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

ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: January 23, 2023

LOCATION: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Renee Barker, Licensee Member
Seung Oh, Licensee Member
Ricardo Sanchez, Public Member

COMMITTEE MEMBERS NOT PRESENT: Indira Cameron-Banks, Public Member
Jig Patel, Licensee Member, Vice Chair

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

I. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Maria Serpa called the meeting to order at 9:00 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Seung Oh, Licensee Member; Ricardo Sanchez, Public Member; and Maria Serpa; Licensing Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda.

A representative of the CRA/NACDS raised an issue that state of emergency would be ending February 28, 2023, and all Department of Consumer Affairs (DCA) waivers would be ending on that date not including Board of Pharmacy waivers that end at the end of May 2023. The representative added the DCA waiver that allows pharmacy technicians to perform COVID immunization and testing expires February 28, 2023. However, the federal Public Readiness and Emergency Preparedness (PREP) Act allows pharmacy technicians to perform COVID immunizations and testing as well as flu vaccines that won't expire until the end of October 2024. The representative requested confirmation from the Board as to whether the Board recognizes the PREP Act preemption and will continue to allow pharmacy technicians to administer COVID testing and COVID and flu vaccines. The representative noted there were references to the PREP Act in state documentation including the Department of Public Health. The representative stated understanding that the Board is pursuing a legislative proposal that would allow for expanded pharmacy technician duties but noted there was a significant amount of time between the end of the state of the emergency and when the legislation would go into effect, if approved, and would like to ensure pharmacy technicians can do the testing and immunization until the PREP Act expires. The representative added this would be a significant impact to services if the services cannot be provided through the end of the PREP Act. If that was the case, the representative requests adding the issue to the February 2023 agenda.

Members were surveyed to see if an item should be added to a future agenda to the Committee or Board; however, no comments were made.

III. Approval of October 4, 2022, Enforcement and Compounding Committee Meeting Minutes

Chairperson Serpa referenced the draft minutes for the October 4, 2022, Enforcement and Compounding Committee Meeting.

Members were provided an opportunity to provide comments on the draft minutes; however, no comments were made.

Motion: Approve the October 4, 2022, Committee Meeting Minutes as presented in the meeting materials

M/S: Oh/Sanchez

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Committee Member	Vote
Barker	Support
Cameron-Banks	Not Present
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support

IV. Discussion and Consideration and Possible Action on Self-Assessment Forms

Chairperson Serpa advised the dynamic nature of the pharmacy law generally results in the need to update the self-assessment forms on an annual basis to incorporate law changes made at either the state or federal level. Dr. Serpa referred to the meeting materials containing four self-assessments provided for review. Staff was recommending action on only one of the self-assessment forms, 17M-112 related to Automated Drug Delivery Systems noting staff recommended that the remainder of the forms be completed through a section 100 regulation change as the proposed changes to the forms themselves do not create a requirement, but rather include a new, update or repealed legal requirement that licensees must follow. Dr. Serpa advised should the Committee agree with this approach, moving forward, the executive officer will be able to move forward with updating these forms through this streamlined process. Dr. Serpa spoke in support of this approach and would offer, as the Chairperson to review proposed changes before future updates are made via the section 100 process.

Chairperson Serpa reviewed the proposed changes and agreed with staff recommendation offered for self-assessments included as agenda item IV a-c, including the Community Pharmacy/Hospital Outpatient Self-Assessment, Hospital Pharmacy Self-Assessment and Wholesaler/Third Party Logistics Provider Self-Assessment.

Chairperson Serpa provided members an opportunity to comment on both the recommendation offered to use the section 100 process as a means to update these three forms as well as recommended changes on the forms themselves. Dr. Serpa noted that the meeting materials and slides summarize the changes offered in these forms.

Members were provided the opportunity to comment.

Member Oh requested clarification on the Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment. Dr. Oh noted in added 1.24 about temporary closure might cause confusion when a pharmacy is closed for a pharmacist's lunch break. Dr. Oh requested that it was clarified this closure was for temporary closure of a pharmacy facility and did not include closure of the pharmacy for lunch breaks.

Member Oh commented on the language in 22.3.7 about inventory reconciliation that "An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the reportable loss." was a very legal nuance. Dr. Oh wanted to emphasize the discovery of the reportable loss so to make it clear that it is for "reportable" loss and not all loss. Dr. Oh noted the term "loss" was confusing to pharmacists and wanted to clarify it was for "reportable" loss. Dr. Oh also commented on 22.3.8 about "inventory activities" which was different from reconciliation.

