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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Compounding Self-Assessment

Business and Professions Code section 4102 requires the pharmacist-in-charge of each pharmacy that compounds drug products to complete a compounding self-assessment form. **The assessment shall be performed by July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a compounding self-assessment form within 30 days of any of the following: (1) a new pharmacy license is issued; (2) there is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy; (3) there is a change in the location of the pharmacy to a new address.** The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Please mark the appropriate box (Yes, No, or N/A) for each question. If "No," enter an explanation in the "Corrective Action Plan" section. If the specific legal requirement referenced in the question clearly and objectively does not apply to your pharmacy, then mark the box "N/A". If more space is needed, you may add additional sheets. The self-assessment form must be completed in its entirety. It may be completed online and printed, initialed, and signed (use original signatures or digital signatures that comply with California Code of Regulations, title 16, section 1700). The completed form shall be kept on file in the pharmacy and made available to the Board upon request. A new self-assessment form must be filled out each time the self-assessment process is required to be completed; do not use or copy from a previous self-assessment form. Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Note: This self-assessment is not an all-inclusive compilation of all laws and regulations applicable to pharmacy compounding. The pharmacist-in-charge is responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy, regardless of whether such laws or regulations are referenced on this self-assessment.

A subscription is required to access the contents of the United States Pharmacopeia (USP). The hyperlinks in this document to USP 795, 797, 800 and 825 go to the home page on USP's website and users will need log in credentials to access the USP chapters.

Pharmacy Name:							
Address:			**Telephone:**				
Pharmacy License #:			**Expiration Date:**				
Sterile Compounding License(s) (LSC/LSE/NSC)/SCE/SCP):	**License #:**	**Location or Address**	**Hours of Operation**				
			M-F	**Sat**	**Sun**	**24 hours**	
Accredited by or N/A:			**Date From:**				
			Date To:				
Centralized Hospital Packaging License # or N/A:			**Expiration Date:**				
DEA Registration #			**Expiration Date:**				
Pharmacist-in-Charge			**License#:**				
			Expiration Date:				

Type of Compounding: Check all that apply.	
	Nonsterile (CNSP)
	Sterile (CSP) – USP 797 Category 1
	Sterile (CSP) – USP 797 Category 2
	Sterile (CSP) – USP 797 Category 3
	Oral Flavoring only – no other compounding activities [CCR 1735.1(i)]
Check all that apply:	
	Radiopharmaceuticals
	Hazardous
	Injectable
	Inhalation
	Intrathecal
	Ophthalmic
	Oral
	Topical
	Other (list):

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding tasks):

Attach additional sheets as necessary

(**APH**=Advanced Pharmacist Practitioner **DEA**=Drug Enforcement Administration **INT**=Intern **RPH** = Pharmacist **TCH**=Technician)

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PIC Initials:________ Date:_________

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REFERENCES

Abbreviation	Full Reference
AMDUCA	Animal Medicinal Drug Use Clarification Act of 1994
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
BPC	California Business and Professions Code
BUD	Beyond Use Date
CAG-003	Controlled Environment Testing Association's (CETA) Certification Guide for Sterile Compounding Facilities, Revised October 2022
CAG-009	Controlled Environment Testing Association's (CETA)Certification Application Guide USP <797> Viable Environmental Monitoring for Sterile Compounding Facilities, Revised September 2020
CC	California Civil Code
CCR	Title 16 California Code of Regulations
CDPH	California Department of Public Health
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CNSP	Compounded Nonsterile Preparation
CR	Compounding Record
CSP	Compounded Sterile Preparation
DRIC	Designated Representative-in-Charge
DP	Designated Person
FDA	Federal Food and Drug Administration
HD	Hazardous Drug
HSC	California Health and Safety Code
IPA	Isopropyl Alcohol
ISO	International Organization for Standardization
MFR	Master Formulation Record
PD	Professional Director
PEC	Primary Engineering Control
PIC	Pharmacist-In-Charge
SCA	Segregated Compounding Area
SEC	Secondary Engineering Control

SOP	Standard Operating Procedure
SRPA	Segregated Radiopharmaceutical Processing Area
USC	United State Code
USP	United States Pharmacopeia
VCPR	Veterinarian-Client-Patient Relationship

TABLE OF CONTENTS:

Section 27: Sterile Compounding – Master Formulation and Compounding Records
Section 28: Sterile Compounding – Release Inspections and Testing
Section 29: Sterile Compounding – Labeling
Section 30: Sterile Compounding – Establishing Beyond-Use Dates
Section 31: Sterile Compounding – Use of Conventionally Manufactured Products as Components
Section 32: Sterile Compounding – Use of CSPs as Components
Section 33: Sterile Compounding – Standard Operating Procedures (SOPs)
Section 34: Sterile Compounding – Quality Assurance and Quality Control
Section 35: Sterile Compounding – CSP Handling, Storage, Packaging, Shipping and Transport
Section 36: Sterile Compounding – Documentation
Section 37: Sterile Compounding – Compounding Allergenic Extracts
Section 38: Hazardous Drugs- Introduction and Scope
Section 39: Hazardous Drugs- List of Hazardous Drugs
Section 40: Hazardous Drugs- Types of Exposure
Section 41: Hazardous Drugs- Responsibilities of Personnel Handling Hazardous Drugs
Section 42: Hazardous Drugs- Facilities and Engineering Controls
Section 43: Hazardous Drugs- Environmental Quality and Control
Section 44: Hazardous Drugs- Personal Protective Equipment (PPE)
Section 45: Hazardous Drugs- Hazard Communication Program
Section 46: Hazardous Drugs- Personnel Training
Section 47: Hazardous Drugs- Receiving
Section 48: Hazardous Drugs- Labeling, Packaging, Transport, and Disposal
Section 49: Hazardous Drugs- Dispensing Final Dosage Forms
Section 50: Hazardous Drugs- Compounding
Section 51: Hazardous Drugs- Administering
Section 52: Hazardous Drugs- Deactivating, Decontamination, Cleaning, and Disinfecting
Section 53: Hazardous Drugs- Spill Control
Section 54: Hazardous Drugs- Documentation and Standard Operating Procedures (SOPs)
Section 55: Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging - Introduction
Section 56: Radiopharmaceutical - Radiation Safety Considerations
Section 57: Radiopharmaceutical - Immediate Use of Sterile Radiopharmaceuticals
Section 58: Radiopharmaceutical - Personnel Qualifications, Training, and Hygiene
Section 59: Radiopharmaceutical - Facilities and Engineering Controls
Section 60: Radiopharmaceutical - Microbiological Air and Surface Monitoring

Section 61: Radiopharmaceutical - Cleaning and Disinfecting
Section 62: Radiopharmaceutical - Assigning BUD
Section 63: Radiopharmaceutical - Documentation
Section 64: Radiopharmaceutical - Preparation
Section 65: Radiopharmaceutical - Compounding
Section 66: Radiopharmaceutical - Dispensing
Section 67: Radiopharmaceutical - Repackaging
Section 68: Radiopharmaceutical - Quality Assurance and Quality Control

CHECK OFF THE TYPE OF COMPOUNDING PERFORMED BY THE LICENSEE AND COMPLETE THE FOLLOWING SECTIONS, AS APPLICABLE:

☐ Adding Flavoring Agents for Oral Preparations ONLY – No other compounding activities [CCR 1735.1(i)] – Complete Section 1.

