycin
   b. Erythromycin
   c. Daptomycin
   d. a and c

26. Which of the following is used to treat gastroesophageal reflux disease (GERD)?
   a. Aripiprazole
   b. Omeprazole
   c. Fluconazole
   d. a and b

27. Lunesta is used for __________.
   a. Treatment of depression
   b. Treatment of anxiety
   c. Sedation during surgery
   d. Insomnia

28. Which of the following is classified as an antiemetic?
   a. Anzemet
   b. Avandamet
   c. Zantac
   d. a and c

29. Epogen is used to treat __________.
   a. Seizures
   b. Anemia in patients with chronic kidney disease
   c. Neutropenia from chemotherapy
   d. Asthma
30. Phenytoin is used to treat
   a. High blood pressure
   b. Arthritis
   c. Seizures
   d. Asthma
Technician Specialized Function—Program Review Form
Chapter 246-901 WAC

Date: 8-26-19

Responsible Pharmacist: Karen Bright

Pharmacy Name: Olympic Memorial Hospital
Pharmacy Address: 934 Caroline St, Port Angeles WA

License #: PHAC CE 0002827-416
Phone #: 360-417-7165

| Does the Program identify pharmacy technicians who meet the criteria for participation? | Yes | No | Unclear |
| Did the responsible pharmacist sign the program proposal? | Yes | No | Unclear |
| Training Program at least 8 hours long and specifies the following categories: | | | |
| a. Basic skills in health system pharmacy, including goals and requirements of unit-dose medication systems. | | | |
| b. Common medication errors and prevention strategies. | NA | | |
| c. Mathematical calculations and medical abbreviations. | | | |
| d. Drug product selection policies and safeguards. | | | |
| e. A comprehensive examination. | | | |

The validation process for individual performance of unit-dose medication checking includes:

a. 1500 doses at several intervals.

b. Pharmacist supervision. NA

c. 99% accuracy for success.

The quality assurance program will annually audit the specialized skills of technicians:

a. Random audits of checking accuracy audits performed by a licensed pharmacist.

b. Retention of audit forms and incident reports related to pharmacy technician medication checking.

Forms used in training, validation and audits are submitted with program?

Utilization plan for specialized pharmacy technician functions is included with the program?

Comments

For Staff Use Only

Review completed on____________________ by____________________ Agreement Type:____________________

Staff decision: [ ] Approved [ ] Revisions Needed [ ] Board Agenda [ ] New

Board decision: [ ] Approved [ ] Denied [ ] Notice sent to Investigator [ ] Renewal

DOH 690-002 (Rev. June 2010)
Pharmacy Technician Ancillary Utilization plan

Specialized Function: Sterile Compounding of Non-hazardous and Hazardous Drugs

Upon completion of the training program and demonstration of proficiency, selected pharmacy technicians may perform the specialized function sterile compounding at Olympic Medical Center (OMC) in compliance with USP Chapter 797 and USP Chapter 800. ASHP Guidelines on Compounding Sterile Preparations (2014) and ISMP guidelines for Safe Preparation of Compounded Sterile Preparations (2016) will be used to support sterile compounding workflow best practice at OMC.

https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/compounding-sterile-preparations.ashx

1. Criteria for selecting pharmacy technicians to perform sterile compounding of non-hazardous medications:
   a. Completion of Critical Point Competency Modules and passing grade on posttest. [Appendix A]
   b. Pharmaceutical calculations test – passing grade
   c. Understanding of OMC Sterile compounding policy and procedures including substances used for cleaning and disinfection. — Attestation on file.
   d. Initial glove fingertip testing with no growth per policy
   e. Media fill testing with no growth per policy
   f. Completion of training on IV compounding tasks occurring outside of the compounding area.
      i. Dispense preparation
      ii. Beyond use date reference
      iii. Ordering and restocking of IV compounding supplies
      iv. Information on the Medication label
   g. Demonstration of Proficiency – Simplifi 797 competency sign off by responsible pharmacist or designee.
      i. Cleaning and disinfection of primary engineering controls and segregated compounding areas.
      ii. Hand hygiene, and garbing.
      iii. Use of primary engineering control to ensure aseptic technique and appropriate use of first air on critical site.
   h. Supervised initial training
      i. A pharmacy technician after completion of above requirements shall begin a training period for IV room workflow and compounding of patient specific sterile non-hazardous medications. Duration of at least 10 working days.
ii. Accuracy rate will be tracked daily by checking pharmacist with immediate follow-up and correction of any errors or process issues.
   i. When accuracy rate averages 99%, technician may begin working independently in the IV room. A log of all sterile compounded IV’s will be maintained during the training period.

2. Ongoing Quality Assurance
   a. Completion of annual competency assessments required by USP 797
   b. Successful completion of annual glove fingertip testing
   c. Successful completion of annual media fill testing
   d. Random audit for hand hygiene, garbing, use of primary engineering control including cleaning and disinfection and accuracy of sterile compounded products.
   e. Audit results and corrective actions will be documented in Simplifi 797.