Member Oh commented 22.5 was supposed to be removed and incorporated in 22.3.9 noting both were not correct. Dr. Oh added the Hospital Pharmacy Self-Assessment was correct.

Member Oh commented that the sections being removed were still helpful and was hopeful the information could still be left on the website as optional for the blood products.

Chairperson Serpa would work with staff to combine 22.5 and 22.3.9. Dr. Serpa was not sure how to provide 27 and suggested possibly as an FAQ. Dr. Serpa noted the intent was to remove the details but keep the references as previous public comment indicated it didn't apply to everyone. Dr. Oh inquired how many pharmacies provided bloodborne products and how many remote dispensing pharmacies there were in California. Ms. Sodergren provided there were few remote dispensing pharmacies and given the number in California, staff's recommendation was to remove the text but keep the reference. Ms. Sodergren stated the Board can add information and create links to the Board's website for more information if the Committee desired. Dr. Oh stated it was acceptable to not do that.

Chairperson Serpa was not sure how to make Dr. Oh's first two comments clearer other than bolding/highlighting. Dr. Oh hoped the first sentence could be clearer regarding the intent of the regulation for closure and reconciliation. Dr. Serpa agreed when going through the Section 100 process to be mindful of the issues.

Members of the public were provided an opportunity to comment.

A member of the public inquired what was defined as considered a loss related to inventory reconciliation. Dr. Serpa referred to 21.14 that specified the regulatory language.

A representative from CVS Health commented there was a mention on community form concerning remote work that may be premature to address. The representative was also curious why it was not consistent with Hospital Self-Assessment Form based on the Board's recent interpretation that drastically restricts remote work also pertains to hospitals.

A retired pharmacist commented meeting participants may not understand the Section 100 process and suggested discussion. Counsel Smiley advised the information covered in the Chairperson's opening remarks; no additional information was required.

Chairperson Serpa reviewed the proposed changes and agreed with the changes and the possible motion offered in the meeting materials related to the automated drug delivery system self-assessment. Dr. Serpa noted the meeting materials and slide highlight the changes.

Chairperson Serpa advised the Committee must address this self-assessment differently than the prior three, because the regulation section, CCR section 1715.1 that includes this self-assessment for, and the form itself are currently going through the rulemaking process. Dr. Serpa advised the comment period closed on December 27, 2022, and comments received during the comment period would be considered by the full Board during the February 2022 Board Meeting.

Chairperson Serpa provided the review and discussion was limited to just the new changes being recommended noting the changes were highlighted in the meeting materials and were reflected in the form. Dr. Serpa added deleted text was shown by italicized double strikethrough and added language is shown as italicized wavy underline. Dr. Serpa noted easy examples to highlight both were included on the first page of the form where the "note" and text added shown as italicized and wavy underline was a new change for our consideration and the update to the revision date at the bottom of the form is an example of deleted text. Dr. Serpa noted because the Board would be considering the comments

received during the comment period, to ensure compliance with the government code, it was very important that comments were limited to only the new changes.

Members were provided the opportunity to provide comment.

Member Oh requested clarification on the Note on page 1 that confirmed one for was required for an entity with many non-licensed ADDS in a hospital.

Motion: Recommend approval of the proposed amendments to self-assessment form 17M-112 and incorporate the proposed amendments into the rulemaking package and initiate a 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking, make any non-substantive changes to the package, and adopt self-assessment form 17M-112.

M/S: Oh/Barker

Members of the public were provided the opportunity to comment; however, comments were not made.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 2

Committee Member	**Vote**
Barker	Support
Cameron-Banks	Not Present
Oh	Support
Patel	Not Present
Sanchez	Support
Serpa	Support

V. Discussion and Consideration of Barriers to Timely Case Resolutions

Chairperson Serpa recalled one of the Committee's strategic objectives was to determine and reduce barriers to timely case resolutions to improve consumer protections. Dr. Serpa provided there were many steps involved in an investigation

and the egregiousness of the violations, if any, would in large part determine the outcome of the matter. Dr. Serpa noted later in the meeting, the Committee will be discussing enforcement statistics but would like to highlight that only about 7 percent of the Board's investigations result in referral to the Office of the Attorney General for discipline. Dr. Serpa highlighted this as there appears to be a perception that the formal discipline taken by the Board constitutes a significant portion of its investigations; however, the data tells otherwise. Dr. Serpa added when aggregated data for investigations was considered, investigation timeframes were currently the longest step.

