Agenda Item/Title: Sixth Avenue Medical Pharmacy

Date SBAR Communication Prepared: 1/16/2020

Reviewer: Irina Tiginyanu

Link to Action Plan:
- Action
- Information
- Follow-up
- Report only

Situation:

Pharmacy is seeking approval for their technician and assistants AUP

Background:

Assessment:

Pharmacy technicians and assistants are performing within their scope of practice

Technicians are performing specialized function:

- Sterile compounding

Recommendation:

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

Follow-up Action:
Pharmacy License Application

This is for: ☑ New ☐ Change of Ownership ☐ Change of Location – Current License # ☐ Name Change Only – Current Facility Name

Check One

☐ Association
☑ Corporation
☐ Federal Government Agency
☐ Limited Liability Company
☐ Limited Liability Partnership

☐ Limited Partnership
☐ Municipality (City)
☐ Municipality (County)
☐ Non-Profit Corporation
☐ Partnership

☑ Sole Proprietor
☐ State Government Agency
☐ Tribal Government Agency
☐ Trust

1. Demographic Information

UBI # 329 014 5260 | Federal Tax ID (FEIN) # 91-0762659

Legal Owner/Operator Name
Sixth Avenue Medical Building Pharmacy, Inc.

Mailing Address
508 W 6th Ave
City: Spokane | State: WA | Zip Code: 99204 | County: Spokane

Phone (enter 10 digit #)
509-455-9345 or 509-868-6559
Fax (enter 10 digit #)
509-455-4479

Email Address
loaavenuepharmacy@gmail.com
Web Address: www.sixthavenuepharmacy.com

Facility/Agency Name (Business name as advertised on signs or Web site)
Sixth Avenue Medical Pharmacy

Physical Address
508 W 6th Ave
City: Spokane | State: WA | Zip Code: 99204 | County: Spokane

Facility Phone (enter 10 digit #)
509-455-9345
Fax (enter 10 digit #)
509-455-4479

Email Address:
loaavenuepharmacy@gmail.com

Mailing Address (If different than physical address)
Same as above

License #

Sixth Avenue Medical Pharmacy
508 W 6th Ave
Spokane, WA 99204-2770
PHAR.CF.60411553
2. Facility Information

Type of Pharmacy (Check all that apply)
- Community/Retail
- Hospital
- Jail
- Long-term Care (LTC)
- Mail-Order
- Nuclear
- Parenteral
- Internet

Pharmacy Hours—Indicate the hours the pharmacy will be open

<table>
<thead>
<tr>
<th>Monday-Friday</th>
<th>Saturday</th>
<th>Sunday</th>
<th>Holidays</th>
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</thead>
<tbody>
<tr>
<td>8:30 AM - 6 PM</td>
<td>Closed</td>
<td>Closed</td>
<td>Closed</td>
</tr>
</tbody>
</table>

Drug Enforcement Administration (DEA) Registration Number

DEA Number: AS11011009

Background Questions

Yes No

1. Have any applicants, partners, or managers had a suspension, revocation, or restriction of a professional license?

   If yes, list and explain on a separate sheet of paper.

2. Have any applicants, partners, or managers been found guilty of a drug or controlled substance violation?

   If yes, list and explain on a separate sheet of paper.

Pharmacist in Charge

Erik Nelson

License Number: PH0343873

3. Contact Information

Contact Person

Erik Nelson

Title: President/Owner

Phone (enter 10 digit #): 509-888-6559

Email Address: erik.nelson@gmail.com

Contact Person

Jeff Harrell

Title: Co-owner/VP

Phone (enter 10 digit #): 360-244-5984

Email Address: Jeff.Harrell@SurecareRx.com

4. Additional Information

Date of Incorporation: 1984

Corporate Number: 338 019 524

State of Corporation: Washington

Legal Owner Information—attach additional completed pages if you need more space.

List names, addresses, phone numbers, and titles of corporate officers, partners, members and managers.