☐ Nonsterile Compounding – Complete sections 2 through 16 if the facility performs nonsterile compounding.

☐ Sterile Compounding - Complete sections 17 through 37 if the facility performs sterile compounding.

☐ Hazardous Drugs – Complete sections 38 through 54 if the facility compounds HDs or crushes or splits tablets or opens capsules of antineoplastic HDs.

☐ Radiopharmaceutical Preparations – Complete sections 55 through 68 if the facility processes radiopharmaceuticals.

For Adding Flavoring Agents for Oral Preparations Only (No other compounding activities): COMPLETE SECTION 1.

Section 1. Adding Flavoring Agents for Oral Preparations Only

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.1	CCR 1735.1(i) CCR 1735.15	The facility limits its compounding to adding a flavoring agent as described in CCR 1735.1(i), and no other compounding activities are done by the facility at any time.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
1.2	CCR 1735.1(a) BPC 4023.5	The facility's compounding as described in CCR 1735.1(i) is performed by or under the direct supervision and control of a licensed pharmacist.				
1.3	CCR 1735.15	The facility has established SOPs as required by CCR 1735.15(a).				
1.4	CCR 1735.15 (a)(5)	The prescription label includes information that a flavoring agent was added.				
1.5	CCR 1735.15 (b)	The pharmacist performing the compounding documents the addition of the flavoring agent in the prescription or compounding record.				

FOR NONSTERILE COMPOUNDING: COMPLETE SECTIONS 2 THROUGH 16.

Section 2: Nonsterile Compounding – Introduction and Scope

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.1	BPC 4126.8 USP 795 21 USC 353A	All nonsterile compounding is performed in compliance with applicable laws, regulations, and USP standards.				
2.2	CCR 1735.1(a) BPC 4023.5	All nonsterile compounding is performed by or under the direct supervision and control of a licensed pharmacist.				
2.3	CCR 1735.1(c) 21 USC 353A	Only a limited quantity of a CNSP is prepared and stored in advance of receipt of a patient specific prescription, and solely in such quantity to ensure continuity of care of individual patients based on a documented history of prescriptions for those patient populations.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
2.4	CCR 1735.1(e) 21 USC 353A	No CNSP is compounded that is essentially a copy of one or more commercially available drug products unless allowed by federal law and CCR 1735.1(e)(1).				
2.5	CCR 1735.1(h) HSC 1602.5	CNSPs with human whole blood or human whole blood derivative are compounded in compliance with HSC 1602.5.				

Section 3: Nonsterile Compounding – Personnel Training and Evaluation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
3.1	CCR 1735.2 BPC 4126.8 USP 795	Training and competency procedures for compounding personnel or persons with direct supervision and control of compounding personnel address the topics required by CCR 1735.2(a), and the facility otherwise complies with the personnel training and evaluation standards and requirements set forth in USP 795 and CCR 1735.2.				

Section 4: Nonsterile Compounding – Personnel Hygiene and Garbing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
4.1	CCR 1735.3 BPC 4126.8 USP 795	Individuals entering the compounding area perform personnel hygiene and garbing as required by the facility's SOPs and as required by law and regulation.				
4.2	CCR 1735.3(e)	Reusable garb and equipment are cleaned as required by the facility's SOPs and as required by law and regulation.				

Section 5: Nonsterile Compounding – Building and Facilities

	Reference	Item	Yes	No	N/A	Corrective Action Plan
5.1	CCR 1735.4(a) CCR 1714(b) CCR 1714(c)	Sinks used for compounding or hand hygiene are not part of a restroom or water closet, have hot and cold running water for pharmaceutical purposes, and otherwise comply with applicable statutory and regulatory requirements.				
5.2	CCR 1735.4(b)	Purified water, distilled water, reverse osmosis water, or higher quality water is used for rinsing equipment and utensils.				
5.3	CCR 1735.4(c)	No CNSP is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the law or the facility's SOPs.				

Section 6: Nonsterile Compounding – Cleaning and Sanitizing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
6.1	CCR 1735.5(a) BPC 4126.8 USP 795	The facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area includes the identity of the person completing the cleaning and sanitizing, as well as the product name(s) of the cleaning and sanitizing agent(s) used.				
6.2	CCR 1735.5(b)	Any cleaning or sanitizing agents used by the facility are used in accordance with manufacturers' specifications.				

Section 7: Nonsterile Compounding – Equipment and Components

	Reference	Item	Yes	No	N/A	Corrective Action Plan
7.1	CCR 1735.6(a)	Any equipment used to compound a CNSP is used in accordance with the manufacturer's specifications, where established by the manufacturer.				
7.2	CCR 1735.6(b)	Any component used to compound a CNSP is used and stored in accordance with all federal laws and regulations and industry standards, including the manufacturers' specifications and requirements.				

Section 8: Nonsterile Compounding – Master Formulation and Compounding Records

	Reference	Item	Yes	No	N/A	Corrective Action Plan
8.1	CCR 1735.7(a) CCR 1735.7(b) BPC 4126.8 USP 795	A CNSP is not compounded until the facility has first prepared a written master formulation record in compliance with USP 795 and that includes the additional elements required by CCR 1735.7(a).				
8.2	CCR 1735.7(c) BPC 4126.8 USP 795	A compounding record (CR) is maintained and, upon request, produced as a single document developed in compliance with USP 795, and includes the additional elements required by CCR 1735.7(c).				

Section 9: Nonsterile Compounding – Release Inspections and Testing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
9.1	CCR 1735.8	The pharmacist performing or supervising the nonsterile compounding and the dispensing pharmacist understand they are responsible for the integrity, strength, quality, and labeled strength of a CNSP until the BUD indicated on the label so long as label instructions for storage and handling are followed after the preparation is dispensed.				

Section 10: Nonsterile Compounding – Labeling

	Reference	Item	Yes	No	N/A	Corrective Action Plan
10.1	CCR 1735.9 BPC 4126.8 USP 795 BPC 4076 CCR 1707.5	Every CNSP is labeled as required by the facility's SOPs and as required by applicable law and regulation.				