Chairperson Serpa referred to information included in the meeting materials and on the meeting slide were recommendations offered by staff that would remove barriers:

- Amend BPC 4081 to require maintenance and release of staffing schedules, job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations as part of the records that must be maintained; and
- Amend BPC 4105 to require maintenance and release of staffing schedules, job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations as part of the records that must be readily retrievable.

Chairperson Serpa noted that the barriers identified and changes offered appear to be consistent with the policy of the legislature and believed the changes were appropriate. Dr. Serpa agreed with the staff recommendations and thanked supervising inspector staff for bringing these recommendations to the Committee for consideration. Dr. Serpa supported staff drafting statutory language for future consideration.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa noted Committee consensus and agreed to work with staff to bring statutory language to a future meeting.

VI. Overview of Federal Requirements for Compounding under the Provisions of 503A

Chairperson Serpa advised licensees of the Board generally must comply with a myriad of state and federal laws noting at times, a licensee may be so focused on a specific section of the law that they may forget the larger picture and other

provisions of law that may be relevant. Dr. Serpa noted this was seen in several areas of pharmacy practice but it was quite pronounced in compounding. Dr. Serpa advised to serve as a reminder of some of the federal legal requirements for compounding, Board Counsel Eileen Smiley provided an overview of the requirements for authorized individuals for qualify for some exemptions to federal law under provisions of section 503A.

Ms. Smiley provided an overview of federal requirements for compounding and the need for exemptions for compounding. Ms. Smiley reviewed the 503A exemption and provided a summary of the 503A exemption. Ms. Smiley reviewed how state requirements also apply.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment. Ms. Smiley reminded participants that pending enforcement issues would not be discussed. However, no public comments were made.

Chairperson Serpa thanked Ms. Smiley for her presentation.

The Committee took a break from 9:54 a.m. – 10:01 a.m. Chairperson Serpa took roll call. Members present included: Renee Barker, Licensee Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was not established. As indicated on the agenda, in the event a quorum of the Committee was unable to attend the meeting, or the Committee was unable to maintain a quorum once the meeting is called to order, the members present may, at the Chair's discretion, continue to discuss items from the agenda and make recommendations to the full board at a future meeting.

Member Sanchez arrived at 10:06 a.m. A quorum was established.

VII. Presentation on USP General Chapter 825, Regarding Radiopharmaceuticals

Chairperson Serpa advised the Committee would hear a presentation from Supervising Inspector Christine Acosta on the new USP 825 Chapter related to Radiopharmaceuticals. Dr. Serpa noted the provisions of this chapter become effective November 1, 2023.

Supervising Inspector Christine Acosta reviewed definitions, generators, PECs, and conventionally manufactured kits, preparation, and dispensing. Dr. Acosta reviewed 1. Introduction; 1.1 Nonsterile Radiopharmaceuticals; 1.2 Sterile Radiopharmaceuticals; 2. Radiation Safety Considerations; 2.4 Radiation Contamination Control; 4. Personnel Qualifications, Training and Hygiene; 4.1

Aseptic Qualifications; 4.2 Re-Evaluations, Retraining and Requalification; 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area; 5.1 Facility Design and Environmental Controls; 5.2 Creating Areas to Achieve Easily Cleanable Conditions; 5.3 Water Sources; 5.7 Environmental Controls; 6. Microbiological Air and Surface Monitors; 6.1 General Monitoring Requirements; 6.2 Monitoring Air Quality for Viable Airborne Particulates; 6.3 Monitoring Surfaces for Viable Particles; 7. Cleaning and Disinfecting; 8. Assigning BUD, Sterility BUD; 9. Documentation; 10.2 Preparation with Minor Deviations; 10.3 Preparation of Radiolabeled Blood Components; 11.1 Compounding Nonsterile Radiopharmaceuticals; 11.2 Sterile Compounding; 12.1 Dispensing and Radioassay; 12.2 Labeling; 13. Repackaging; and 14. Quality Assurance and Quality Control.

Members were provided the opportunity to comment.

Member Barker inquired about the qualifications for the workers in 4.1 Aseptic Qualification that Qualifications may be conducted at a different site if all SOPs are identical for the applicable job function. Dr. Barker noted that it varies from how training for sterile compounding. Dr. Acosta provided in the scope of radiopharmaceutical, the primary engineering control (PEC) will always be a biological safety cabinet where it could be different in a hospital practice setting using different PECs. Dr. Acosta advised for aseptic technique that was carried over also because there are only 3-4 different companies that do this and trained staffing is limited. However, it was possible this presents a risk to the consumer.