Name | Address | Phone (enter 10 digit #) | Title
--- | --- | --- | ---
Erik Nelson | 3029 E 19th Ave, Spokane, WA 99203 | 509-888-6559 | President
Jeff Harrell | 101 First Ave South, Ilwaco, WA 98624 | 360-244-5984 | Vice President/Co-owner

Change of Ownership Information

Previous Name of Legal Owner: Gerald L Stocker

Previous Name of Facility: Sixth Avenue Medical Pharmacy

Previous Pharmacy License #: PHAR.CF.000070A

Effective Date of Ownership Change: to be determined
<table>
<thead>
<tr>
<th>Name</th>
<th>License #</th>
</tr>
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<tbody>
<tr>
<td>Erik Nelson</td>
<td>PH603432873</td>
</tr>
<tr>
<td>Jennifer Bramley-Dailey</td>
<td>PH00043389</td>
</tr>
<tr>
<td>Susan Marchi-Kellogg</td>
<td>PH00011013</td>
</tr>
</tbody>
</table>

**Signature**

I certify I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify the information herein submitted is true to the best of my knowledge and belief.

Erik Nelson

Signature of Owner/Authorized Representative of Pharmacy

Date: 8-13-13
Pharmacy Ancillary Utilization Application

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

1. Demographic Information

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<th>Federal Tax ID (FEIN) #</th>
<th>91-0702659</th>
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<tr>
<td>Legal Owner/Operator Name</td>
<td><strong>Erik Nelson</strong></td>
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<tr>
<td>Pharmacy License #</td>
<td><strong>PHAR.CF, 00000786</strong></td>
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<tr>
<td>Pharmacy Name</td>
<td><strong>Sixth Avenue Medical Pharmacy</strong></td>
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<tr>
<td>Physical Address</td>
<td><strong>508 W 16th Ave</strong></td>
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<tr>
<td>City</td>
<td><strong>Spokane</strong></td>
<td>State (WA)</td>
<td>Zip Code</td>
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<tr>
<td>Facility Phone (enter 10 digit #)</td>
<td><strong>509-455-7345</strong></td>
<td>Fax (enter 10 digit #)</td>
<td><strong>509-455-4479</strong></td>
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2. Facility Specific Information

Number of Employees:
- Pharmacists: 2
- Technicians: 2
- Assistants: 1

3. Key Individuals

Responsible Pharmacist: **Erik Nelson**
License #: **PH160343873**

Signature

I certify I have received, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify the information herein submitted is true to the best of my knowledge and belief.

Signature of Owner/Authorized Representative of Pharmacy

**Erik Nelson**

Print Name

Date: 8/12/13

RECEIVED

President CREDENTIALING

Print Title
Sixth Avenue Medical Pharmacy
508 W 6th Ave
Spokane, WA 99204
(509) 455-9345

Ancillary Personnel Utilization Plan

Sixth Avenue Medical Pharmacy will utilize pharmacy technicians and assistants in the course of its normal business processes. Technicians will be utilized in a ratio of no more than 3 to each 1 pharmacist. Assistants will be utilized as needed and determined by a licensed pharmacist. General job duties are outlined below.

Technicians

A. Places, receives, unpacks and stores drug orders.
B. Files and retrieves various pharmacy records as required.
C. Files completed prescriptions alphabetically on the shelf for patient pickup.
D. Maintains assigned work areas and equipment in clean and orderly condition.
E. Hands out refills when specifically requested to do so by a pharmacist where no counseling is deemed necessary.
   1. Helps customers at the front counter with prescription pickups and purchases.
   2. Helps customers at the drive through window.
F. Handles nonprofessional phone calls to/from:
   1. Patients requesting refill of a prescription by number.
   2. Calls to physician’s office requesting refill authorization:
      a. Refill requests shall be made stating the patient’s name, medication and strength, number of doses and date of prior refills.
      b. Any additional inquiries by the office concerning the prescription must be referred to the pharmacist.
   3. Calls from physician’s office authorizing refills providing no changes in the prescription are involved.
   5. Calls regarding business hours or delivery services.
   6. Calls regarding the availability of goods and services—these might require transferring the call to another person.
   7. Inquiries from patients asking if their prescriptions are refillable or the number of refills left, etc.
8. Calls dealing with the ordering of drugs and supplies from wholesalers and distributors.

