California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GAVIN NEWSOM, GOVERNOR

COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of ea pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug pro s to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The asses nt shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also com a self-assessment within 30 days whenever; (1) a new pharmacy permit has b issued, or (2) there change in the pharmacist-in-charge; or (3) there is a change in the licensed locatio t rmacy. The pri purpose of the self-assessment is to promote compliance through self-exam tion a tion.**

The self-assessment must be competed in entirety and may be co pleted online inted d retaine the pharmacy. Do not copy a previous assessment.

Each self-assessment must be kept on file in the pha cy for three s after it is formed.

Pharmacy Name: _____

Address: _____ hone: _____

Ownership: Sole Owner ☐ Partnershi ☐ Corporation ☐ LLC ☐
Non-License Owner ☐ Othe ease specify) ☐ _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile ounding mit # _____ Expiration: _____

lited by: _____ From: _____ To: _____

EA Registrati #: _____ Exp. Date: _____ Date of DEA Inventory: _____

rs: *ily* _____ *Sat* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

REPEAL

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

2. _____ RPH # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

REPEAL

PIC Initials _____

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 8.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ 1.1. The pharmacy compounds prescriptions as defined in CCR 1

☐☐☐ 1.2. The compounding pharmacist understands the definitions of equ ent, i grity, p , quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requiremen (CCR 1735

The pharmacy does not compound dr oduct pr o receipt of a val prescription unless under the following conditions. (CCR 1735.2[a]

Yes No N/A

☐☐☐ 2.1. The pharmacy prepares stores mited qu of a c ounded drug product in advance of receipt of a patient sp c prescripti olely in su y as is necessary to ensure continuity of care of an identi patient popula as defined. R 1735.2[b])

☐☐☐ 2.2. The pharmacy comp s a rea able quantity of drug product that is furnished to a prescriber for office u pon pres r as allowed in CCR 1735.2 (c) that:

- ☐ 2.2 s sufficient for ad stration or application to patients in the prescriber's office or for distribution of not more a 72-hour supply, (CCR 1735.2[c][1])
- ☐ 2.2.2. Is rea ble considerin e intended use of the compounded medication and the natur the prescriber's practice, (CCR 1735.2[c][2]) AND
- ☐ n amount, whi e pharmacy is capable of compounding in compliance with rmaceutical st ards for integrity, potency, quality and strength for any individual p iber or fo prescribers taken as a whole. (CCR 1735.2[c][3])

☐☐☐ 2. he pharmacy ot compound medication until it has prepared a written master formula that includes the follow ng elements (CCR 1735.2[d][1-6]):

- ☐ e ingredients used.
- ☐ 2.3.2. Equipment to be used.
- ☐ 2.3.3. Expiration dating requirements.
- ☐ 2.3.4. Inactive ingredients used.
- ☐ 2.3.5. Process and/or procedure used to prepare the drug.
- ☐ 2.3.6. Quality reviews required at each step in the preparation of the drug.
- ☐ 2.3.7. Post-compounding process or procedures if required.

REPEAL

PIC Initials _____

Yes No N/A

☐☐☐ 2.4. The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])

☐☐☐ 2.5. All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])

☐☐☐ 2.6. Compounded drug products are given an expiration date representing the d[illegible]beyond which, in the professional judgment of the pharmacist performing or supervising the co[illegible]nding, it should not be used. The "beyond use date" of the compounded drug product does not e[illegible]d 180 days from preparation or the shortest expiration date of any component in the compound[illegible]ug product, unless a longer date is supported by stability studie[illegible]hed drugs or com[illegible]ded drug products using the same components and packaging. S[illegible]rte[illegible] may be used deemed appropriate in the professional judgment of the respo[illegible]le pha[illegible] (CCR 173[illegible][n])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Records of Compounded Drug Products [illegible]R 1735

Yes No N/A

☐☐☐ 3.1. A record for each compo[illegible]d d[illegible]roduct i[illegible]es the fol[illegible]ng (CCR 1735.3[a][1-10]):