Member Barker mentioned having experience with someone who was learning aseptic technique but trying to manipulate with lead gloves as part of a qualification to don sterile gloves on top of lead gloves and inquired if Dr. Acosta came across that situation. Dr. Acosta had not seen a lead glove and was not sure how the needle would be manipulated. Dr. Acosta noted it was the balance of protecting the person and the stability of the product. Dr. Acosta was accustomed to seeing people using sterile gloves.

Member Barker inquired about the stages when the frequent application of sterile isopropyl alcohol would be done and if the sterile alcohol was exposed in the hood. Dr. Acosta indicated in her experience it was in the biological safety cabinet or in a cart next to it where hands are sprayed after coming out of the ISO 5 similar to a regular USP 797. Cleaning and disinfecting were to be done on a regular basis but the more isopropyl alcohol can be sprayed the better.

Member Barker was unfamiliar with the dose calibrator and inquired how the crucible calibrator calibrates the dose. Dr. Acosta explained there was a pully system that had the syringe or vial and calculates the radiopharmaceutical activity. The math equation is done for what is needed during the time needed. Dr.

Barker asked if the needle was capped after the dose was drawn. Dr. Acosta believed the needle was removed but wasn't able to verify.

Members of the public were provided the opportunity to comment; however, no comments were made.

VIII. Discussion and Consideration of Proposed Addition to Title 16, California Code of Regulations Section 1738 related to Radiopharmaceuticals

Chairperson Serpa advised the Committee would begin work to review the various USP chapters and review current and proposed regulations that may be necessary to implement, clarify, or make more specific requirements related to those respective chapters. Dr. Serpa believed it was appropriate that any such regulations mirror the structure of the respective chapters. Dr. Serpa noted as the Board is a consumer protection agency and as the Committee considered the development of the regulations, the work must be through the lens of the Board's consumer protection mandate as the law makes clear whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Dr. Serpa noted it was a dynamic process and individuals would have opportunities to participate throughout the development and rulemaking process.

Chairperson Serpa intended to discuss each section first as a committee, and then ask the moderator to open the lines for public comment with the refining of the language through the discussion with the understanding that any language we amended at the meeting would be reviewed by counsel. Dr. Serpa added after public comment, Dr. Serpa would summarize comments received for each section and the Committee can determine if additional changes to the proposed language was appropriate. Dr. Serpa requested staff display the language during this portion of the meeting to allow for edits to be made during the meeting where changes were appropriate.

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa advised the first proposed change was the proposed repeal of CCR sections 1708.3 through 1708.5 with the new regulations as proposed would be established in a new section 1738. Dr. Serpa believed this was appropriate and would make compliance easier for licensees by having information centralized.

Repeal:

~~1708.3. Radioactive Drugs.~~

~~A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.~~

~~1708.4. Pharmacist Handling Radioactive Drugs.~~

~~A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.~~

~~1708.5. Pharmacy Furnishing Radioactive Drugs.~~

~~A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.~~

~~A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.~~

~~Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.~~

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa advised the first new proposed section was CCR section 1738. Dr. Serpa provided the proposed language incorporates USP Chapter 825 into the regulation, providing clarity to the Board's regulated public that the requirements of the Chapter must be met. Dr. Serpa added the authority for such a requirement was established in several sections of pharmacy law as detailed in the language.

Proposal to Add Article XX as proposed with the following:

Article XX Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging* ("USP Chapter 825" for the purposes of this Article).

Necessity: Clarity to the regulated public about the requirements to comply with the Section consistent with authority established in the law and the requirements of the Chapter.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa provided CCR section 1738.1 as proposed reinforces the applicability of the USP Chapter 825 and the definitions included within the chapter. Dr. Serpa added it further provides additional definitions for terms used in the chapter and proposed regulations that were not otherwise defined. Dr. Serpa noted providing these definitions ensures members of the regulated public have a

clear understanding of the Board's definitions when applying both the provisions of the chapter and the board's regulations.

The proposed definitions include:
- Added substances
- Designated person
- Component
- Diluent
- Processing, processed or processing activity
- As well as requirements for use of technologies, techniques, materials, and procedures not described in USP 825 as well as provisions for processing with human whole blood or human whole blood derivatives.

1738.1 INTRODUCTION SCOPE AND COMPOUNDING DEFINITIONS

In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825 when not otherwise provided in USP Chapter 825.