G. Operates cash register and related front counter tasks.

H. Counts and pours from stock bottles 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 initialed by a licensed pharmacist.

I. Reconstitutes restoration of original form of medication previously altered for preservation and storage by addition of a specific quantity of distilled water or provided diluent requiring no calculation. In 100% of the cases, the accuracy of the technician is checked and the work initialed by a licensed pharmacist.

J. Enters prescription data from traditional hard copy prescriptions into the computer and monitors label printing.

K. Retrieves electronic prescription data and enters it into the computer database.

L. Reviews patient profile to retrieve specific clerical and other information as directed by a pharmacist.

M. Calls to and/or from the physician's office dealing with profile information where no interpretation is necessary, i.e., quantity, date last filled, price, etc.

N. Performs tasks under pharmacist’s supervision such as obtaining individual prepackaged, labeled medications for prescriptions, obtains stock bottles for prescription filling.

O. Fills compliance packaging “blister packs” and Phillips Medication Machine boxes with appropriate medications. This function is performed under the direct supervision of a licensed pharmacist and the accuracy of the prescription contents is checked and initialed by a licensed pharmacist.

P. With appropriate training, compounds custom medications according to a preset formula with specific procedures. This function is performed under the direct supervision of a licensed pharmacist. In 100% of the cases, the accuracy of the technician is checked and the work initialed by a licensed pharmacist.

Q. Delivers medications to patient homes as directed by a licensed pharmacist.

**Assistants**

A. Places, receives, unpacks and stores drug orders.

B. Files and retrieves various pharmacy records as required.

C. Prepares mail and UPS packages for delivery.

D. Maintains assigned work areas and equipment in clean and orderly condition.
E. Hands out refills when specifically requested to do so by a pharmacist where no counseling is deemed necessary.
   1. Helps customers at the front counter with prescription pickups and purchases.
   2. Helps customers at the drive through window.

F. Handles nonprofessional phone calls to/from:
   1. Patients requesting refill of a prescription by number.
   2. Calls concerning price information.
   3. Calls regarding business hours or delivery services.
   4. Calls regarding the availability of goods and services—these might require transferring the call to another person.
   5. Inquiries from patients asking if their prescriptions are refillable or the number of refills left, etc.
   6. Calls dealing with the ordering of drugs and supplies from wholesalers and distributors.

G. Operates cash register and related front counter tasks.

H. Counts and pours from stock bottles, which have been pulled by either a technician or pharmacist, 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 initialed by a licensed pharmacist.

I. Fills compliance packaging “blister packs” and Phillips Medication Machine boxes with appropriate medications, which have been pulled from the shelf by a technician or pharmacist. This function is performed under the direct supervision of a licensed pharmacist and the accuracy of the prescription contents is checked and initialed by a licensed pharmacist.

J. Delivers medications to patient homes as directed by a licensed pharmacist including writing up the deliveries for each day.

K. Refills supplies daily including:
   1. Paper sacks
   2. Vials, caps & liquid bottles
   3. Soda pop, chips & candy (both out front, in back and drawer by cash register).
   4. Empties shred bins that contain sensitive patient information
# Technician Specialized Function—Program Review Form

**Chapter 246-901 WAC**

**Date:** 1/16/2020  
**Responsible Pharmacist:** Erik Nelson

**Pharmacy Name:** Sixth Avenue Medical Pharmacy  
**License #:** __________

**Pharmacy Address:** 508 W 6th Ave, Spokane, WA 99204  
**Phone #:** 509-455-9345

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<tr>
<th>Does the Program identify pharmacy technicians who meet the criteria for participation?</th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
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<th>Did the responsible pharmacist sign the program proposal?</th>
<th>Yes</th>
<th>No</th>
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<tr>
<th>Training Program at least 8 hours long and specifies the following categories:</th>
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| a. Basic skills in health system pharmacy, including goals and requirements of unit-dose medication systems.  
  b. Common medication errors and prevention strategies.  
  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.  
  c. 99% accuracy for success. |
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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. |
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Forms used in training, validation and audits are submitted with program?

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<tr>
<th>Yes</th>
<th>No</th>
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Utilization plan for specialized pharmacy technician functions is included with the program?