3. Criteria for selecting pharmacy technicians to perform sterile compounding of hazardous medications:
   a. After completing 6 months of routine sterile compounding of non-hazardous medication, a pharmacy technician may complete training for sterile compounding of hazardous medications.
      i. Completion of Critical Point competency Modules specific to Hazardous Medication Handling.
      ii. Completion of competency related to use of closed system transfer device.
      iii. Review of OMC Hazardous Medication handling policy and procedures – Attestation on file
      iv. Review of OMC hazardous Medication list and process for identifying hazardous drugs.
   b. Demonstration of Proficiency – Simplifi 797 Competency sign off by responsible pharmacist or designee.
      i. Cleaning, disinfection and decontamination of primary engineer controls and segregated compounding area
      ii. Use of PPE specific to-hazardous drug handling at-all-points (receiving, storing, preparation).
      iii. Negative pressure segregated compounding area – entry and exit requirements.
      iv. Use of closed system transfer device
      v. Use of Primary engineering control to avoid contamination of operator and to ensure appropriate use of first aid on critical sites.
   c. Supervised initial training
      i. After completion of above requirements, the pharmacy technician shall begin a training period for the sterile compounding of patient specific hazardous medications. Duration sufficient to accurately complete 80 Hazardous medication orders as determined by the pharmacist in charge.

4. Utilization Plan
   a. A licensed pharmacy technician competent to perform sterile compounding will be assigned to this duty 7 days per week between the hours of 0530 and midnight daily.

Pharmacy Director

Date 8-26-19
APPENDIX A
Training Schedule of Pharmacy Technician
Sterile Compounding

I. Non-Hazardous Medication Sterile Compounding
   Step 1. Critical Point eLearning’s and Posttests (13+ hours):
      i. Primary Engineering controls: Function, Use, Testing and Certification
      ii. Secondary Engineering controls: Function, Use, Testing and Certification
      iii. Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling
      iv. Personnel Aseptic Media Fill and Competency Evaluation
      v. Overview of Quality and Responsibilities of compounding Personnel
      vi. Proper Material Handling
      vii. Use of Syringes, Needles, Ampules and Filters
      viii. Aseptic Technique and Conduct in Controlled Environments
      ix. Overview of Cleaning and Disinfection of Pharmacy Controlled Environments
      x. Cleaning and Disinfection of Primary Engineering Controls
      xi. Cleaning and Disinfection of Secondary Engineering Controls and SCA’s
      xii. Determining Beyond-Use Dating
      xiii. Labeling and Packaging
   Step 2. Pharmaceutical Calculations Test
   Step 3. Glove Finger Tip testing – Initial
   Step 4. Media Fill Testing
   Step 5. Demonstration of proficiency
   Step 6. Supervised workflow training outside of segregated compounding area – [2 weeks]
   Step 7. Upon passing initial glove Finger Tip testing and media Fill testing begin supervised training
          in IV room [10 working days]

II. Hazardous Medication Sterile Compounding
   Step 1. Complete 6 months of routine non-hazardous sterile compounding.
   Step 2. Critical Point eLearning’s and Posttests (3+ hours)
      i. Hazardous Drug Compounding: Introduction and Overview
      ii. Hazardous Drug Compounding: Engineering Controls and PPE
      iii. Hazardous Drug Compounding: Work Practice Strategies
   Step 3. Demonstration of Proficiency
   Step 4. Supervised Training to accurately complete sterile compounding of 80 hazardous Medication orders.
<table>
<thead>
<tr>
<th>Training steps Non-hazardous</th>
<th>Date Started</th>
<th>Date completed</th>
<th>Responsible pharmacist or designee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Critical Point eLearning's</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Pharmaceutical Calculations Test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Glove Finger Tip Testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Media Fill testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Demonstration of Proficiency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Supervised Workflow training – outside of SCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Supervised sterile compounding training in SCA (99% accuracy)</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Training Steps Hazardous</th>
<th>Date Started</th>
<th>Date completed</th>
<th>Responsible pharmacist or designee.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Critical point eLearning</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Demonstration of Proficiency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Supervised Sterile Compounding (80 hazardous drug orders)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audit</td>
<td>Date</td>
<td>Compliant</td>
<td>Responsible pharmacist or designee</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>------</td>
<td>-----------</td>
<td>----------------------------------</td>
</tr>
<tr>
<td>Dispense prep used if applicable</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All items sanitized prior to entry into SCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Components for each order are segregated into separate bins.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand Hygiene procedure followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Garbing procedure followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile gloves used in isolator</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single order compound completed at one time.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Production label includes:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• method for reconstitution,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• vial concentration,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• volume of drug use.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product label include correct BUD and preparers initials.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sterile compounded products meet quality standards.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary engineering control and SCA cleaning and disinfection per policy.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Standards for Compounding Sterile Products

<table>
<thead>
<tr>
<th>Group</th>
<th>Process</th>
<th>Approved Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Services Support</td>
<td>Pharmacy</td>
<td>3/28/2019</td>
</tr>
</tbody>
</table>

Note: Printed copies are for reference only. Please refer to SharePoint for the latest version.

Policy Statement:
Sterile Compounded products will be prepared in compliance with all **USP Chapters 797 and 800**.

Primary engineering controls will be located in segregated compounding areas with limited access by competent pharmacy personnel and environmental services personnel performing daily and monthly cleaning.
Compounding shall be limited to **low and medium risk compounds**.