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

(b) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Processing," "processed" or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

(e) The use of technologies, techniques, material, and procedures not described in USP 825 shall be based upon published peer-reviewed literature or documents meeting 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.

(f) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa provided CCR proposed section 1738.2 related to Radiation Safety Considerations relied on the standards established in the Chapter. Dr. Serpa added the language will ensure the appropriate placement of equipment etc. to minimize disruptions of airflow. The language will require that disposable absorbent pads are changed to prevent cross-contamination and requires documentation within the SOP of the necessity of deviations.

1738.2 RADIATION SAFETY CONSIDERATIONS

In addition to the standards in the USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.

(a) Radiation detectors and measuring devices, and other necessary equipment may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.
Necessity: To provide clarity and ensure the appropriate type and material is used. The language establishes a requirement about what actions must be done versus should be done.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

Necessity: To provide clarity as the Chapter does not specify that pads must be changed. Changing pads is necessary to avoid cross contamination.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health 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 pursuant to section 32.72 of title 10 of the Code of Federal Regulations.

Necessity: Provides clarity to ensure that SOPs document the need for deviations.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa advised CCR proposed Section 1738.3 establishes the standards for the immediate use of sterile radiopharmaceuticals and will ensure licensees have a clear understanding that the records required in the Chapter must be maintained consistent with the provisions of BPC section 4081.

1738.3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided an opportunity to comment; however, no comments were made.

Members of the public were provided an opportunity to comment; however, no comments were made.

Chairperson Serpa advised CCR section 1738.4 was related to personnel qualifications, training, and hygiene. Dr. Serpa advised this section establishes requirements necessary for public protection while providing for professional judgement of the designated person to make site specific and person specific decisions on a case-by-case basis. Dr. Serpa noted the regulation was relying on appropriate SOPs to appropriately define how some processes may occur.

1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic qualifications from one premises may be used for another premises if the SOPs, facilities, and equipment are identical.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the ante-room or the SPRA at the same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed the language strikes the right balance for radiopharmaceuticals and was comfortable with the proposed language as it specifically relates to radiopharmaceuticals in this section. Members were provided the opportunity to comment.

Member Barker inquired about subsection (c) regarding if the SOPs, facilities, and equipment were to be identical and if identical meant the exact same extending to the same brand, manufacturers, etc. Dr. Barker recommended clarification. Dr. Serpa noted in regulations, the Board is clarifying and making known what the California expectations are as USP is a little broader, whereas in California regulations state requirements more specifically. Dr. Acosta deferred to legal regarding the term "identical" as when primary engineering control (PEC) the types of equipment are grouped (e.g., biological horizontal flow, CAI, CACI, etc.) together. Counsel Grace Arupo Rodriguez advised the pure meaning is exact and identical which allows for an opportunity to clarify if desired but was not something that would trigger clarification with the Office of Administrative Law. With regard to enforcement, it would help to provide parameters. Dr. Barker thought identical should apply to SOPs but perhaps facilities and equipment could have elaboration. The Committee discussed different iterations of verbiage. Dr. Acosta advised having SOPs and facility remain identical but equipment was more difficult. The Committee agreed to remove equipment and let USP 825 address equipment.

(c) Aseptic qualifications from one premises may be used for another premises if the SOPs and, facilities are identical~~, and equipment are identical~~.

Members of the public were provided the opportunity to comment.

A representative from CPhA commented in appreciation for discussion striving for clarity.

Chairperson Serpa believed the changes were appropriate and requested if the Committee had additional comments. The Committee reached consensus on the updated language for proposed CCR section 1738.4.

1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic qualifications from one premises may be used for another premises if the SOPs and, facilities are identical~~, and equipment are identical~~.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the ante-room or the SPRA at the same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa provided CCR Section 1738.5 establishes the requirements for facilities and engineering control. Dr. Serpa noted in addition to the standards established in the Chapter, among other changes the proposed regulation will require that the sink used for compounding or hand hygiene shall not be part of the restroom or water closet. Dr. Serpa noted some of the regulation language was being included where the chapter was silent to provide clarity. Dr. Serpa provided an example of proposed 1738.5(h) explicitly states that only activities necessary for processing a radiopharmaceutical may be perform in the SRPA.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate.

1738.5. FACILITIES AND ENGINEERING CONTROLS

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored in SRPAs segregated radiopharmaceutical processing area and classified areas each day that processing is performed, either manually or by a continuous recording device.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(3) Compounding shall not take place in the SRPA.