- ☐ 3.1.1. The maste[illegible]mula record
- ☐ 3.1.2. The da[illegible]e drug produc[illegible]as compounded.
- ☐ 3.1.3. The identity[illegible]e ph[illegible]acy personnel who compounded the drug product.
- ☐ 3.1[illegible]e identity of t[illegible]armacist reviewing the final drug product.
- ☐ [illegible]5. The quantity of eac[illegible]ponent used in compounding the drug product.
- ☐ 3.1.6. The m[illegible]facturer or sup[illegible], expiration date and lot number of each component. Exem[illegible]om this requirement are sterile drug products compounded on a one-time basis for[illegible]inistration with[illegible] seventy-two (72) hours and stored in accordance with standards "[illegible]redispensed C[illegible]s" found in Chapter 797 of the United States Pharmacopeia – [illegible]onal Formul[illegible](USP-NF) (35th Revision, Effective May 1, 2012), to an inpatient in a he[illegible]care fa[illegible]licensed under section 1250 of the Health and Safety Code.
- ☐ 3.1.7. The [illegible]acy assigned reference or lot number for the compounded drug product.
- ☐ 3.1.8. The expiration date of the final compounded drug product.
- ☐ 3.1.[illegible]e quantity or amount of drug product compounded.

☐☐☐ 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])

☐☐☐ Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])

PREPEAL

PIC Initials _____

Yes No N/A

☐☐☐ 3.4. The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])

☐☐☐ 3.5. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

☐☐☐ 4.1. The label of the compounded drug product contains the gen[illegible] of the principle[illegible] ingredient(s). (CCR 1735.4[a])

☐☐☐ 4.2. The prescription label contains all the information required in B&[illegible] 4076[illegible] is for[illegible] in accordance with CCR 1707.5. (CCR 1735.4[a])

☐☐☐ 4.3. If requested by the patient, the prescriptio[illegible]el is printed in 12-po[illegible]ypeface. (CCR 1707.5[a])

☐☐☐ 4.4. The pharmacy is exempt from the pr[illegible]ption label r[illegible]ements in C[illegible]1707.5. (B&PC 4076.5[d])

Exemption approved by the board fro[illegible] _____ to[illegible] _____

☐☐☐ 4.5. The container or receipt [illegible]ains [illegible]tement t[illegible]he drug h[illegible]been compounded by the pharmacy. (CCR 173[illegible]5])

☐☐☐ 4.6. Drug products co[illegible]unded into un[illegible]ose containers t[illegible]at are too small or otherwise impractical for full compliance with [illegible]equirem[illegible] of [a] and [b] are labeled with at least the name(s) of the active ingre[illegible]nt(s), co[illegible]tra[illegible] of strength, volume or weight, pharmacy reference or lot number[illegible] expiration da[illegible]CR 1735.4[c])

CORRECTIVE AC[illegible]N OR ACTIO[illegible] PLAN: _____

_____

5. [illegible]unding [illegible]ies and P[illegible]edures (CCR 1735.5)

Y[illegible]No N/A

☐☐☐ 5[illegible] The pharmacy m[illegible]ntains a written policy and procedure manual for compounding that establishes th[illegible]following (CCR 1735.5 [a]):

- ☐ 5.1.1. [illegible]ocurement procedures.
- ☐ 5.1.2. Methodologies for the formulation and compounding of drugs.
- ☐ 5.1.3. Facilities and equipment cleaning, maintenance and operations.
- ☐ 5.1.4. Other standard operating procedures related to compounding.

☐☐☐ 5.2. The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])

REPEAL

_____
PIC Initials

Yes No N/A

☐☐☐ 5.3. The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])

☐☐☐ 5.4. The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2])

☐☐☐ 5.5. The manual includes procedures for maintaining, storing, calibrating, clean[illegible]nd disinfecting equipment used in compounding and for training on these procedures. (CCR [illegible]5[c][3])

☐☐☐ 5.6. The manual includes documentation on the methodology used to test integrity, pote[illegible] quality and labeled strength of compounded drug products. (CCR [illegible][4])

☐☐☐ 5.7. The manual includes documentation of the methodology used [illegible]determi[illegible]opriate exp[illegible]ion dates for compounded drug products. (CCR 1735.5[c][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Compounding Facilities and Equipment (C[illegible] 1735[illegible]

Yes No N/A

☐☐☐ 6.1. The pharmacy maintain[illegible]itten do[illegible]entation [illegible]arding t[illegible]acilities and equipment necessary for safe and accurate [illegible]mpounded d[illegible] products t[illegible]l[illegible] records of certification of facilities or equipment, if appli[illegible]e. (CCR 1735[illegible])

☐☐☐ 6.2. All equipment used t[illegible]mpoun[illegible]ug products is stored, used and maintained in accordance with manufactu[illegible] specifica[illegible]s. (CCR 1735.6[b])

☐☐☐ 6.3. All e[illegible]ment used to compo[illegible] drug products is calibrated prior to use to ensure accuracy. (C[illegible]1735.6[c])

☐☐☐ 6.4. [illegible]umentatio[illegible] each calibration is recorded in writing and maintained and retained in the ph[illegible]cy. (CCR 1735.6[c])