Section 11: Nonsterile Compounding – Establishing Beyond-Use Dates

	Reference	Item	Yes	No	N/A	Corrective Action Plan
11.1	CCR 1735.10 BPC 4126.8 USP 795	All CNSPs are assigned a beyond-use-date (BUD) that complies with the facility's SOPs and applicable law and regulation.				

Section 12: Nonsterile Compounding – Standard Operating Procedures (SOPs)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
12.1	CCR 1735.11(a) BPC 4126.8 USP 795	The facility has and follows Standard Operating Procedures (SOPs) for nonsterile compounding, and such SOPs comply with USP 1163, Quality Assurance in Pharmaceutical Compounding.				
12.2	CCR 1735.11(a)	The facility SOPs for nonsterile compounding describe methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.				
12.3	CCR 1735.11(a)	The facility SOPs for nonsterile compounding describe the methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.				
12.4	CCR 1735.11(a)	The facility SOPs for nonsterile compounding describe the validated processes for storage, for shipping containers (as applicable), and for transportation of temperature sensitive CNSPs (as applicable) to preserve quality standards for integrity, quality and labeled strength.				
12.5	CCR 1735.11(a)	The facility SOPs for nonsterile compounding describe actions to be taken if the compounding area or equipment is rendered unusable or in a downtime situation.				
12.6	CCR 1735.11(b)	The PIC reviews the SOPs annually and documents this review as required by law and regulation.				
12.7	CCR 1735.11(b)	The SOPs are updated any time changes are made to compounding processes, the facility, or other changes occur that impact the CNSP, and all SOP changes are disseminated to the affected staff prior to implementation.				

Section 13: Nonsterile Compounding – Quality Assurance and Quality Control

	Reference	Item	Yes	No	N/A	Corrective Action Plan
13.1	CCR 1735.12(a) BPC 4126.8 USP 795 CCR 1711 USP 1163	The facility has a quality assurance program that complies with CCR 1711 and the standards contained in USP 795 and USP 1163, Quality Assurance in Pharmacy Compounding.				
13.2	CCR 1735.12(b) BPC 4126.8 USP 795	The Board is notified in writing within 96 hours of the facility's receipt of a complaint of a potential quality problem involving a CNSP.				
13.3	CCR 1735.12(c)	A review is initiated of any complaints made to the facility related to a potential quality problem with a CNSP within 72 hours of receipt of the complaint, and such review is documented and dated as defined in the facility's SOPs.				

Section 14: Nonsterile Compounding – CNSP Packaging and Transporting

	Reference	Item	Yes	No	N/A	Corrective Action Plan
14.1	CCR 1735.13	The facility ensures appropriate processes for storage, shipping containers and temperature sensitive CNSPs as provided for in the facility's SOPs.				

Section 15: Nonsterile Compounding – Documentation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
15.1	CCR 1735.14(a) BPC 4070	Records are maintained as required by USP 795 and Article 4.5 of Division 17 of the CCR in a readily retrievable form for at least three years from the date the record was created or relied on to meet the requirements of Article 4.5, and if only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by BPC 4070.				
15.2	CCR 1735.14(b) BPC 4070	Records are created and maintained in a manner that will provide an audit trail for revisions and updates of each record document.				

Section 16: Nonsterile Compounding – Flavoring Agents

	Reference	Item	Yes	No	N/A	Corrective Action Plan
16.1	CCR 1735.15(b)	A pharmacist who compounds by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent documents the compounding in the prescription or compounding record.				

FOR STERILE COMPOUNDING: COMPLETE SECTIONS 17 THROUGH 37

Section 17: Sterile Compounding – Introduction and Scope

	Reference	Item	Yes	No	N/A	Corrective Action Plan
17.1	BPC 4126.8 USP 797 21 USC 353A	All sterile compounding is performed in compliance with applicable laws, regulations, and USP standards.				
17.2	CCR 1736.1(a) BPC 4023.5	All sterile compounding is performed by or under the direct supervision and control of a licensed pharmacist.				
17.3	CCR 1736.1(b) BPC 4126.8 USP 797	CSPs for direct and immediate administration as provided in USP 797 are compounded in compliance with applicable law and regulation.				
17.4	CCR 1736.1(c) 21 USC 353A	Only a limited quantity of CSP is prepared and stored in advance of receipt of a patient specific prescription where, and solely in such quantity, as is necessary to ensure continuity of care for identified patients based on a documented history of prescriptions for that patient population.				
17.5	CCR 1736.1(e)(1) 21 USC 353A	No CSP is compounded that is essentially a copy of one or more commercially available drug products unless allowed by federal law and CCR 1736.1(e)(1).				
17.6	CCR 1736.1(e)(2) 21 USC 353A BPC 4126.8 USP 797	No CSP is compounded that is made with any component not suitable for use in a CSP for the intended veterinary population, unless allowable under AMDUCA.				
17.7	CCR 1736.1(h) HSC 1602.5	CSPs with human whole blood or human whole blood derivatives are produced in compliance with HSC 1602.5.				

Section 18: Sterile Compounding – Personnel Training and Evaluation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
18.1	CCR 1736.2 BPC 4126.8 USP 797	Training and competency procedures for compounding personnel or persons with direct supervision and control of compounding personnel address the topics required by CCR 1736.2(a), and the facility otherwise complies with personnel training and evaluation standards and requirements set forth in USP 797 and CCR 1736.2.				

Section 19: Sterile Compounding – Personnel Hygiene and Garbing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
19.1	CCR 1736.3(a) BPC 4126.8 USP 797	Personnel with potentially contaminating conditions are not allowed to enter the designated compounding area.				
19.2	CCR 1736.3 BPC 4126.8 USP 797	Garb is donned and doffed in compliance with the standards and requirements set forth in USP 797 and CCR 1736.3.				
19.3	CCR 1736.3(d)	Restricted access barrier system and pharmaceutical isolator sleeves and gloves are changed according to both the manufacturer's recommendations and the facility's SOPs.				

Section 20: Sterile Compounding – Facilities and Engineering Controls

	Reference	Item	Yes	No	N/A	Corrective Action Plan
20.1	CCR 1736.4(a) CCR 1714(b) CCR 1714(c) 24 CCR 1250.4	Sinks used for compounding or hand hygiene are not part of a restroom or water closet, have hot and cold running water for pharmaceutical purposes, and otherwise comply with applicable statutory and regulatory requirements.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
20.2	CCR 1736.4(b)	If an SCA is used, it is located, designed, maintained, and used in compliance with the standards and requirements set forth in USP 797 and CCR 1736.4(b).				
20.3	CCR 1736.4(c)	Designated compounding area(s) are typically maintained at a temperature of 20 degrees Celsius or cooler, and the temperature is monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.				
20.4	CCR 1736.4(e)	No CSP is compounded if the compounding environment fails to meet criteria specified in law or the facility's SOPs, unless such compounding is being performed consistent with immediate use provisions.				