(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or under the direct supervision of an individual who possesses a current accreditation issued by CETA Certification shall be completed consistent with the provisions established in the USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP Chapter 797). The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as required and specified in USP Chapter 797.

(f) SOPs shall specify steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includeswhen the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Members were provided the opportunity to comment. The Committee discussed the term "water closet" and determined it was a term of trade used by Department of Health Care Access and Information formerly known as OSHPD and was consistent.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa provided CCR section 1738.6 incorporates the USP standards related to microbiological air and surface monitoring and as proposed include requirements that are silent in the chapter. Such an approach provided clarity to the regulated and ensures everyone has a clear understanding of the Board's requirements.

1738.6. MICROBIOLOGICAL AIR AND SURFACE MONITORING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) SOPs shall 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.

(b) At a minimum, to trend for growth of microorganisms, during biannual (every 6 months) recertification, any microorganism recovered (growth) shall be identified at least to the genus species, regardless of the CFU count. Professional judgement shall be used to determine the appropriate action necessary to remedy identified trends regardless on the action level. Investigation of a microorganism growth must be consistent with the deviation identified and must include evaluation of trends.

(c) The designated person shall review the sampling results and identify data trends at least every time sample results are received. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(d) Incubators must be calibrated and operated in accordance with the manufacturer's specifications and temperatures must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa advised CCR proposed section 1738.7 establishes provisions for cleaning and disinfecting again requiring compliance with the provisions of the Chapter as well as explicitly stating that the agents use must be done so consistent with the manufacturer's specifications. Dr. Serpa added the regulation language as proposed prohibits the storage of reusable cleaning supplies within 1 meter of the PEC. This prohibition was included in Chapter 797 but was not included in 825.

1738.7. CLEANING AND DISINFECTING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies shall not be stored within 1 meter of the PEC.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa advised CCR proposed section 1738.8 will provide additional requirements for assigning beyond use dates to provide clarity and address issues not specifically included in the Chapter. The Chapter provides the process performed but does account for the expiration date of the ingredients. This was a common violation found in compounding making inclusion appropriate as it provides clarity to the regulated public and not all manufacture package inserts allow for an extension of the use-by time. Dr. Serpa noted the proposed language allows for an extension by establishing minimum provisions that must be satisfied to extend the use-by time.

1738.8. ASSIGNING BUD

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a)A radiopharmaceutical CSP's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a conventionally manufactured kit with a suggested use-by time shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.
Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the SOPs must document at a minimum the following:
(1) Factors which necessitate its extension, which shall include a full assessment of patient needs for the extension.
(2) Evidence which supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa provided CCR section 1738.9 relates to the documentation requirements. As proposed the language will establish a requirement for a compounding record if the facility is deviating from the manufacturers approved labeling and makes clear that records must meet the requirements established in BPC section 4081 and establishes an audit trail for revisions and updates of records.

1738.9. DOCUMENTATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A record of a preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) Records of preparation with minor deviations or compounding shall be a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.
(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. Documenting solely the National Drug Code (NDC) does not meet this requirement.
(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation
(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4081 and 4105.

(d) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document as described in this subsection. Prior versions of each record must be maintained in a readily retrievable format (easily readable or
easily rendered into an electronic or paper format that a person can read) and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa advised CCR section 1738.10 establishes the standards for preparation noting in some instances, the proposed regulation will be requiring something that is permissive in the Chapter. Dr. Serpa added as proposed the language requires documentation when deviations from the manufacturers approved labeling occur in the specified areas. The proposed language also addresses requirements for blood components to avoid cross contamination.

1738.10. PREPARATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing nonsterile radiopharmaceutical shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Only use an area which is suitably cleaned and is uncluttered.
(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) Processing sterile radiopharmaceutical (including intravascular devices) shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in the USP Chapter 825) an SOP shall at least define the circumstances which necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each location and manufacturer. Preparations with minor deviations shall maintain the same ingredients but may differ in their proportions. A deviation from the ingredients or proportions thereof exceeds the provisions allowed under a minor deviation and is not allowed under this Article.

(d) Equipment and supplies initially used for processing of blood components (included Red Blood Cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next patient's prescription.

(e) When processing blood components all garb must be removed and replaced for each patient.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa provided CCR Section 1738.11 relates to compounding and as proposed adds language to ensure the regulated public understands the need to following requirements for RAM licensure related to specified areas. RAM licensure requirements should be specified per the above by CDPH or other comparable authority, NRC. Dr. Serpa added the proposed language also references federal requirements related to components and documentation requirements related specifically to bacterial endotoxin testing.