This policy will provide standards for the following as they relate to the preparation of compounded sterile products:
1. Training and Competency of Compounding Personnel
2. Aseptic Media Fill Testing
3. Environmental Sampling Plan
4. Temperature and Humidity Monitoring
5. Certification and Preventive Maintenance of Primary Engineering Controls
6. Hand Hygiene and Garbing
7. Cleaning and Disinfection of Compounding Facilities and Primary Engineering Controls
8. Maintenance and Use of Aseptic Isolators
9. Assigning Beyond Use Date, Redispensing CSP’s
10. Handling Multidose Vials within the Pharmacy Environment
11. Batch Compounding Quality Assurance

### 1. PROCEDURE – Training and Competency

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy staff</td>
<td>A. Required to pass assigned didactic (Critical Point) coursework; practical skill assessments through competency evaluation; and media-fill testing both initially and on an ongoing basis.</td>
</tr>
<tr>
<td></td>
<td>B. The following competencies are required to be completed upon hire and regularly thereafter per USP Chapters 797 and 800:</td>
</tr>
<tr>
<td></td>
<td>a. Competency Assessment: Hand Hygiene and Garbing</td>
</tr>
<tr>
<td></td>
<td>b. Competency Assessment: Aseptic Technique</td>
</tr>
<tr>
<td></td>
<td>c. Competency Assessment: Cleaning and Disinfecting</td>
</tr>
<tr>
<td></td>
<td>C. Additional competencies will be assigned based on specific roles and responsibilities.</td>
</tr>
<tr>
<td></td>
<td>D. Ongoing competency evaluation (Aseptic Technique, Hand Hygiene and Garbing and Cleaning and Disinfecting) and media-fill must at a minimum be completed annually.</td>
</tr>
<tr>
<td></td>
<td>E. Any employee handling, disposing or compounding Hazardous Drugs must successfully complete the Competency Assessment: Hazardous Drugs prior to working with hazardous drugs and annually thereafter. Employees are not eligible to complete the Hazardous Drug Competency Assessment until they successfully complete the three base competencies mentioned above.</td>
</tr>
<tr>
<td></td>
<td>F. Personnel who fail written or media-fill tests, will be immediately re instructed and reevaluated by expert compounding personnel to ensure correction to all aseptic processes as well as demonstrate the ability to pass repeated written and/or media-fill tests.</td>
</tr>
</tbody>
</table>
2. **PROCEDURE – Aseptic Media Fill Testing**

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Pharmacy staff     | A. A commercially available sterile fluid culture medium such as Soybean-Casein Digest Medium that promotes the colonization of bacteria most likely to be transmitted to CSPs from compounding personnel and the environment is used. The medium used must be accompanied by certification from the manufacturer that it is able to support microbial growth as a result of growth promotion tests. All microbial growth study data will be kept on file in a designated secured area.  
B. The preparation of media fill units (MFUs) will not be performed during normal production hours. Routine media fills will be conducted after normal compounding activity has occurred to simulate a worst case scenario.  
C. Passing or successful MFUs require that NO observed growth occurs during the entire incubation period. The MFUs are “read” at 7 and 14 days by checking for observable turbidity or cloudiness which indicates microbial contamination.  
D. Only upon completion and successful incubation of all MFUs, will the compounding employee be qualified to compound sterile preparations for human use. There are no exceptions to this policy.  
E. Any compounding employee generating greater than two (2) media fill positives in an ongoing media-fill test where there is no assignable system cause must repeat the initial qualification procedure as outlined above  
F. Retraining shall consist of reviewing the appropriate policy and procedures, learning tools as well as direct observation, and completion of the Competencies Hand Hygiene and Garbing and Aseptic Technique  
G. The Pharmacy Manager or designee must utilize professional judgment to determine the actions taken in the event an employee has one (1) or two (2) positive MFUs.  
H. Procedure for conducting Media Fill test |

3. **PROCEDURE – Environmental Sampling Plan**

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Hood Certification Vendor | A. Non-viable Particle counts  
 i. Every 6 months during recertification of engineering controls  
 ii. Document completion and results in Simplifi 797  
 iii. Monitor trends  |
| Pharmacist in Charge or Designee |   |

<table>
<thead>
<tr>
<th>Type of Air</th>
<th>Class Name</th>
<th>Particle Count limit FS 209E, ft³</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5 Air</td>
<td>Class 100</td>
<td>100</td>
</tr>
<tr>
<td>ISO Class 7 Air</td>
<td>Class 10,000</td>
<td>10,000</td>
</tr>
<tr>
<td>ISO Class 8 Air</td>
<td>Class 100,000</td>
<td>100,000</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Air</th>
<th>Alert Level (not required) Sample = 1000 liters/plate</th>
<th>Action Level* Sample = 1000 liters/plate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5 Air</td>
<td>any growth is problematic</td>
<td>&gt;1 CFU</td>
</tr>
<tr>
<td>ISO Class 7 Air</td>
<td>Alert Level</td>
<td>Action Level</td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
<td>--------------</td>
</tr>
<tr>
<td>&gt;5 CFUs</td>
<td>&gt;3 CFU per sample</td>
<td>&gt;3 CFU per plate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ISO Class 8 Air</th>
<th>Alert Level</th>
<th>Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;50 CFUs</td>
<td>&gt;2 CFUs per sample</td>
<td>&gt;5 CFUs per plate</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ISO Class 8 Air</th>
<th>Alert Level</th>
<th>Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;100 CFUs per plate</td>
<td>&gt;50 CFUs per plate</td>
<td>&gt;100 CFUs per plate</td>
</tr>
</tbody>
</table>

* CFUs per cubic meter of air per plate (cubic meter = 1000 liters) are taken from Table 2 in Chapter <797> so if < 1000 liters of air sampled per plate must convert to 1000 liter equivalent (e.g., if 400 liters sampled in ISO Class 7, Action Level = >4 CFU/plate).

iv. Action level results requires 3 times cleaning and repeat testing.