Section 21: Sterile Compounding – Certification and Recertification

	Reference	Item	Yes	No	N/A	Corrective Action Plan
21.1	CCR 1736.5	Certification and recertification is performed in compliance with the standards and requirements set forth in USP 797 and CCR 1736.5.				

Section 22: Sterile Compounding – Microbiological Air and Surface Monitoring

	Reference	Item	Yes	No	N/A	Corrective Action Plan
22.1	CCR 1736.6	In addition to the requirements in USP 797, environmental sampling is done in compliance with CAG-009, revised September 2020.				

Section 23: Sterile Compounding – Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

	Reference	Item	Yes	No	N/A	Corrective Action Plan
23.1	CCR 1736.7(a) BPC 4126.8 USP 797	Any cleaning, disinfecting, and sporicidal disinfectants are used in accordance with manufacturers' specifications.				
23.2	CCR 1736.7(b)	Reusable cleaning supplies, not for use in the PEC, are not stored within 1 meter of the PEC.				
23.3	CCR 1736.7(c)	The facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area includes the identity of the person completing the cleaning and disinfecting as well as the product name(s) of the cleaning, disinfecting, and sporicidal agent(s) used.				

Section 24: Sterile Compounding - Introducing Items into the SEC and PEC

	Reference	Item	Yes	No	N/A	Corrective Action Plan
24.1	CCR 1736.8 BPC 4126.8 USP 797	In addition to the requirements in USP 797, introducing items into the SEC and PEC complies with the SOPs as required in CCR 1736.17.				

Section 25: Sterile Compounding - Equipment, Supplies, and Components

	Reference	Item	Yes	No	N/A	Corrective Action Plan
25.1	CCR 1736.9(a)	All equipment and supplies used to compound a CSP are used in accordance with manufacturers' specifications and are surface compatible.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
25.2	CCR 1736.9(b)	Incubators used by the facility are cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning takes place at least every 30 days and calibration takes place at least every 12 months. Temperatures are monitored either manually or by a continuous recording device during incubation, and the results are reviewed and documented as described in the facility's SOPs.				
25.3	CCR 1736.9(c)	Any component used to compound a CSP is used and stored in accordance with all state and federal laws and the manufacturer's specifications and requirements.				
25.4	CCR 1736.9(d) 21 USC 353A BPC 4126.8 USP 797	All APIs used to compound a CSP are manufactured by an FDA-registered facility, are accompanied by Certificate of Analysis (COA), and are suitable for use in sterile pharmaceuticals.				
25.5	CCR 1736.9(e) 21 USC 353A	All APIs and other components used are evaluated for suitability for use in sterile drug preparations, as provided in USP 797, Section 9.3 Components, and follow the USP drug monograph if one exists.				
25.6	CCR 1736.9(f) 21 USC 353A BPC 4126.8 USP 797	If a component included in the published 503A Category 1 bulk drug substances list is used, it has been found suitable for sterile drug preparations as provided in USP Chapter 797, Section 9.3 Components, and the facility's SOPs establish a process to determine the quality of the API.				

Section 26: Sterile Compounding – Sterilization and Depyrogenation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
26.1	CCR 1736.10(a) BPC 4126.8 USP 797 USP 1228.1	In addition to the requirements in USP 797, dry heat depyrogenation is done in compliance with USP 1228.1, Dry Heat Depyrogenation.				
26.2	CCR 1736.10(b) BPC 4126.8 USP 797 USP 1229.4	In addition to the requirements in USP 797, sterilization by filtration is done in compliance with USP 1229.4, Sterilizing Filtration of Liquids, and filter dimensions and the CSP to be sterilized by filtration permit the sterilization process to be completed without the need for replacement of the filter during the process.				
26.3	CCR 1736.10(c) BPC 4126.8 USP 797 USP 1229.1	In addition to the requirements in USP 797, steam sterilization is done in compliance with USP 1229.1, Steam Sterilization by Direct Contact.				
26.4	CCR 1736.10(d) BPC 4126.8 USP 797 USP 1229.8	In addition to the requirements in USP 797, dry heat sterilization is done in compliance with USP 1229.8, Dry Heat Sterilization.				
26.5	CCR 1736.10(e)	No compound of a CSP from nonsterile components is prepared when the licensed location cannot also sterilize the CSP as described in CCR 1736.10.				
26.6	CCR 1736.10(f) USP 1229	Sterilization of supplies and container–closure systems is done in compliance with USP 1229, Sterilization of Compendial Articles.				

Section 27: Sterile Compounding – Master Formulation and Compounding Records

	Reference	Item	Yes	No	N/A	Corrective Action Plan
27.1	CCR 1736.11(a) BPC 4126.8 USP 797	A CSP is not compounded until the facility has first prepared a written master formulation record in compliance with USP 797 and that record includes the additional elements required by CCR 1736.11(a).				
27.2	CCR 1736.11(c) BPC 4126.8 USP 797	A compounding record is maintained and, upon request, produced as a single document which satisfies the requirements of USP 797 and also contains the additional elements required by CCR 1736.11(c).				

Sterile 28: Sterile Compounding – Release Inspections and Testing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
28.1	CCR 1736.12(a)	Pharmacists performing or who have direct supervision and control of compounding personnel understand they are responsible for ensuring the integrity, quality, and labeled strength of a CSP until the BUD indicated on the label, provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.				
28.2	CCR 1736.12(b) BPC 4126.8 USP 797 USP 1223	Pharmacists performing or who have direct supervision and control of compounding personnel understand they are responsible for ensuring validation of an alternative method for sterility testing is done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods, and any such pharmacist receives and maintains documentation of the method-suitability for each CSP formulation for which the alternate method is used.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
28.3	CCR 1736.12(c) BPC 4126.8 USP 797 USP 85	Pharmacists performing or who have direct supervision and control of compounding personnel understand they are responsible for ensuring injectable CSPs made from nonsterile components, regardless of USP Category, are tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP 85, Bacterial Endotoxins, and the results are reviewed and documented in the CR prior to furnishing.				

Section 29: Sterile Compounding – Labeling

	Reference	Item	Yes	No	N/A	Corrective Action Plan
29.1	CCR 1736.13 BPC 4126.8 USP 797 BPC 4076 CCR 1707.5	Every CSP is labeled as required by the facility's SOPs and as required by applicable law and regulation.				