1738.11. COMPOUNDING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, another state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

(b) Any active pharmaceutical ingredient (API) or added component used to compound a radiopharmaceutical shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum, in English.

(c) 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 shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of the USP Chapter 825.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa provided as proposed CCR section 1738.12 establishes dispensing requirements and provides clarity around labeling requirements but does not appear to be understood for outpatient dispensing.

1738.12. DISPENSING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa advised as proposed CCR section 1738.13 proposes requirements for repackaging that will apply making mandatory labeling provisions that are included in the Chapter, but currently not required.

1738.13. REPACKAGING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time

(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time
(5) Volume, or number of units (e.g., capsules), as applicable
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable
(7) Special storage and handling instructions

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa provided as proposed CCR section 1738.14 proposes requirements for quality assurance and quality control as cross reference to the Board's quality assurance requirement included in existing regulation as well as the requirement established in USP Chapter 1163 and includes a requirement for scheduled actions, such as recalls. Dr. Serpa added as proposed, the regulation establishes notification requirements for adverse drug events, establishes timeframes for review of specified complaints, and specifies that failure to comply with SOPs shall constitute a basis for action.

1738.14. QUALITY ASSURANCE AND QUALITY CONTROL

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, titled "Quality Assurance in Pharmaceutical Compounding". In addition, the program shall include a written procedure for any scheduled action, such as a recall, in the event that radiopharmaceutical processing is discovered to be outside the expected quality and purity of the radiopharmaceutical.

(b)The Board shall be notified in writing within 72 hours of a complaint or adverse drug event involving a radiopharmaceutical.

(c) All complaints related to a potential quality problem with a radiopharmaceutical and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 125.9, 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

Chairperson Serpa reviewed the language as proposed and believed it was appropriate. Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

Chairperson Serpa thanked everyone for their diligence during the review. Dr. Serpa advised at the next meeting, the Committee will follow the same process for USP Chapter 795. Dr. Serpa added after the Committee has completed all of the chapters and proposed regulations, the Committee will consider acting and offer a recommendation to the Board for action.

A summary of the reviewed and updated sections is provided for Board records.

Repeal:

~~**1708.3. Radioactive Drugs.**~~

~~A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug~~

~~or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.~~
~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.~~

~~1708.4. Pharmacist Handling Radioactive Drugs.~~
~~A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.~~
~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.~~

~~1708.5. Pharmacy Furnishing Radioactive Drugs.~~
~~A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.~~
~~A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.~~
~~Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.~~

Proposal to Add Article XX as proposed with the following:

Article XX Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

1738. Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals –Preparation, Compounding, Dispensing, and Repackaging* ("USP Chapter 825" for the purposes of this Article).

Necessity: Clarity to the regulated public about the requirements to comply with the Section consistent with authority established in the law and the requirements of the Chapter.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.1 INTRODUCTION SCOPE AND COMPOUNDING DEFINITIONS

In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825 when not otherwise provided in USP Chapter 825.

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

(b) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Processing," "processed" or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

(e) The use of technologies, techniques, material, and procedures not described in USP 825 shall be based upon published peer-reviewed literature or documents meeting 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.

(f) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.2 RADIATION SAFETY CONSIDERATIONS

In addition to the standards in the USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.

(a) Radiation detectors and measuring devices, and other necessary equipment may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.
Necessity: To provide clarity and ensure the appropriate type and material is used. The language establishes a requirement about what actions must be done versus should be done.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

Necessity: To provide clarity as the Chapter does not specify that pads must be changed. Changing pads is necessary to avoid cross contamination.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health 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 pursuant to section 32.72 of title 10 of the Code of Federal Regulations.

Necessity: Provides clarity to ensure that SOPs document the need for deviations.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic qualifications from one premises may be used for another premises if the SOPs and, facilities are identical ~~, and equipment are identical~~.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the ante-room or the SPRA at the same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.5. FACILITIES AND ENGINEERING CONTROLS

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored in SRPAs segregated radiopharmaceutical processing area and classified areas each day that processing is performed, either manually or by a continuous recording device.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(3) Compounding shall not take place in the SRPA.

(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or under the direct supervision of an individual who possesses a current accreditation issued by CETA Certification shall be completed consistent with the provisions established in the USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP Chapter 797). The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as required and specified in USP Chapter 797.