Pharmacist in Charge or Designee

C. Glove Fingertip Sampling (GFS)
   i. Initially during garbing x 3 samples (new staff)
   ii. Annually during media fill
   iii. The designated action level for gloved fingertip samples is dependent upon the location of the employee when the sample is taken.
   iv. When the GFS is taken immediately after performing hand hygiene, garbing and immediately after donning sterile gloves but before sanitizing gloved hands with sterile 70% IPA, the Action Level is 0 CFUs (total both hands).
   v. On occasions that GFS are taken randomly when the employee is working within the ISO Class 5 PEC but not immediately after hand sanitization with sterile 70% IPA, then the Action Level is > 3 CFUs (both hands).
   vi. Action Levels designate the number of CFUs on both gloves (total left hand + total right hand = > 0 CFUs in 2.4.1 and > 3CFUs in 2.4.2.
   vii. Document as part of Annual competency assessment in Simplifi 797

D. Surface Sampling (job aid)
   i. Monthly
   ii. Per site diagram located on Simplifi 797
   iii. Action level:

<table>
<thead>
<tr>
<th>Type of Air</th>
<th>Alert Level</th>
<th>Action Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO Class 5 Air</td>
<td>&gt;1 CFU per sample</td>
<td>&gt;3 CFU per plate</td>
</tr>
<tr>
<td>ISO Class 7 Air</td>
<td>&gt;2 CFUs per sample</td>
<td>&gt;5 CFUs per plate</td>
</tr>
<tr>
<td>ISO Class 8 Air</td>
<td>&gt;50 CFUs per plate</td>
<td>&gt;100 CFUs per plate</td>
</tr>
</tbody>
</table>

iv. Action level requires 3 times cleaning of engineering control and retesting.

v. Any growth requires identification to at least the Genus level.
4. **PROCEDURE – Temperature and Humidity Monitoring**

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Pharmacy Technician | A. Temperature monitoring – compounding areas  
  i. Daily during the AM shift on days pharmacy is open  
  ii. Acceptable temperature range 64-70’ F  
  iii. Out of range temperatures reported to Pharmacist in Charge  
  iv. Place a Maintenance work ticket to correct temperature range as soon as possible  
  v. Document temperature readings daily in Simplifi 797 on days pharmacy is open |
| Pharmacist in Charge | B. Humidity monitoring- compounding areas  
  i. Daily during the AM shift on days pharmacy is open  
  ii. Acceptable range 25-65% (not required by USP 797)  
  iii. Report variance to Pharmacist in Charge  
  iv. Place a Maintenance work ticket to address variation  
  v. Document humidity readings daily in Simplify 797 on days pharmacy is open |

5. **PROCEDURE – Certification and Preventative Maintenance of Primary Engineering Controls**

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities Maintenance Pharmacy Staff</td>
<td>A. Pre-filters on all PECs, if accessible will be inspected and cleaned or replaced if needed according to the provisions in this policy. Inspection will occur monthly and replacement will take place at least quarterly</td>
</tr>
<tr>
<td></td>
<td>B. All equipment maintenance/or testing will be performed in a manner consistent with the manufacturers recommendations</td>
</tr>
<tr>
<td></td>
<td>C. Pre-filter changes will be documented in Simplifi 797, work orders will be scanned and saved to reference documents.</td>
</tr>
<tr>
<td>PEC Certification vendor</td>
<td>D. Certification by a properly credentialed vendor will occur at least every six months.</td>
</tr>
</tbody>
</table>

6. **PROCEDURE – Hand Hygiene and Garbing**

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Pharmacy staff | A. Personnel who must enter the segregated compounding area to perform their job duties must report to their supervisor any illnesses that may adversely affect the safety or integrity of CSPs by causing either increased particle shedding or introduction of other infectious material such as but not limited to the following:  
  i. Fever  
  ii. Moderate to severe sunburn  
  iii. Eczema or other severe skin rash  
  iv. Cough, runny nose or active respiratory infection  
  v. Conjunctivitis  
  vi. Open wounds or weeping sores  
  B. If one of these conditions is present, the affected person will be excluded from working in the ISO classified areas by the supervisor until the condition is remedied. |
| Environmental Svc. Facilities Maintenance | C. Personnel must don the garb and perform hand hygiene in an order that generally proceeds from the dirtiest to cleanest body parts, top to bottom (head, face, and feet) prior to commencing sterile compounding activities including room cleaning and disinfection. |
| | D. Personnel shall don a surgical cover coat or chemotherapy-approved gown prior to entering the segregated compounding area to check compounded products or to put |
away IV room stock. The surgical cover coats are replaced daily. The chemotherapy gowns are disposable.
E. Sterile gloves will be used in controlled environment (primary engineering controls) over the isolator gloves.
F. No garb may be worn outside of the segregated compounding area.
G. Hand hygiene and garbing must be repeated anytime the worker leaves the SCA
H. Refer to Hand Hygiene and Garbing procedure.