Section 30: Sterile Compounding – Establishing Beyond-Use Dates

	Reference	Item	Yes	No	N/A	Corrective Action Plan
30.1	CCR 1736.14 BPC 4126.8 USP 797	All CSPs are assigned a beyond-use date (BUD), that complies with the facility's SOPs and applicable law and regulation.				
30.2	CCR 1736.14(c) BPC 4126.8 USP 85 USP 71 USP 797	When sterility or endotoxin testing is required, pharmacists performing or with direct supervision and control of compounding personnel understand they are responsible for ensuring such testing is performed. All test results are reviewed prior to furnishing a CSP. Test results must be within acceptable USP limits and are retained as part of the CR				

Section 31: Sterile Compounding – Use of Conventionally Manufactured Products as Components

	Reference	Item	Yes	No	N/A	Corrective Action Plan
31.1	CCR 1736.15 BPC 4126.8 USP 797	The facility follows the standards and requirements set forth in USP 797, Section 15 Use of Conventionally Manufactured Products as Components, and CCR 1736.15.				

Section 32: Sterile Compounding – Use of CSPs as Components

	Reference	Item	Yes	No	N/A	Corrective Action Plan
32.1	CCR 1736.16(a) BPC 4126.8 USP 797	A compounded stock solution intended for use in a CSP complies with the standards and requirements set forth in USP 797 and CCR 1736.16.				

Section 33: Sterile Compounding – Standard Operating Procedures (SOPs)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
33.1	CCR 1736.17(a) BPC 4126.8 USP 797	The facility has and follows SOPs for sterile compounding and such SOPs comply with USP 1163, Quality Assurance in Pharmaceutical Compounding and define the methods, procedures, and protocols set forth in CCR 1736.17(a)(2).				
33.2	CCR 1736.17(b)	The facility SOPs specify the steps to be taken if a classified area(s), including PEC, fails to meet the specified ISO classification, including the investigative and corrective actions, allowable activities, and retesting procedures.				
33.3	CCR 1736.17(b)	The facility SOPs describe the actions to be taken if the compounding area or equipment is rendered unusable or in a downtime situation.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
33.4	CCR 1736.17(c)	The facility SOPs specifies the steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.				
33.5	CCR 1736.17(d)	The facility SOPs specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA.				
33.6	CCR 1736.17(e)	The facility SOPs specify the frequency and processes for cleaning, maintenance, and calibration of equipment, supplies and components, including when incubation of samples is taking place, such that samples are not compromised.				
33.7	CCR 1736.17(f)	The facility SOPs specify which pharmacist is responsible for the review of all complaints related to a potential quality problem with a CSP and all adverse drug experiences in the event that the PIC is not available within 72 hours of the receipt of the complaint or occurrence.				
33.8	CCR 1736.17(g)	The facility has written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality, and labeled strength.				
33.9	CCR 1736.17(h)	The PIC reviews the SOPs annually and documents this review as required by law and regulation.				
33.10	CCR 1736.17(h)	The SOPs are updated to reflect changes to compounding processes, facility changes, and other changes that impact the CSP, and all SOP changes are disseminated to affected staff prior to implementation.				

Section 34: Sterile Compounding – Quality Assurance and Quality Control

	Reference	Item	Yes	No	N/A	Corrective Action Plan
34.1	CCR 1736.18(a) BPC 4126.8 USP 797 CCR 1711 USP 1163	The facility has a quality assurance program that complies with CCR 1711, CCR 1736.18, and the standards contained in USP 797 and USP 1163, Quality Assurance in Pharmacy Compounding.				
34.2	CCR 1736.18(b) BPC 4126.8 USP 797 BPC 4127.1 21 CFR 310.305(b)	The facility reports all recalls and adverse drug experiences, as defined in 21 CFR 310.305(b), as required by the facility's SOPs and in compliance with relevant provisions of law and regulation. Adverse effects reported or potentially attributable to the facility's sterile drug product are reported to the Board within 12 hours and immediately reported to the FDA MedWatch program. Reports to the Board are sent to: compoundingreport@dca.ca.gov.				
34.3	CCR 1736.18(c)	The PIC initiates a review of any complaints made to the facility related to a potential quality problem with a CSP and any adverse drug experiences within 72 hours of receipt of the complaint or occurrence of the adverse drug experience.				

Section 35: Sterile Compounding – CSP Handling, Storage, Packaging, Shipping and Transport

	Reference	Item	Yes	No	N/A	Corrective Action Plan
35.1	CCR 1736.19	In addition to the requirements in USP 797, packaging materials protect CSPs from damage and leakage while also preventing transportation personnel from inadvertent exposure.				

Section 36: Sterile Compounding – Documentation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
36.1	CCR 1736.20(a) BPC 4070	Records are maintained as required by USP 797 and Article 4.6 of Division 17 of the CCR, in a readily retrievable form, for at least three years from the date the record was created or relied upon, and if only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by BPC 4070.				
36.2	CCR 1736.20(b) BPC 4070	Records are created and maintained in a manner that will provide an audit trail for revisions and updates of each record document.				

Section 37: Sterile Compounding – Compounding Allergenic Extracts

	Reference	Item	Yes	No	N/A	Corrective Action Plan
37.1	CCR 1736.21	In addition to the requirements in USP 797, any allergenic extracts compounding takes place in a dedicated allergenic extract compounding area (AECA) or PEC; no other CSP is made in this PEC at the same time allergenic extract compounding is occurring; work surface of the PEC is cleaned and disinfected immediately after allergenic extract compounding; and compounding of allergenic extracts is limited to patient-specific prescriptions.				

FOR HAZARDOUS DRUGS: COMPLETE SECTIONS 38 THROUGH 54.

Section 38: Hazardous Drugs- Introduction and Scope

	Reference	Item	Yes	No	N/A	Corrective Action Plan
38.1	CCR 1737 USP 800	All compounding of hazardous drugs or crushing or splitting tablets or opening capsules of antineoplastic hazardous drugs is performed in compliance with applicable laws, regulations, and USP standards.				
38.2	CCR 1737.1 BPC 4126.8 USP 800 CCR 1707.2 BPC 4074	In addition to the provisions of CCR 1707.2, consultation is provided on handling and disposal of a compounded HD or related supplies furnished, as required by law and regulation.				

Section 39: Hazardous Drugs- List of Hazardous Drugs

	Reference	Item	Yes	No	N/A	Corrective Action Plan
39.1	CCR 1737.2(a) BPC 4126.8 USP 800	The facility's list of HDs as required by USP 800 is reviewed and approved by the PIC, or the PD of a clinic, or the DRIC, as applicable, and such approval is documented at least every 12 months.				
39.2	CCR 1737.2(b)	If an assessment of risk approach is taken as authorized in USP 800, it is approved by the DP and the PIC, PD of a clinic, or DRIC, as applicable.				