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<th>Yes</th>
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**Comments:** Approve the sterile compounding function

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### For staff use only

**Review completed on January 16, 2020 by Irina Tiginyanu**  
**Agreement type:** New

**Staff decision:** Approved  
**Board decision:** Approved  
**Board agenda:**

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Title of SOP: General Aseptic Technique

1.0 PURPOSE
1.1 The purpose of this procedure is to establish requirements for using aseptic technique in any area to minimize contamination.

2.0 SCOPE
2.1 This procedure applies to all compounding personnel at Sixth Avenue Medical Pharmacy.

3.0 RESPONSIBILITY
3.1 The Pharmacist-in-Charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

4.0 REFERENCES
4.1 USP Current Version <797> “Pharmaceutical Compounding – Sterile Preparations”
4.2 SOP 9.090 “Proper Hand Washing Procedure”
4.3 SOP 9.100 “Required Garb for Clean Room Facility Access”

5.0 DEFINITIONS
5.1 Microbial Control – produces a known state of microbial contamination
5.2 Aseptic Technique – methodology used in any area to minimize contamination of microbes
5.3 Sterile Filling – production process performed in the absence of microorganisms in an aseptic processing area (APA)
5.4 Bioburden – number of microorganisms in the final product prior to sterilization
5.5 Disinfectant – agent (usually chemical) used to kill, inhibit the growth of or physically remove microorganisms
5.6 Aseptic Area – region in which microbial and particulate contamination is maintained within specified limits

6.0 FREQUENCY
6.1 Daily when compounding activities involving aseptic technique are planned

7.0 EQUIPMENT & SUPPLIES
7.1 N/A

8.0 GENERAL INFORMATION
8.1 N/A

9.0 PROCEDURE
9.1 Prior to working in the compounding area:
9.1.1 Work surfaces should be disinfected before and after use.

Approved by __________________________ Date ______________
Implemented by __________________________ Date ______________
9.1.1 Compounding equipment and samples should be disinfected prior to placement on the bench-top.

9.2 When working in an aseptic area, the following should be avoided:

9.2.1 Leaning over the work area and open containers.
9.2.1 Resting hands on the work area.
9.2.2 Coughing over the work area.
9.2.3 Leaning objects against the back wall of the hood.
9.2.4 Moving rapidly in the compounding area.
9.2.5 Using a hood as a storage space when not in use.
9.2.6 Eating, drinking, chewing gum, etc.
9.2.7 Storing food, drinks or personal items in the aseptic area.
9.2.8 Performing any activities unrelated to compounding.

9.3 When working in an aseptic area, the following should be performed:

9.3.1 Wearing appropriate clean room apparel for the level of sterile compounding to be performed.
9.3.2 Disinfecting hoods, compounding equipment and bench-tops prior to use.
9.3.3 Keeping work areas clutter-free.
9.3.4 Disinfecting work surfaces in between testing of batches/samples.
9.3.5 Limiting arm movement in hoods.
9.3.6 Using slow, purposeful bodily movements.
9.3.7 Immediately wiping spills using appropriate disinfecting procedures.
9.3.8 Immediately discarding any bio-hazard or contaminated material.
9.3.9 When working with a sterile container with a cap/lid, placing the cap/lid on its side if it must be laid on the work surface.

9.4 When working in a laminar air-flow workbench (LAFW) or compounding aseptic isolator (CAI), the following should be performed:

9.4.1 Personnel should wash their hands prior to entering the hood and when re-entering the sterile compounding area.
9.4.2 Appropriate gowning suitable for sterile compounding should be worn. Anyone working under a hood should don shoe covers or dedicated shoes, hair covering, facemask, a full-length lab coat and gloves as required.
9.4.3 The hood blower should be operating continually, 24 hours a day. If this is not possible, the hood should be turned on at least 30 minutes prior to use.
9.4.4 The interior work surface and sides should be cleaned with a suitable disinfectant prior to and after each use. Avoid spraying or squirting solutions directly onto the HEPA filter.
9.4.5 Any bottles, vials, or containers should be wiped down with alcohol or disinfectant prior to placement in the hood to prevent possible contamination.
9.4.6 Gloves should be disinfected periodically during compounding. Allow disinfected gloves to air-dry before handling samples or instruments. **NOTE:** gloves should not be wet with disinfectant while compounding.