7. PROCEDURE - Cleaning and Disinfection of Compounding Facilities and Primary Engineering Controls

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Services</td>
<td><strong>Cleaning Supplies:</strong></td>
</tr>
<tr>
<td></td>
<td>A. Cleaning supplies are stored in designated area to ensure segregation from compounding supplies.</td>
</tr>
<tr>
<td></td>
<td>B. See Table 1 List of Pharmacy approved cleaning and disinfecting products</td>
</tr>
<tr>
<td></td>
<td>C. Wipers, sponges and mops used are non-shedding.</td>
</tr>
<tr>
<td></td>
<td>D. Cleaning materials must be dedicated to the areas used and not be removed from those areas except for disposal. A mop and bucket will be stored in the segregated compounding areas. Pre-diluted cleaning solution containers will be sanitized stored in the SCA while in use. Alternatively pre-wetted cleaning supplies (mop heads, wipers) may be taken into the compounding area for use in cleaning.</td>
</tr>
<tr>
<td></td>
<td>E. Tacky mats that are used will be changed frequently as they become soiled. Frequency of the mat change is determined by organizational policy but no less frequently than daily and change may be required more frequently depending on need.</td>
</tr>
<tr>
<td></td>
<td>F. Refer to Job Aid <strong>Cleaning and Disinfecting</strong> for cleaning procedure.</td>
</tr>
<tr>
<td></td>
<td>G. Refer to Job Aid – <strong>Decontaminating and Cleaning CACI and BSC’s</strong> for cleaning procedure</td>
</tr>
<tr>
<td>Pharmacy technician</td>
<td><strong>Primary Engineering controls:</strong></td>
</tr>
<tr>
<td>Pharmacist</td>
<td>A. A germicidal all-purpose cleaning agent will be used for daily and monthly cleaning of PEC</td>
</tr>
<tr>
<td></td>
<td>B. A cleaning agent with sporidical properties will be used at least once per month during daily cleaning in place of the all-purpose germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>C. Disinfect with sterile 70% isopropyl alcohol (IPA) as follows:</td>
</tr>
<tr>
<td></td>
<td>D. The beginning of each compounding shift;</td>
</tr>
<tr>
<td></td>
<td>E. Immediately prior to each batch;</td>
</tr>
<tr>
<td></td>
<td>F. Every 30 minutes throughout the compounding shift when ongoing compounding activities are occurring;</td>
</tr>
<tr>
<td></td>
<td>G. After spills and</td>
</tr>
<tr>
<td></td>
<td>H. When microbial contamination is known to have been or is suspected of having been introduced.</td>
</tr>
<tr>
<td></td>
<td>I. Cleaning and disinfection of the controlled environments will not be performed while compounding is taking place</td>
</tr>
<tr>
<td></td>
<td>J. For the hazardous PEC: Cleaning will take place in the order of deactivation, decontamination followed with sIAPA. These 3 steps are performed at the beginning and end of the each shift, between different compounding sessions, if there is a spill or if a suspected contamination has taken place.</td>
</tr>
</tbody>
</table>

| Environmental Services | **Compounding Areas:**                                               |
|                        | A. A germicidal all-purpose cleaning agent will be used for daily and monthly cleaning of all surfaces in the segregated compounding area. |
| Pharmacy technician    | B. A cleaning agent with sporidical properties will be used at least once per month during daily cleaning in place of the all-purpose germicidal detergent for cleaning surfaces in segregated compounding area. |
| Pharmacist             | C. Environmental Services staff must don appropriate PPE when entering the room for daily and monthly cleaning: Gown, sterile gloves and eye protection. |
### Three-Time Cleaning:

D. Environmental Services staff will initial each cleaning activity on a paper checklist on a daily basis.

- A. Three-time cleaning may be performed when the following conditions occur:
- B. Before the first use and testing of a new facility
- C. Before the introduction of new furniture or equipment into controlled environments
- D. After action levels are exceeded occurring during environmental monitoring air or surface sampling procedures
- E. After any maintenance work performed in the segregated compounding area that would compromise environmental integrity
- F. Power outages of greater than 59 minutes affecting the primary and secondary engineering controls (effectiveness validated through environmental sampling).
- G. Additionally at the discretion of the pharmacy manager
- H. Three-time cleaning will be performed using a germicidal detergent for the first two cleanings with the designated sporidical agent used for the final cleaning. The sporidical agent is used last to increase the dwell time on surfaces.
- I. The areas cleaned in a Three-Time Clean, unless otherwise noted include all surfaces inside the PECs as well as all surfaces in the controlled environment (all activities of both daily and monthly cleaning).

### 8. PROCEDURE – Maintenance and Use of Aseptic Isolators

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy technician</td>
<td>A. Sterile gloves shall be worn on top of the isolator gloves (closest to the products) within the ISO Class 5 chamber during compounding and other critical aseptic conditions. Fresh sterile gloves must be donned when compounding begins; in the event that compounding staff change and anytime continuous compounding is stopped.</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>B. When compounding is completed for the shift or operators change, the sterile gloves donned over the isolator gloves will be removed and properly disposed of.</td>
</tr>
<tr>
<td></td>
<td>C. In general, do not turn off any primary engineering control, including CAIs or CACIs. They are made to run continuously. The blower and light may be turned off per the manufacturer if the isolator is not going to be used within 8 hours.</td>
</tr>
<tr>
<td></td>
<td>D. Utilize sharps container hook ups that permit placement of sharps units outside of the isolator thereby minimizing disruption of air flows.</td>
</tr>
<tr>
<td></td>
<td>E. Consider ergonomic issues in working in isolators to improve worker comfort and reduce worker injury by adjusting the height of the isolator.</td>
</tr>
<tr>
<td></td>
<td>F. All components, supplies and equipment needed to compound a specific batch or patient-specific preparation must be gathered and disinfected with the appropriate disinfecting agent prior to introduction into the isolator.</td>
</tr>
<tr>
<td></td>
<td>G. The door to the pass through chamber and the door from the pass thru chamber to the compounding chamber must never be open simultaneously except during cleaning which occurs at least 20 minutes after compounding is completed.</td>
</tr>
<tr>
<td></td>
<td>H. At no time will components for multiple batches or multiple patient-specific preparations be placed inside of an isolator at the same time.</td>
</tr>
<tr>
<td></td>
<td>I. Prior to placing items into the pass through chamber, verify that the inner door from the pass through chamber to the compounding chamber is closed.</td>
</tr>
<tr>
<td></td>
<td>J. Place all items that have been wiped with sterile 70% IPA inside the pass through chamber and close the outer door to the pass through chamber.</td>
</tr>
<tr>
<td></td>
<td>i. <strong>CAI</strong>: No wait or purge time is required during material transfer process (NU-PR797 CAI).</td>
</tr>
<tr>
<td></td>
<td>ii. <strong>CACI</strong>: A minimum of a 1 minute pass-through purge or wait time is recommended for hazardous drug removal to dilute and flush hazardous drug residue from compounded materials.</td>
</tr>
</tbody>
</table>
Hand hygiene and Garbing when working in CAI/CACI:

A. **CAI**: All standard garb required except shoe, head, facial hair or face covers when working in the isolator; refer to manufacturer performance evaluation for garbing requirements.