Section 40: Hazardous Drugs- Types of Exposure

	Reference	Item	Yes	No	N/A	Corrective Action Plan
40.1	CCR 1737.3 BPC 4126.8 USP 800	If compounding of HDs is performed or if crushing or splitting tablets or opening capsules of antineoplastic HDs is performed, the facility ensures that all employees are aware of the types of HD exposures that may occur as referenced in USP Chapter 800.				

Section 41: Hazardous Drugs- Responsibilities of Personnel Handling Hazardous Drugs

	Reference	Item	Yes	No	N/A	Corrective Action Plan
41.1	CCR 1737.4 BPC 4126.8 USP 800	The PIC, DRIC, or PD, as applicable, understand that they are responsible for all activities and decisions made or approved by the DP when the facility is compounding HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs.				

Section 42: Hazardous Drugs - Facilities and Engineering Controls

	Reference	Item	Yes	No	N/A	Corrective Action Plan
42.1	CCR 1737.5(a) BPC 4126.8 USP 800	When containment primary engineering controls (C-PECs) used for nonsterile and sterile HDs are placed in the same room, biannual certification documents that the room can continuously maintain an ISO 7 classification throughout the nonsterile compounding activity.				
42.2	CCR 1737.5(b)	A biological-safety cabinet as defined in USP Chapter 800 Class II Type A1 is not used for sterile compounding of a volatile HD.				
42.3	CCR 1737.5(c)	Where there is a pass-through in a containment secondary engineering control (C-SEC), the doors are gasketed and interlocking by January 1, 2027.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
42.4	CCR 1737.5(d)	On or after January 1, 2028, prior to installing a new pass-through, a facility considers the use of a HEPA purge type pass-through, and documentation is maintained showing compliance with this requirement if such a pass-through is not used.				
42.5	CCR 1737.5(e) CAG-003	Where sterile hazardous compounding is performed, facility room pressure monitoring equipment is placed consistent with CAG-003, Revised October 2022.				
42.6	CCR 1737.5(f)	Containment Supplemental Engineering Controls (CSTDs) are not used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.				

Section 43: Hazardous Drugs - Environmental Quality and Control

	Reference	Item	Yes	No	N/A	Corrective Action Plan
43.1	CCR 1737.6	The facility considers environmental wipe sampling, and the facility's SOPs describe the consideration of and provisions for environmental wipe sampling for HD surface residue.				

Section 44: Hazardous Drugs - Personal Protective Equipment (PPE)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
44.1	CCR 1737.7(a) BPC 4126.8 USP 800, Section 7.6	Outer gloves used for HD compounding are carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC, or contained in a sealable bag for discarding outside the C-PEC as established in USP 800, Section 7.6.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
44.2	CCR 1737.7(b) BPC 4126.8 USP 800	The PPE removal profess is done in a manner to avoid transferring contamination to skin, the environment, and other surfaces; outer PPE worn during compounding is disposed of in the proper waste container before leaving the C-SEC; and SOPs detail the donning and doffing of PPE and where it takes place in the C-SEC.				

Section 45: Hazardous Drugs- Hazard Communication Program

	Reference	Item	Yes	No	N/A	Corrective Action Plan
45.1	CCR 1737.8 BPC 4126.8 USP 800	The DP is involved in the premise's hazardous communication program and documents the program in the SOPs and training documents.				

Section 46: Hazardous Drugs- Personnel Training

	Reference	Item	Yes	No	N/A	Corrective Action Plan
46.1	CCR 1737.9(a) BPC 4126.8 USP 800	Any person assigned to provide training has demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility's SOPs as referenced in CCR 1737.17.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
46.2	CCR 1737.9(b)	All personnel responsible for compounding HDs or crushing or splitting tablets or opening capsules of antineoplastic HDs who fail any aspect of ongoing evaluation and training in compounding or crushing or splitting tablets or opening capsules of antineoplastic HDs do not compound HDs or perform crushing or splitting tablets or opening capsules of antineoplastic HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. Any failure in personnel competency complies with the provisions of CCR 1735.2(c) or 1736.2(d), as applicable.				

Section 47: Hazardous Drugs- Receiving

	Reference	Item	Yes	No	N/A	Corrective Action Plan
47.1	CCR 1737.10 BPC 4126.8 USP 800	All HD APIs and antineoplastic HDs are transported by the supplier in segregated impervious plastic and labeled as HDs on the outside of the delivery container.				

Section 48: Hazardous Drugs- Labeling, Packaging, Transport, and Disposal

	Reference	Item	Yes	No	N/A	Corrective Action Plan
48.1	CCR 1737.11(a) BPC 4126.8 USP 800 BPC 4076 CCR 1707.5	All HDs are labeled as required by the facility's SOPs, and as required by applicable law and regulation.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
48.2	CCR 1737.11(b)	All compounded antineoplastic HDs are transported from the facility in an impervious plastic container and labeled as Hazardous Drugs on the outside of the container, unless the label is visible through the outer container.				
48.3	CCR 1737.11(c)	When furnishing a compounded antineoplastic HD for administration within a health care facility licensed pursuant to Health and Safety Code section 1250, the HD is placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the outer container.				

Section 49: Hazardous Drugs- Dispensing Final Dosage Form

	Reference	Item	Yes	No	N/A	Corrective Action Plan
49.1	CCR 1737.12 BPC 4126.8 USP 800	All equipment used in nonsterile HD compounding is dedicated for use with HDs and is decontaminated after each use.				

Section 50: Hazardous Drugs- Compounding

	Reference	Item	Yes	No	N/A	Corrective Action Plan
50.1	CCR 1737.13(a) BPC 4126.8 USP 800	If a disposable preparation mat is used for compounding a CSP, it is sterile and it is changed immediately if a spill occurs, after each different HD preparation unless multiple preparations of the same drug or for a single patient is occurring, and at the end of the daily compounding activity.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
50.2	CCR 1737.13(b)	Only one HD preparation is handled in a C-PEC at one time, unless the multiple HD preparations are of the same drug, or are multiple HD preparations for a single patient.				

Section 51: Hazardous Drugs- Administering

	Reference	Item	Yes	No	N/A	Corrective Action Plan
51.1	CCR 1737.14(a) BPC 4126.8 USP 800	When furnishing an infused compounded antineoplastic HD for administration, the facility attaches and primes tubing and attaches a Closed System Drug-Transfer Device (CSTD) when appropriate.				
51.2	CCR 1737.14(b)	When dispensing a compounded antineoplastic HD to a patient or patient's agent, the pharmacy provides, or offers for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves to allow for appropriate handling and disposal of the HD.				