COR[illegible]ACTION [illegible]CTION P[illegible]: _____

_____

Tr[illegible]ng of C[illegible]ding Staff (CCR 1735.7)

Yes [illegible]A

☐☐☐ 7.1. The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

☐☐☐ 7.2. The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

_____
PIC Initials

REPEAL

Yes No N/A

☐☐☐ 7.3. Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

☐☐☐ 7.4. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ 8.1. The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

☐☐☐ 8.2. The pharmacy's quality assurance plan includes the written procedures and standards for the following:

- ☐ 8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of such processes by qualified pharmacy personnel. (CCR 1735.8[b])
- ☐ 8.2.2. Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[
- ☐ 8.2.3. Such records are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])
- ☐ 8.2.4. Unscheduled actions in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

(*Continued on Next Page*)

REPEAL

_____
PIC Initials

COMPOUNDING STERILE INJECTABLE DRUGS

Does the pharmacy compound sterile injectable drugs? ☐ **Yes** ☐ **No**

If yes, complete Sections 9 through 19.

9. FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS: Permit or Accreditation

Yes No N/A

☐☐☐ The pharmacy has a board issued Licensed Sterile Compounding Pharmacy permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

10. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

☐☐☐ 10.1. The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

☐ 10.1.1. The contract and arrangement is reported to the board within 30 days of commencing that compounding.

11. Sterile Injectable Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ 11.1. If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

☐ 11.1.1. An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

☐ 11.1.2. An ISO class 5 cleanroom (B&PC 4127.7[b])

☐ 11.1.3. A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

☐☐☐ 11.2. The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is ventilated (CCR 1751)

☐ 11.2.1. The laminar airflow hoods and clean room are certified annually; (CCR 1751)

☐ 11.2.2. Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)

☐ 11.2.3. A sink with hot and cold running water; (CCR 1751)

☐ 11.2.4. A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

REPEAL

_____
PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

12. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ 12.1. Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, that contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

☐☐☐ 12.2. Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

- ☐ 12.2.1. The training and competency evaluation of employees for sterile product procedures;
- ☐ 12.2.2. Refrigerator and freezer temperatures;
- ☐ 12.2.3. Certification of the sterile compounding environment;
- ☐ 12.2.4. Other facility quality control as specified in the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);
- ☐ 12.2.5. Inspection for expired, recalled, or pharmaceutical products or raw ingredients; and
- ☐ 12.2.6. Preparation records including the master work sheet, the preparation work sheet, and records of end product evaluation results.

☐☐☐ 12.3. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

13. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ 13. In addition to the labeling information required under Business and Professions Code section 4076 and CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])

- ☐ 13.1.1. Telephone number of the pharmacy, unless dispensed for a hospital in-patient;
- ☐ 13.1.2. Name and concentrations of ingredients contained in the product;
- ☐ 13.1.3. Instructions for storage and handling; and
- ☐ 13.1.4. A special label that states "Chemotherapy—Dispose of Properly" or "Cytotoxic – Dispose of Properly" for all cytotoxic agents.

REPEAL

PIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

14. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

☐☐☐ 14.1. The pharmacy has a written manual documenting the policies and proced[illegible] associated with the preparation and dispensing of sterile injectable products and, in addition to the [illegible]ments required by section 1735.5, includes: (CCR 1751.2[a][1-7])

- ☐ 14.1.1. Compounding, filling, and labeling of sterile inject[illegible] compounds;
- ☐ 14.1.2. Labeling of the sterile injectable product based on [illegible] route of admi[illegible]n and recommended rate of administration;
- ☐ 14.1.3. Equipment and supplies;
- ☐ 14.1.4. Training of staff in preparation of s[illegible] injectable prod[illegible]
- ☐ 14.1.5. Training of patient and/or care[illegible]n in the administration [illegible]ompounded sterile injectable products;
- ☐ 14.1.6. Procedures for the handl[illegible]nd disposal [illegible]cytotoxic agent[illegible]
- ☐ 14.1.7. Quality assurance program; a[illegible]
- ☐ 14.1.8. Record keeping[illegible]ents.