B. **CACI**: All standard garb required except head, facial hair or face covers when working in the isolator. Operator must don a chemo gown and shoe covers; refer to manufacturer performance evaluation for garbing requirements.
   a. The compounding employee must also decontaminate their gloved gauntlet hands with sterile 70% IPA and then don sterile gloves over the isolator gauntlet gloves prior to compounding.
   b. Chemotherapy rated sterile gloves must be donned over isolator gauntlet gloves

C. The Pharmacy PAPR must be worn if the front panel of the CACI is opened for decontamination and cleaning.

D. Gloved Fingertip Sampling (initial sampling performed during garbing competency) must be completed inside of the CAI or CACI

Disinfection and cleaning:

A. The exterior of all isolators will be cleaned with the designated disinfecting agent during monthly cleaning.

B. Never use abrasive cleaners or organic solvents on the acrylic components such as the windows or view ports. Consult the manufacturer’s recommendations for cleaning agents.

C. Never spray any type of cleaner directly onto the control panel, gauges of the unit, grills or HEPA filters.

D. Follow the manufacturer’s instructions to clean these parts of the isolator for cleaning sliding trays and drip trays if present.

E. **Refer to Job Aid- Cleaning and Disinfecting** (see section 7 above)

F. **Refer to Job Aid – Decontaminating and Cleaning CACI and BSC’s** (see section 7 above)

### 9. PROCEDURE – Beyond Use Dating

<table>
<thead>
<tr>
<th>Responsible Person</th>
<th>Steps</th>
</tr>
</thead>
</table>
| Pharmacist in Charge | A. Pharmacy Manager or designee is responsible for determining beyond use dating.  
B. Beyond use dating is assigned to CSPs based on the default storage periods in USP <797> and is based on both the chemical stability and microbial sterility of the components as well as the compounding risk level of a given CSP.  
C. BUDs may NOT exceed those based on the storage times published in USP Chapter <797> (refer to Table 2 in this policy) unless sterility testing is performed for each batch in accordance with USP Chapter <71>. (see Addendum)  
D. If a given CSPs chemical stability is a lesser time than the maximum storage period published in USP Chapter <797>, then the CSP’s BUD is assigned based on the shorter chemical stability of the formulation. When weighing both the stability and the sterility (storage) dates, the lesser time is always used to assign the BUD.  
E. Maximum BUDs for CSPs according to risk level are valid as long as the temperature of the storage area (controlled room, cold or frozen temperatures) are within limits and documented |

Page 7 of 10
F. See Table 2 and Table 3 Beyond use Dating and Risk levels (see part C in this section)
G. Valid References will be used to determine appropriate beyond use dating
H. The “EXP” field on the EPIC product label will be used to indicate the BUD for compounded sterile products. The field will also be used to indicate the out of overwrap BUD for premixed products.

<table>
<thead>
<tr>
<th>Pharmacist Pharmacy technician</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Multidose vials, Single use vials and Pharmacy Bulk Package</strong></td>
</tr>
<tr>
<td>A. BUD for MDVs once punctured that are kept at their proper storage temperature is 28 days subsequent to initial use or based on expiration date on packaging or other manufacturer instructions.</td>
</tr>
<tr>
<td>B. MDVs of this type must be dated with the specific beyond use date and time based on the time and date of initial use.</td>
</tr>
<tr>
<td>C. Contents remaining past the established BUD must be properly discarded.</td>
</tr>
<tr>
<td>D. Single use vials, bags, bottles that are sterile but that have been opened or punctured must be used for compounding within 1 hour if exposed to air quality less than ISO Class 5.</td>
</tr>
<tr>
<td>E. Single use containers that have been punctured may be used for up to 6 hours if exposed to air that is ISO Class 5.</td>
</tr>
<tr>
<td>F. Single use containers of this type must be dated with the specific beyond use date and time based on the time and date of initial use.</td>
</tr>
<tr>
<td>G. Contents remaining past the established BUD must be properly discarded.</td>
</tr>
<tr>
<td>H. Ampules are never retained for any period of time. Once they are opened, the remaining contents must be promptly discarded.</td>
</tr>
<tr>
<td>I. Pharmacy Bulk Packages (PBP) are to be treated in the same manner as single use vials since these formulations were intended for use by a pharmacy to compound many doses at once and they do not contain preservatives</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pharmacy technician Pharmacist</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Redispensing CSP</strong></td>
</tr>
<tr>
<td>A. CSPs may only be redispensed if all of the following conditions are met:</td>
</tr>
<tr>
<td>a. It can be verified that the CSP was continually stored under required conditions (refrigerated, protected from light, etc.) AND</td>
</tr>
<tr>
<td>b. There is no evidence of tampering AND</td>
</tr>
<tr>
<td>c. The CSP will be administered before the original BUD assigned.</td>
</tr>
<tr>
<td>B. BUDs will not be reassigned beyond the original assignment unless there is supporting evidence from sterility testing and a quantitative assay of ingredients</td>
</tr>
<tr>
<td>C. CSP returned to the pharmacy for redispensing must be wiped with a Sanicloth prior to placing in Pharmacy storage location.</td>
</tr>
</tbody>
</table>