9.5 Aseptic Technique in the LAFW or CAI

9.5.1 Outer pouches and wraps should be removed at the edge of the hood as the sterile contents are brought into the hood.

9.5.2 Objects placed in the hood should be positioned to allow sufficient airflow with minimal obstruction. A direct path must be maintained between the filter and the area inside the hood where manipulations are being performed. Large objects should never be placed near the back of the hood.

9.5.3 Always minimize clutter.

9.5.4 Waste and other items unrelated to compounding should never enter the hood.

9.5.5 Work should always be performed approximately in the center of the work surface. When working in a horizontal LAFW, all work must be performed at a distance of no less than 6 inches from the front edge of the work surface.

9.5.6 Disinfect gloves periodically. Glove cleanliness is reduced each time non-sterile items are handled.

9.6 Syringes and Needles

9.6.1 Commercially sterilized, disposable, and latex-free syringes with a locking mechanism for needles shall be used to compound sterile preparations.

9.6.2 To maximize accuracy, the smallest syringe that can hold a desired amount of solution shall be used.

9.6.3 To maintain sterility, two parts of the syringe shall never be touched: (1) the tip and (2) the plunger.

9.6.4 After proper sanitizing of the exterior package of the syringe, the syringe shall be removed from the protective syringe package in the LAFW.

9.6.5 The exterior package shall be discarded appropriately and shall not be placed on any surface within the LAFW.

9.6.6 Needles shall be selected and opened following the same procedure for selecting/opening syringes.

9.6.7 To maintain sterility, two parts of the needle shall never be touched or swabbed with alcohol: (1) the hub and (2) the shaft.

9.6.8 Before inserting a needle into a vial/bag, the injection site must be wiped with sterile 70% isopropyl alcohol using an alcohol swab or a low-lint wipe. Make sure to wipe in one direction to sterilize the port and to reduce particulate matter.

9.6.9 Used syringes and needles shall be placed in an appropriate medical sharps container. Once the medical sharps container has reached the maximum fill limit, it shall be sealed appropriately and discarded with a contracted medical waste company.

9.7 Personal Hygiene

9.7.1 Hair and exposed skin surfaces should be cleaned daily.
9.7.2 Long hair should be pulled back.
9.7.3 Cosmetics and jewelry should not be worn in controlled areas such as the clean room.
9.7.4 Personnel who have a potentially contagious disease or who have open wounds/lacerations should immediately contact the Pharmacist-in-charge to determine if access to controlled areas will be allowed.

9.8 Membrane Filtration
9.8.1 Membrane filtration should be performed in a LAFW or CAI.
9.8.2 Sterile forceps should be used to transfer the filter to the media to reduce microbial contamination.
9.8.3 The manifold, filter flask, and vacuum tubing should be sterilized prior to use. One batch/sample should be filtered individually to prevent the possibility of cross contamination.

9.9 Sterile Equipment and Materials
9.9.1 Check the expiration dates when using autoclaved equipment.
9.9.2 Ensure the color indicator (if applicable) has changed to the proper color, indicating sterilization has occurred.
9.9.3 When removing the autoclave wrapping, handle the material with gloved hands and with minimal manipulations.

10.0 ATTACHMENTS

10.1 N/A

11.0 HISTORY

<table>
<thead>
<tr>
<th>Version Number</th>
<th>Date Effective</th>
<th>Description of Change</th>
<th>Change Request Number</th>
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</thead>
<tbody>
<tr>
<td>1.0</td>
<td>New SOP.</td>
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Purpose:
Sixth Avenue Medical Pharmacy shall require basic qualifications for each employee active in the process of sterile compounding.

Scope:
This procedure applies to all sterile compounding personnel at Sixth Avenue Medical Pharmacy.

Responsibility:
The Pharmacist-in-Charge or compliance officer shall supervise this procedure or document that another staff member has been designated to complete this task.
Each pharmacist shall be responsible for ensuring his or her professional license is kept current and in good standing.