Section 52: Hazardous Drugs- Deactivating, Decontamination, Cleaning, and Disinfecting

	Reference	Item	Yes	No	N/A	Corrective Action Plan
52.1	CCR 1737.15(a) BPC 4126.8 USP 800	Deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents are used in accordance with manufacturers' specifications, or subsequent manufacturer approved studies, and are surface compatible.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
52.2	CCR 1737.15(b)	Agents used for deactivation, decontamination, cleaning, and disinfecting all areas and equipment involved in the compounding of HDs or performing crushing or splitting tablets or opening capsules of antineoplastics HDs are applied through the use of wipes wetted with the appropriate solution.				

Section 53: Hazardous Drugs- Spill Control

	Reference	Item	Yes	No	N/A	Corrective Action Plan
53.1	CCR 1737.16 BPC 4126.8 USP 800	A facility where compounding of HDs is performed outlines how a qualified person will be available at all times while HDs are compounded within the facility's SOPs.				

Section 54: Hazardous Drugs- Documentation and Standard Operating Procedures (SOPs)

	Reference	Item	Yes	No	N/A	Corrective Action Plan
54.1	CCR 1737.17 BPC 4126.8 USP 800	A facility maintains and follows written SOPs for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.				
54.2	CCR 1737.17(c)	The PIC, PD of a clinic, or DRIC, as applicable, works with the facility's DP to ensure SOPs are reviewed at least every 12 months and the review is documented as required by law and regulation.				
54.3	CCR 1737.17(d)	SOPs are updated whenever changes are implemented. Such changes are disseminated in a written format to the staff responsible for HDs prior to implementation.				

FOR RADIOPHARMACEUTICAL PREPARATIONS: COMPLETE SECTIONS 55 THROUGH 68.

Section 55: Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging- Introduction

	Reference	Item	Yes	No	N/A	Corrective Action Plan
55.1	CCR 1738.1(a)	The use of technologies, techniques, material, and procedures not described in USP Chapter 825 is based upon published peer-reviewed literature or documents and meets FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.				
55.2	CCR 1738.1(b) CCR 1738.10(e) HSC 1602.5	Processing with human whole blood or human whole blood derivatives is done in compliance with HSC 1602.5.				

Section 56: Radiopharmaceutical- Radiation Safety Considerations

	Reference	Item	Yes	No	N/A	Corrective Action Plan
56.1	CCR 1738.2(a) BPC 4126.8 USP 825	Radiation detectors and measuring devices, and other necessary equipment, placed inside an ISO Class 5 PEC are placed in a manner that minimizes disruptions of airflow.				
56.2	CCR 1738.2(b)	Disposable absorbent pads are changed after each type of radiopharmaceutical processing.				
56.3	CCR 1738.2(c)	Any deviation made to lower radiation exposure to workers is evaluated and documented in an SOP by the DP prior to the deviation occurring.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
56.4	CCR 1738.2(c) 17 CCR 30190 10 CFR 32.72	Exceptions to the environmental controls requirements are documented in the specific radioactive materials license conditions issued by the CDPH pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to section 32.72 of title 10 of the Code of Federal Regulations.				

Section 57: Radiopharmaceutical- - Immediate Use of Sterile Radiopharmaceuticals

	Reference	Item	Yes	No	N/A	Corrective Action Plan
57.1	CCR 1738.3 BPC 4126.8 USP 825 BPC 4081	The processing of radiopharmaceuticals for immediate use is only done in a patient care setting meets the applicable requirements of Article 4.8 of Division 17 of the CCR, and the patient care facility maintains all records required in Section 9 of USP Chapter 825 in accordance with BPC 4081.				

Section 58: Radiopharmaceutical- - Personnel Qualifications, Training, and Hygiene

	Reference	Item	Yes	No	N/A	Corrective Action Plan
58.1	CCR 1738.4(a)	Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or other conditions that could contaminate a sterile radiopharmaceutical or the environment are not allowed to enter the compounding area unless approved by the DP.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
58.2	CCR 1738.4(b)	The pharmacist with direct supervision and control of personnel performing radiopharmaceutical processing demonstrates proficiency in the skills necessary to ensure the integrity, strength, quality, and labeled strength of radiopharmaceuticals, as defined in the facility's SOPs.				
58.3	CCR 1738.4(c) CCR 1738.4 (g) CCR 1738.4 (h) BPC 4126.8 USP 825	Aseptic manipulation competency initial training and competency and ongoing training and competency documentation includes the PEC's type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification is performed using the same procedures, type of equipment, and materials used in aseptic compounding.				
58.4	CCR 1738.4(d)	SOPs clearly define the acceptable use and cleaning for reusable gowns in order to prevent possible contamination of the sterile radiopharmaceuticals and designated compounding area, and the facility's SOPs describe the process to be followed should the facility allow for the reuse of garb.				
58.5	CCR 1738.4(e)	Eyeglasses are cleaned as part of hand hygiene and garbing, consistent with the standards specified in the facility's SOPs.				
58.6	CCR 1738.4(f) BPC 4126.8 USP 825	Garb is donned and removed in an ante-area or immediately outside the segregated radiopharmaceutical processing area (SRPA), and donning and doffing garb does not occur in the anteroom at the same time unless the SOPs define specific processes that must be followed to prevent contamination.				

Section 59: Radiopharmaceutical - Facilities and Engineering Controls

	Reference	Item	Yes	No	N/A	Corrective Action Plan
59.1	CCR 1738.5(a) CCR 1714(b) CCR 1714(c) 24 CCR 1250.4	Sinks used for hand hygiene and compounding are not part of a restroom or water closet, have hot and cold running water for pharmaceutical purposes, and otherwise comply with applicable statutory and regulatory requirements.				
59.2	CCR 1738.5(b) CCR 1738.6(d)	Temperatures are monitored either manually or by a continuous recording device in the SRPA and classified areas each day that processing is performed.				
59.3	CCR 1738.5(c)	Storage and elution of non-direct infusion radionuclide generators takes place in an ISO Class 9 or better area.				
59.4	CCR 1738.5(d) CCR 1738.5 (e) CCR 1738.5(f) CCR 1738.5 (g) BPC 4126.8 USP 825	If an SRPA is used, it is designed, maintained, tested, certified/recertified, and used in compliance with and as required by the facility's SOPs and applicable law and regulation.				
59.5	CCR 1738.5(h) CCR 1738.5(i)	Activities or tasks carried out within the SRPA and classified areas are limited to only those necessary for processing a radiopharmaceutical.				