☐☐☐ 14.2. Ingredients and com[illegible]nding proc[illegible] for each p[illegible]ra[illegible] is determined in writing and reviewed by a pharmacist b[illegible] compounding[illegible]gins. (CCR 1[illegible]3[b])

☐☐☐ 14.3. Policies and proced[illegible] addres[illegible]e disposal of infectious materials and/or materials containing cytotoxic r[illegible]ues and l[illegible]d[illegible]anup of spills in conformance with local health jurisdictions. (CCR 17[illegible]3 [c])

☐☐☐ 14.4. If [illegible]mpounding st[illegible]ile injecta[illegible]roducts from one or more non-sterile ingredients, the pharmacy [illegible]written polici[illegible]nd procedure[illegible]t comply with the following: (CCR 1751.3[d][1-3])

- ☐ 14.4.1. P[illegible]es and procedures are immediately available to all compounding personnel and [illegible]h[illegible] inspectors (CC[illegible]751.3[d][1]); and
- ☐ 14.4[illegible] All compoun[illegible] personnel have read the policies and procedures, any additions, rev[illegible]s, and [illegible]etions before compounding. (CCR 1751.3 [d][2])

☐☐☐ 14[illegible] Policies and p[illegible]ures address the following: (CCR 1751.3 [d][3] [A-K])

- ☐ [illegible]1. Competency evaluation;
- ☐ 14.5.2. Storage and handling of products and supplies;
- ☐ 14.5.3. Storage and delivery of final products;
- ☐ 14.5.4. Process validation;
- ☐ 14.5.5. Personnel access and movement of materials into and near the controlled area;
- ☐ 14.5.6. Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations;

REPEAL

_____
PIC Initials

☐ 14.5.7. A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

☐ 14.5.8. Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

☐ 14.5.9. For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

☐ 14.5.10. Sterilization; and

☐ 14.5.11. End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

15. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ 15.1. The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])

☐☐☐ 15.2. Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])

☐☐☐ 15.3. All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected materials. (CCR 1751.4[c])

☐☐☐ 15.4. Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])

☐☐☐ 15.5. The preparation of parenteral cytotoxic agents is done in accordance with Section 505.5.1 of Title 24, Chapter 4 of the California Code of Regulations and includes: (CCR 1751.4[e])

☐ 15.5.1. A laminar airflow hood, which is certified annually.

☐ 15.5.2. Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

16. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No

☐☐☐ 16.1. When preparing cytotoxic agents, gowns and gloves are worn. (CCR 1751.5[a])

☐☐☐ 16.2. When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])

REPEAL

☐ 16.2.1. Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])

☐ 16.2.2. Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])

☐ 16.2.3. No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])

☐ 16.2.4. Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and

☐ 16.2.5. Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

17. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

Yes No N/A

☐☐☐ 17.1. Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐☐☐ 17.2. The pharmacist-in-charge ensures that pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competency in the safe handling of those products, including cytotoxic and the pharmacy compounding such agents. (CCR 1751.6[b])

☐☐☐ 17.3. Records of training and demonstrated competency are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])

☐☐☐ 17.4. The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])

☐☐☐ 17.5. When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])

☐☐☐ 17.5.1. The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])

☐ 17.6.1. Aseptic technique;

☐ 17.6.2. Pharmaceutical calculations and terminology;

☐ 17.6.3. Sterile product compounding documentation;

☐ 17.6.4. Quality assurance procedures;

☐ 17.6.5. Aseptic preparation procedures;

☐ 17.6.6. Proper gowning and gloving technique;

☐ 17.6.7. General conduct in the controlled area;

☐ 17.6.8. Cleaning, sanitizing, and maintaining equipment used in the controlled area;

☐ 17.6.9. Sterilization techniques; and

REPEAL

PIC Initials

☐ 17.6.10. Container, equipment, and closure system selection.

Yes No N/A

☐☐☐ 17.7. Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])

☐ 17.7.1. checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])

☐ 17.7.2. Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])

☐ 17.7.3. Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

18. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ 18.1. There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment and facilities, and the pharmacist-in--charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

☐☐☐ 18.2. The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])

☐ 18.2.1. Cleaning and sanitization of the parenteral medication preparation area;

☐ 18.2.2. The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

☐ 18.2.3. Actions to be taken in the event of a drug recall; and

☐ 18.2.4. Written justification of beyond-use chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).

☐☐☐ 18.3. Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

☐ 18.3.1. The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

☐ 18.3.2. The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

☐ 18.3.3. The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

☐ 18.3.4. Completed medium samples are incubated. (CCR 1751.7[b])

☐ 18.3.5. If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

REPEAL

PIC Initials _____

☐ 18.3.6. Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])

Yes No N/A

☐☐☐ 18.4. Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

19. <u>Sterile Injectable Compounding Reference Materials (CCR 1751.8)</u>

Yes No N/A

☐☐☐ Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

(Continued on next page.)

REPEAL

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

I, (please print) _____ hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

(Pharmacist-in-Charge)

REPEAL

PIC Initials _____