References:
All licensure certificates
All sterile compounding training course certificates
“Sterile Compounding Process Validation (Media Fills)”
USP <797>

Definitions:
N/A

Frequency:
Commencement of employment & Semi-annually
Policy reviewed annually

Equipment & Supplies:
N/A

Procedures
A. Pharmacist
   a. Each pharmacist must provide documentation of a current license in good standing with the appropriate State Board of Pharmacy.
   b. Each pharmacist must operate according to the appropriate State Board of Pharmacy – Pharmacy Practice Rules and Regulations.
   c. Sixth Avenue Medical Pharmacy must provide documentation to verify that compounding is performed according to standards of practice adopted by the appropriate State Board of Pharmacy and the practices and standards that are adopted by non-governmental standards setting organizations (USP, etc.).
d. Each pharmacist will be responsible for obtaining the appropriate number of continuing education hours, for licensure, as required by the appropriate State Board of Pharmacy - Pharmacy Practice Rules and Regulations.

e. All licensed professionals are required to display their licensure certificates in the pharmacy area for easy access to regulatory agents and the public.

f. All licensed professionals shall display any additional information required by the Appropriate State Board of Pharmacy.

g. Each pharmacist must be able to make clinical and compounding formulation decisions.

B. Pharmacy Technician

a. A pharmacy technician may prepare sterile compounds, including parenteral drugs. A licensed pharmacist must check each parenteral drug prepared by a pharmacy technician.

b. All licensed professionals are required to display their licensure certificates in the pharmacy area for easy access to regulatory agents and the public.

c. All licensed professionals shall display any additional information required by the Appropriate State Board of Pharmacy.

d. Personnel involved in the sterile compounding process will be evaluated on his or her physical ability to perform the assigned compounding responsibility without compromising the integrity of the compound. This will include handicap issues (along with dexterity skills) and any illness or injury.

e. All sterile compounding personnel shall undergo training and validation of sterile compounding in compliance with USP <797> guidelines.

f. Garbing Competency and Hand Hygiene evaluation will be performed three times before sterile compounding for human use may be performed.

g. Garbing Competency and Hand Hygiene evaluation will be performed on an on-going basis of every sixth months for high-risk preparations during Aseptic Process evaluation.

h. Garbing Competency evaluation will be documented and retained appropriately in the designated employee portfolio.

i. Each employee shall be evaluated on his or her designated aseptic process a minimum of every six months for high-risk preparations.

j. Compounding personnel shall perform a written didactic competency test every 6 months.

k. A validation test shall also be required whenever the quality assurance program yields an unacceptable result or unacceptable techniques are observed.

l. Should an employee or procedure fail an evaluation test, he or she will be restricted from performing the task until an evaluation test is passed.

m. The Pharmacist-in-Charge or Quality Assurance/QC officer shall be responsible for determining if the employee or procedure requires testing more frequently than semi-annually.

n. Documentation of the evaluation and verification process shall be documented and retained appropriately in the designated employee portfolio.
o. Pharmacy Students/Interns and PharmD Candidates shall be supervised and tested for competency on same criteria as Pharmacy Technicians with the exception that Students shall **not** perform Sterile Compounding—See SOP 2.030 for non-sterile compounding.

Attachments:

10.1 Attachment 1 – Personnel Training Verification – Sterile Compounding  
10.2 Attachment 2 – Validation of Personnel – Sterile Compounding

History:

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<tr>
<td>1.0</td>
<td>New SOP.</td>
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PERSONNEL TRAINING VERIFICATION – STERILE COMPOUNDING

Sterile compounding personnel shall be trained on proper compounding techniques and processes necessary to compound sterile preparations.

<table>
<thead>
<tr>
<th>Date</th>
<th>Training Provided</th>
<th>Materials/References Used</th>
<th>Initials of Employee</th>
<th>Initials of Trainer</th>
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Signature: __________________________________________ Date: ______________________

Compounding Pharmacist

Signature: __________________________________________ Date: ______________________

Pharmacist-in-Charge or compliance officer

Approved by __________________________________________ Date ______________________

Implemented by __________________________________________ Date ______________________
VALIDATION OF PERSONNEL – STERILE COMPOUNDING

Personnel involved in preparing drug compounds shall be validated for proper technique and understanding of the concepts behind the procedures to be performed. Validation shall be handled under a “pass/fail” grading system. If the individual performing the procedure does not “pass” then proper retraining and education shall be given and the individual shall be allowed to perform the procedure again until competency is demonstrated.