### 10. Multidose Vial Handling in the Pharmacy Environment

<table>
<thead>
<tr>
<th>Responsible person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy Staff</td>
<td>To prevent contamination of in use multidose vials the following procedure will be followed:</td>
</tr>
<tr>
<td></td>
<td>A. Multidose vials are only punctured in an ISO 5 environment.</td>
</tr>
<tr>
<td></td>
<td>B. The vial stopper is swabbed with sterile IPA prior to each vial entry</td>
</tr>
<tr>
<td></td>
<td>C. The vial is capped with a foil cap prior to removal from the ISO 5 environment.</td>
</tr>
<tr>
<td></td>
<td>D. The vial is labeled with the date of first use, the beyond use date and the users initials</td>
</tr>
<tr>
<td></td>
<td>E. The vial is placed in a clean zip lock bag prior to removal from the ISO 7 SCA</td>
</tr>
<tr>
<td></td>
<td>F. The vial is stored at the appropriate temperature in the designated storage location</td>
</tr>
<tr>
<td></td>
<td>G. To ensure multidose vials are used efficiently the vials will be returned to original designated storage location.</td>
</tr>
<tr>
<td></td>
<td>H. Refer to <strong>RX 4004</strong> for handling of in use multidose vials in patient care areas</td>
</tr>
</tbody>
</table>
11. Procedure – Batch Compounding Quality Assurance

<table>
<thead>
<tr>
<th>Responsible person</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacist Pharmacy Technician</td>
<td>CSPs which are prepared as a batch process must be prepared in a manner that provides that packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices. Controlled Substance CSPs will be prepared as follows:</td>
</tr>
<tr>
<td></td>
<td>1. Complete C-II Safe compounding transaction</td>
</tr>
<tr>
<td></td>
<td>2. ENTER PROCESS LOT NUMBER = C-II SAFE ASSIGNED CS NUMBER.</td>
</tr>
<tr>
<td></td>
<td>3. Change Compounding LOT to &quot;Sterile IV Compounding&quot; and fill in all required fields</td>
</tr>
<tr>
<td></td>
<td>4. Include the component NDC in the manufacturer fields</td>
</tr>
<tr>
<td></td>
<td>5. Print product labels</td>
</tr>
<tr>
<td></td>
<td>6. Print Batch template</td>
</tr>
<tr>
<td></td>
<td>7. Prep and transport all components needed into the SCA.</td>
</tr>
<tr>
<td></td>
<td>8. Draw up components as directed in batch template.</td>
</tr>
<tr>
<td></td>
<td>11. Store finished batch in CII Safe Refrigerator.</td>
</tr>
<tr>
<td></td>
<td>12. Attach batch template to CII safe standard compounding record and file.</td>
</tr>
</tbody>
</table>

Definitions

**USP Chapter 797: Pharmaceutical Compounding-Sterile Preparations:** Provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices.

**USP Chapter 800: Hazardous Drugs—Handling in Healthcare Settings:** Describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety and environmental protection.

**Aseptic media fill:** Verify and continuously monitor the quality of the aseptic technique of all individuals involved in compounding of sterile preparations. Verify and continuously monitor the capability of the compounding environment and processes used to produce compounded sterile preparations (CSPs).

**Viable Air Sampling:** Viable air sampling is a facility metric of the Environmental Sampling Plan (ESP). The objective of viable air sampling (VAS) is to obtain representative estimates of viable bioburden in compounding areas.

**Surface Sampling:** Surface sampling is primarily a personnel metric of the Environmental Sampling Plan (ESP). Data from surface sampling are used along with other environmental sampling results to detect adverse shifts in microbiological conditions in a timely manner, allowing for effective corrective action.

Primary Engineering controls (PEC)

- Compounding Aseptic Isolator
- Compounding Aseptic Containment Isolator
- ISO 5 environment
Beyond Use Date: a beyond-use date (BUD) is the date that identifies the time by which a CSP must be used before it is at risk for chemical degradation or contamination and signifies the date and time beyond which a CSP cannot be begun to be administered.

Expiration date: is only assigned by product manufacturers at the time a given component is packaged. It is determined by multiple, scientifically valid, product/package-specific research studies and approved by the FDA as part of the official package insert. The expiration date is stamped on the vial and is dependent on the storage of the unopened container per manufacturer's instructions.

Multi dose vial: preparation intended for parenteral administration only and usually containing antimicrobial preservatives.

Single dose vial: parenteral preparation intended for single use and labeled as such.

Regulatory Requirements
USP Chapter <797> Pharmaceutical Compounding-Sterile Preparations.
USP Chapter <800> Hazardous Drugs – Handling in Healthcare settings

References
The USP Compounding Compendium 2019
Simplifi 797 reference documents
Simplifi 797 and CriticalPoint Crosswalk

To start, identify the Simplifi 797 Competency that you wish to train for. Your assigned competencies are displayed on the Simplifi 797 Competency tab. To access training courses, click the CriticalPoint link on the Competency Tab and sign-in using your CriticalPoint account credentials.

Once in CriticalPoint, a list of Courses will appear on the Enrolled tab under Learning Activities. Locate the Course that correlates to the Simplifi 797 Competency you wish to prepare for using the guide below as a reference. Courses are made up of one Lesson and one Post Test. Click on the Course’s “Go” button to drill into the corresponding Lesson and Post Test.