Section 60: Radiopharmaceutical- Microbiological Air and Surface Monitoring

	Reference	Item	Yes	No	N/A	Corrective Action Plan
60.1	CCR 1738.6(a)	SOPs specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.				
60.2	CCR 1738.6(b) CCR 1738.9	The DP reviews and identifies data trends for all sampling results and evaluates trends to determine if corrective action is needed. The results of the review are documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in CCR 1738.9.				
60.3	CCR 1738.6(c) CAG-009	Environmental sampling is done in compliance with CAG-009, revised September 2020.				
60.4	CCR 1738.6(d)	Incubators used by the facility are cleaned, maintained, calibrated, and operated in accordance with the manufacturers' specifications. Temperatures are monitored either manually or by a continuous recording device during incubation, and the result are reviewed and documented as described in the facility's SOPs. For incubators without specific manufacturers' specifications, cleaning takes place at least every 30 days and calibration takes place at least every 12 months.				

Section 61: Radiopharmaceutical- Cleaning and Disinfecting

	Reference	Item	Yes	No	N/A	Corrective Action Plan
61.1	CCR 1738.7(a) BPC 4126.8 USP 825	Cleaning, disinfection, and sporicidal agents are used in accordance with manufacturers' specifications and occur at the minimum frequencies listed in Table 5 of USP Chapter 825.				
61.2	CCR 1738.7(b)	Reusable cleaning supplies, not for use in the PEC, are not stored within 1 meter of the PEC.				

Section 62: Radiopharmaceutical- Assigning BUD

	Reference	Item	Yes	No	N/A	Corrective Action Plan
62.1	CCR 1738.8(a)	A radiopharmaceutical's beyond-use date (BUD) does not exceed the shortest BUD of any of its components.				
62.2	CCR 1738.8(b)	No radiopharmaceutical CSP is administered after the labeled BUD.				
62.3	CCR 1738.8(c) CCR 1738.8(d)	Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the pharmacy maintains documentation of at least the elements listed in CCR 1738.8(d) .				

Section 63: Radiopharmaceutical- - Documentation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
63.1	CCR 1738.9(a) CCR 1738.9(b) CCR 1738.9(c) BPC 4126.8 USP 825	A record of preparation includes a compounding record compliant with section 9.2 of USP Chapter 825.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
63.2	CCR 1738.9(b)	A record for preparation with minor deviations or a record of compounding is maintained and, upon request, can be produced as a single document that satisfies the requirements of USP Chapter 825 as well as the requirements of CCR 1738.9(b)(1)-(5).				
63.3	CCR 1738.9(d)	Records are created and maintained in a manner to provide an audit trail for revisions and updates of each record document.				

Section 64: Radiopharmaceutical- - Preparation

	Reference	Item	Yes	No	N/A	Corrective Action Plan
64.1	CCR 1738 CCR 1738.10	All processing (i.e., preparation, compounding, repackaging, or dispensing) of radiopharmaceuticals is performed in compliance with applicable laws, regulations, and USP standards.				

Section 65: Radiopharmaceutical - Compounding

	Reference	Item	Yes	No	N/A	Corrective Action Plan
65.1	CCR 1738.11(a) 17 CCR 30190 10 CFR 32.72	All compounding of radiopharmaceuticals complies with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the CDPH pursuant to section 30190 of Title 17 of the California Code of Regulations, any other state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear Regulatory Commission pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilizes applicable environmental controls.				

	Reference	Item	Yes	No	N/A	Corrective Action Plan
65.2	CCR 1738.11(b)	All API and excipient components used to compound a radiopharmaceutical are manufactured by an FDA-registered facility, are accompanied by Certificate of Analysis (COA), and are suitable for use in sterile pharmaceuticals.				
65.3	CCR 1738.11(c) BPC 4126.8 USP 825	Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s), results of bacterial endotoxin testing are reviewed and recorded, and results are documented in the compounding record specified in Section 9.2 of USP Chapter 825.				

Section 66: Radiopharmaceutical- Dispensing

	Reference	Item	Yes	No	N/A	Corrective Action Plan
66.1	CCR 1738.12 BPC 4126.8 USP 825 BPC 4076 CCR 1707.5	All dispensed radiopharmaceutical doses are labeled with the information required by BPC 4076 and CCR 1707.5, and outer shielding labels contain the name and contact information of the dispensing pharmacy.				

Section 67: Radiopharmaceutical- Repackaging

	Reference	Item	Yes	No	N/A	Corrective Action Plan
67.1	CCR 1738.13(a) CCR 1738.13(b) BPC 4126.8 USP 825 BPC 4076 CCR 1707.5	The inner container and outer shielding of a repackaged radiopharmaceutical are labeled as required by law and regulation.				

Section 68: Radiopharmaceutical- Quality Assurance and Quality Control

	Reference	Item	Yes	No	N/A	Corrective Action Plan
68.1	CCR 1738.14(a) BPC 4126.8 USP 825 CCR 1711 USP 1163	The facility has a quality assurance program that complies with CCR 1711, CCR 1738.14, and the standards contained in USP 825 and USP 1163, Quality Assurance in Pharmacy Compounding.				
68.2	CCR 1738.14(b) BPC 4126.8 USP 825 BPC 4127.1 21 CFR 310.305(b)	The facility reports all recalls and adverse drug experiences as defined in 21 CFR 310.30(b) to the Board and other agencies in compliance with relevant provisions of law. Reports to the Board are sent to: compoundingreport@dca.ca.gov.				
68.3	CCR 1738.14(c)	The PIC initiates a review of any complaints made to the facility related to a potential quality problem with a radiopharmaceutical and any reported adverse drug experiences within 72 hours of receipt of the complaint or occurrence.				
68.4	CCR 1738.14(e)	The PIC reviews the SOPs annually and documents this review consistent with the SOPs.				

ADDITIONAL REFERENCES

Licensees are encouraged to review the additional references provided below for more information about the listed topics. Licensees are advised that the below is a list of selective references that licensees may find helpful, but not an exhaustive list of all pharmacy laws and regulations that may apply to any given topic or in any specific case.

Reference	Topic
BPC 688 21 CFR 1306.08 21 CFR Part 1311	Electronic Prescription Requirements
CCR 1708.4 CCR 1708.5 CCR 1751 et al	Nuclear Pharmacies
BPC 22949.92.1	Pharmacy Closures
CCR 1708.1	Temporary Closures

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 to the best of my professional ability. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I acknowledge the self-assessment will be readily available for review during any inspection by the Board. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature* _____ Date: _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OR AUTHORIZED OFFICER OF THE FACILITY:

I, (please print) _____, hereby certify 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 action by the California State Board of Pharmacy.

Signature* _____ Date: _____
Owner or Authorized Officer of the Facility

*Consistent with 16 CCR Section 1700, the Board will accept digital signatures.