Compounder: ___________________________ Location: ISO 5 CA

Sterile compounding validation: □ sterility □ potency Drug: ___________________________

Filter Brand/Description: ___________________________

Lot #/Expiration Date: ___________________________

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<th>Results (assay, sterility)</th>
<th>Pass/Fail</th>
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* If rejected, explain: __________________________________________________________

Comments: ________________________________________________________________

Sterile compounding validation: □ sterility □ potency Drug: ___________________________

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* If rejected, explain: __________________________________________________________

Comments: ________________________________________________________________

Reviewed By: ___________________________ Date: ___________________________

Approved by ___________________________ Date: ___________________________

Implemented by ___________________________ Date: ___________________________

Page 5 of 5
Title of SOP: QUALITY ASSESSMENT OF STERILE COMPOUNDS

PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation and provide an overview of quality assurance activities for sterile compounded preparations.

2.0 SCOPE

2.1 This procedure applies to all sterile compounding personnel at Sixth Avenue Medical Pharmacy.

3.0 RESPONSIBILITY

3.1 The Pharmacist-In-Charge or designee shall supervise this procedure and document that all sterile compounding personnel responsible for finished preparation testing comply with this procedure.

3.2 It is the responsibility of Sixth Avenue Medical Pharmacy to review and assess the contract laboratory for appropriate regulatory compliance.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding - Sterile Preparations"
4.2 USP Current Version <71> "Sterility Testing"
4.3 USP Current Version <85> "Bacterial Endotoxin Testing"
4.4 USP Current Version <1075> "Good Compounding Practices"
4.5 All applicable State Board requirements

5.0 FREQUENCY

5.1 It is the responsibility of Sixth Avenue Medical Pharmacy to determine which tests can be performed in-house and which tests must be performed at a contract facility.

6.0 GENERAL INFORMATION

6.1 This procedure is designed to verify and demonstrate effectiveness of all procedures critical to the accuracy and purity of the finished compounded product.

6.2 Sterile products that are scheduled for testing must be tested according to USP <797> and other referenced chapters and monographs.

6.2.1 USP <71> must be followed when a sterility test is required. Within chapter <71>, the number of units, volume per unit and specific methods are discussed.
7.0 PROCEDURE

7.1 Sterility Testing

7.1.1 Low-risk level preparations shall be tested for sterility:
   7.1.1.1 If stored at room temperature for more than 48 hours.
   7.1.1.2 If stored at 2°C – 8°C for more than 14 days.
   7.1.1.3 If stored at frozen conditions (less than -20°C) for more than 45 days.

7.1.2 Medium-risk level preparations shall be tested for sterility:
   7.1.2.1 If stored at room temperature for more than 30 hours.
   7.1.2.2 If stored at 2°C – 8°C for more than 7 days.
   7.1.2.3 If stored at frozen conditions (less than -20°C) for more than 45 days.

7.1.3 High-risk level preparations shall be tested for sterility:
   7.1.3.1 If stored at room temperature for more than 24 hours.
   7.1.3.2 If stored at 2°C – 8°C for more than 3 days.
   7.1.3.3 If stored at frozen conditions (less than -20°C) for more than 45 days.
   7.1.3.4 If drug(s) that will be injected into vascular and/or central nervous systems is/are prepared in groups of more than 25 identical, individual single-dose packages, or in multiple dose vials for administration to multiple patients.
   7.1.3.5 If, prior to sterilization, drug(s) that will be injected into vascular and/or central nervous systems is/are stored at 2°C – 8°C for more than 12 hours or stored at temperatures above 8°C for more than 6 hours.