Complete the Lesson first. Next, finish the Post Test to receive credit. When done with both, click the My Account link to return to the main Course list. All Post Tests are 1 CE Credit unless otherwise indicated.

Note: Some CriticalPoint Lessons and Post Tests will help prepare you for multiple Simplifi 797 Competencies. These items are marked with an asterisk. Ask your administrator which you are required to complete.

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<th>Simplifi 797 Competency</th>
<th>CriticalPoint Course</th>
<th>Lessons &amp; Post Test</th>
</tr>
</thead>
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<tr>
<td>Cleaning and Disinfection</td>
<td>(5) Sanitization of Pharmacy Controlled Environments</td>
<td>1. Overview of Cleaning and Disinfection of Pharmacy Controlled Environments</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Cleaning and Disinfection of Primary Engineering Controls</td>
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<td>3. Cleaning and Disinfection of Secondary Engineering Controls and Segregated</td>
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<td>Compounding Areas</td>
</tr>
<tr>
<td>Contamination Control/Aseptic Processing</td>
<td>(6) Aseptic Technique and Related Work Practices</td>
<td>1. Overview of Quality and Responsibilities of Compounding Personnel</td>
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<td>2. Aseptic Technique and Conduct in Controlled Environments</td>
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<td>3. Proper Material Handling</td>
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<td></td>
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<td>4. Use of Syringes, Needles, Vials, Ampules and Filter</td>
</tr>
<tr>
<td>Initial Goved Fingertip Sampling</td>
<td>(3) Personal Sampling Metrics</td>
<td>1. Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling*</td>
</tr>
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<td>(2 CE Credits available)</td>
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<tr>
<td>Ongoing Goved Fingertip Sampling</td>
<td>(3) Personal Sampling Metrics</td>
<td>1. Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling*</td>
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<td></td>
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<td>(2 CE Credits available)</td>
</tr>
<tr>
<td>Personnel hygiene, handwashing, garbing</td>
<td>(3) Personal Sampling Metrics</td>
<td>1. Personnel Hand Hygiene, Garbing and Gloved Fingertip Sampling*</td>
</tr>
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<td>(2 CE Credits available)</td>
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<tr>
<td>Simplifi 797 Competency</td>
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<td>Personnel Media Fill Skill Verification</td>
<td>(3) Personal Sampling Metrics</td>
<td>1. Personnel Aseptic Media Fill and Competency Evaluation*</td>
</tr>
<tr>
<td>Automated Compounding Devices</td>
<td>(1) Fundamentals of Sterile Compounding</td>
<td>1. Use of Automated Compounding Devices (ACDs)</td>
</tr>
<tr>
<td>Environmental Sampling</td>
<td>(3) Personal Sampling Metrics</td>
<td>1. Personnel Hand Hygiene, Garbing and Gloved Finger Tip Sample* (2 CE Credits Available) 2. Personnel Aseptic Media Fill and Competency Evaluation*</td>
</tr>
<tr>
<td>Final Release checks: Filter Integrity Testing (Bubble Point)</td>
<td>(7) High Risk Compounding</td>
<td>1. Moist Dry Heat Sterilization</td>
</tr>
<tr>
<td>Final Release checks: Pyrogen Testing (Gel Clot Method)</td>
<td>(1) Fundamentals of Sterile Compounding</td>
<td>1. Quality Releases and Final Checks of CSPs 2. Bacterial Endotoxin (Pyrogen) Testing</td>
</tr>
<tr>
<td></td>
<td>(7) High Risk Compounding Practices</td>
<td>1. Filtration and Sterility Testing</td>
</tr>
<tr>
<td>Simplifi 797 Competency</td>
<td>CriticalPoint Course</td>
<td>Lessons &amp; Post Test</td>
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<tr>
<td>Material Handling</td>
<td>(1) Fundamentals of Sterile Compounding</td>
<td>1. Labeling and Packaging</td>
</tr>
<tr>
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<td>(6) Aseptic Technique and Related Work Practices</td>
<td>2. Proper Material Handling*</td>
</tr>
<tr>
<td>Primary Engineering Controls: Barrier Isolator</td>
<td>(2) Engineering Controls for Sterile Compounding</td>
<td>3. Primary Engineering Controls: Function, Use, Testing and Certification* (2 CE Credits available)</td>
</tr>
<tr>
<td>Primary Engineering Controls: Biological Safety Cabinets</td>
<td>(2) Engineering Controls for Sterile Compounding</td>
<td>1. Primary Engineering Controls: Function, Use, Testing and Certification* (2 CE Credits available)</td>
</tr>
<tr>
<td>Primary Engineering Controls: Laminar Air Flow Workbenches</td>
<td>(2) Engineering Controls for Sterile Compounding</td>
<td>1. Primary Engineering Controls: Function, Use, Testing and Certification* (2 CE Credits available)</td>
</tr>
<tr>
<td></td>
<td>(1) Fundamentals of Sterile Compounding</td>
<td>1. Determining Beyond-Use Dating</td>
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<td>2. Master Formulation and Compounding Records</td>
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<td>3. General Elements of Documentation</td>
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<td>4. Purpose and Effective Use of Standard Operating Procedures</td>
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<td></td>
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<td>5. The History of Compounding and USP Sterile Compounding Chapters</td>
</tr>
<tr>
<td></td>
<td>(6) Aseptic Technique and Related Work Practices</td>
<td>1. Sterile Compounding on Patient Units</td>
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<td><em>(for nursing and medical staff)</em></td>
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