(f) SOPs shall specify steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includeswhen the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.6. MICROBIOLOGICAL AIR AND SURFACE MONITORING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) SOPs shall 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.

(b) At a minimum, to trend for growth of microorganisms, during biannual (every 6 months) recertification, any microorganism recovered (growth) shall be identified at least to the genus species, regardless of the CFU count. Professional judgement shall be used to determine the appropriate action necessary to remedy identified

trends regardless on the action level. Investigation of a microorganism growth must be consistent with the deviation identified and must include evaluation of trends.

(c) The designated person shall review the sampling results and identify data trends at least every time sample results are received. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(d) Incubators must be calibrated and operated in accordance with the manufacturer's specifications and temperatures must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.7. CLEANING AND DISINFECTING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies shall not be stored within 1 meter of the PEC.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.8. ASSIGNING BUD

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A radiopharmaceutical CSP's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a conventionally manufactured kit with a suggested use-by time shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.
Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the SOPs must document at a minimum the following:
(1) Factors which necessitate its extension, which shall include a full assessment of patient needs for the extension.
(2) Evidence which supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code.
Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.9. DOCUMENTATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A record of a preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) Records of preparation with minor deviations or compounding shall be a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.
(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. Documenting solely the National Drug Code (NDC) does not meet this requirement.
(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.
(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation
(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic

media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4081 and 4105.

(d) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document as described in this subsection. Prior versions of each record must be maintained in a readily retrievable format (easily readable or
easily rendered into an electronic or paper format that a person can read) and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.10. PREPARATION

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing nonsterile radiopharmaceutical shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Only use an area which is suitably cleaned and is uncluttered.
(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) Processing sterile radiopharmaceutical (including intravascular devices) shall:
(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in the USP Chapter 825) an SOP shall at least define the circumstances which necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each location and manufacturer. Preparations with minor deviations shall maintain the same ingredients but may differ in their proportions. A deviation from the ingredients or proportions thereof exceeds the provisions allowed under a minor deviation and is not allowed under this Article.

(d) Equipment and supplies initially used for processing of blood components (included Red Blood Cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next patient's prescription.

(e) When processing blood components all garb must be removed and replaced for each patient.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.11. COMPOUNDING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, another state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

(b) Any active pharmaceutical ingredient (API) or added component used to compound a radiopharmaceutical shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum, in English.

(c) 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 shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of the USP Chapter 825.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.12. DISPENSING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.13. REPACKAGING

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time

(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:
(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time
(5) Volume, or number of units (e.g., capsules), as applicable
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable
(7) Special storage and handling instructions

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

1738.14. QUALITY ASSURANCE AND QUALITY CONTROL

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, titled "Quality Assurance in Pharmaceutical Compounding". In addition, the program shall include a written procedure for any scheduled action, such as a recall, in the event that radiopharmaceutical processing is discovered to be outside the expected quality and purity of the radiopharmaceutical.

(b)The Board shall be notified in writing within 72 hours of a complaint or adverse drug event involving a radiopharmaceutical.

(c) All complaints related to a potential quality problem with a radiopharmaceutical and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 125.9, 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

IX. Review and Discussion of Enforcement Statistics

Chairperson Serpa advised included in the meeting materials were enforcement statistics reflecting enforcement related activities between July 1 and December 31, 2022. Dr. Serpa summarized the Board received 1,839 complaints during this period and closed 1,459 investigations. The Board secured three (3) interim suspensions orders, two (2) automatic suspension orders and has been granted four (4) penal code 23 restriction.

Chairperson Serpa provided as of January 1, 2023, the Board had 1,450 field investigations pending. Dr. Serpa noted the average days for various stages of the investigation process were included in the meeting materials. Dr. Serpa noted there had been a large increase in the supervisor review time and second level review time. Dr. Serpa believed was in part due to a vacancy at the supervising inspector level. Dr. Serpa added the Committee should monitor for improvement in both areas. Dr. Serpa hoped that as the position was filled and onboarding completed, improvement will be seen.

Members were provided the opportunity to comment; however, no comments were made.

Members of the public were provided the opportunity to comment; however, no comments were made.

X. Future Committee Meeting Dates

Chairperson Serpa reminded the next meeting was scheduled for February 15, 2023, noting the meeting will be conducted in person, in Sacramento and members of the public were welcome to attend either in person or via WebEx. Dr. Serpa advised the Board respectfully requested that individuals attending in person follow COVID protocols.

XI. Adjournment

The meeting adjourned at 11:35 a.m.