7.1.4 Sterility sampling requirements must follow the tables in USP <71>, “Sterility Testing.”

7.1.5 Sterility methods must follow the USP <71> membrane filtration method (if applicable). If not performing membrane filtration, other methods outlined in USP <71> are acceptable.

7.1.6 If a rapid sterility test is used, it must be proven that the method is as effective and as reliable as the USP method(s).
7.2 Endotoxin (Pyrogen) Testing

7.2.1 High-risk level preparations:

7.2.1.1 CSPs for administration via injection into the vascular and central nervous systems that are prepared in groups of more than 25 identical individual single-dose packages, or in multiple dose vials for administration to multiple patients, must not contain excessive bacterial endotoxins.

7.2.1.2 CSPs that are exposed to 2°C – 8°C for more than 12 hours or that are exposed to temperatures above 8°C for more than 6 hours before sterilization must be tested for excessive endotoxins.

7.2.2 The endotoxin testing shall follow the USP <85> bacterial endotoxin test method(s).

7.2.3 In the absence of a bacterial endotoxin limit in the official monograph or other CSP formula source, the CSP must not exceed the amount of USP Endotoxin Units (EU per hour per kg of body weight or m² of body surface area) specified in USP <85> for the appropriate route of administration.

7.2.4 One unit per batch must be sampled.

7.3 Physical Testing Requirements

7.3.1 The end product must be visually inspected for:

7.3.1.1 Container leaks

7.3.1.2 Integrity

7.3.1.3 Solution cloudiness or phase separation

7.3.1.4 Appropriate color

7.3.1.5 Appropriate volume

7.3.2 Particulate testing (liquids)

7.3.2.1 Sampling (one unit per batch and, if placed in storage, immediately before shipping).

7.3.2.2 Wipe the container with a damp, lint-free wipe to remove any external particles.

7.3.2.3 Using powder-free gloves, hold the container by its top and swirl the contents by rotating the wrist in a circular motion.

7.3.2.4 Hold the container horizontally about four inches below a light source against a white and/or black background and move the container back and forth.

7.3.2.5 Slowly invert the container and look for heavy particles that may have settled on the bottom of the container.
Title of SOP: QUALITY ASSESSMENT OF STERILE COMPOUNDS

7.4 Accuracy Requirements
7.4.1 Accuracy must meet appropriate State Board requirements.
7.4.2 All calculations and volumes must be verified on the formulation sheet (e.g. if total volume is 5mL, compare to 5mL of water in a similar vial or syringe.)

7.5 Identification and Potency Requirements
7.5.1 Verify the label has the correct:
7.5.1.1 Names
7.5.1.2 Amounts or concentrations of ingredients
7.5.1.3 Total volume
7.5.1.4 Beyond-use date
7.5.1.5 Storage conditions
7.5.2 Verify the compounding record to the original written order for correct identities of ingredients, purity of ingredients and amounts of ingredients. If any of these cannot be confirmed accurate, the preparation must be assayed by methods that are specific for the active ingredients based on USP monographs
7.5.3 Verify that correct fill volumes and quantities of units were prepared.
7.5.4 According to the schedule determined by the QA officer(s), samples shall be tested for potency using the appropriate method or samples shall be sent to a contract lab for testing. Samples that are awaiting potency results must be quarantined as per SOP 9.060, "Product Quarantine, Storage and Release."

7.6 If a pH requirement exists, test pH as per SOP 4.080, "Use, Calibration and Maintenance of the pH Meter."

7.7 Follow manufacturer’s instructions or send the drug(s) to a contract laboratory if osmolality testing is necessary.

7.8 If any of the finished product testing is out of specification, the documentation must be reviewed, an analysis done of the process and a plan of correction formulated. Results of OOS products are reported as part of the Performance Improvement plan.

7.9 Visual appearance inspection is confirmed on the worksheet by the compounder and the checking pharmacist. This includes Physical, Particulate & Accuracy as well as sterility and pH.

7.10 Review of Testing is audited monthly per SOP 9.03 and included in QA monthly and quarterly reviews as well as annual Performance Improvement Plan report.

8.0 HISTORY

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<th>Description of Change</th>
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Approved by ___________________________ Date ____________
Implemented by __________________________ Date ____________

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SOP 9.130