California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 515-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

DRAFT

COMPOUNDING COMMITTEE MEETING MINUTES

DATE:	June 4, 2019
LOCATION:	Department of Consumer Affairs First Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Maria Serpa, Licensee Member, Chairperson Victor Law, Licensee Member Allen Schaad, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Shirley Kim, Public Member Stan Weisser, Licensee Member, Vice Chairperson
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Julia Ansel, Chief of Enforcement Christine Acosta, Supervising Inspector Debbie Damoth, Administration Manager Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel

1. **Call to Order and Establishment of Quorum and General Announcements**

   Chairperson Serpa called the meeting to order at 10:04 am. Board members present at the meeting were: Allen Schaad, Maria Serpa, and Victor Law. A quorum was established.

2. **Public Comment on Items not on the Agenda/Agenda Items for Future Meetings**

   There were no comments from the committee or the public.

3. **Presentation on the Proposed USP Chapter 825 – Radiopharmaceutical – Preparation, Compounding, Dispensing, and Repackaging**

   The committee heard a presentation on the current proposed revisions to USP General Chapter 825 regarding radio pharmaceutical preparation, compounding, dispensing, and repackaging by Paul B. Mahan, RPh., BCNP, Senior Regulatory Affairs Specialist with PETNET Solutions/Siemens Corporation. A copy of the presentation is attached to the minutes.

Mr. Mahan provided the committee that he is a member of the Regulatory Affairs department at PETNET Solutions/Siemens Corporation and a member of the USP <825> Expert Panel. Mr. Mahan stated he is not representing the USP Organization during the presentation.

- USP Chapter <825> - Mr. Mahan provided an overview of the history of USP <825> as well as the official effective date of official effective date of Dec. 1, 2019. He explained USP <825> is not enforceable at the state level unless all USP standards have been incorporated by reference into regulations. USP Chapters under 1000 are enforceable by the 1938 Food, Drug and Cosmetic Act. USP Chapters over 1000 are informational Chapters.
- Representation within <825> - Mr. Mahan explained the representation of the committee as a diverse group including engagements with FDA agents and USP <797> Committee.
- Types of Nuclear Pharmacies – Mr. Mahan explained the two types of nuclear pharmacies as non-PET or SPET (single-photon emission computed tomography) and PET (positron emission tomography). In SPET, all activities conducted are included in the practice of pharmacy (e.g., diagnostic imaging, therapeutic and blood component agents). In PET, most of the activities conducted as an FDA-registered manufacturer where multi-dose vials of radiopharmaceuticals are made. For PET, pharmacy processes are limited to dispensing and repackaging after the product release.
- Table of Contents and Glossary – Mr. Mahan provided the USP <825> table of contents and industry terms.
- Introduction – Mr. Mahan informed the committee that USP <825> intends to provide uniform minimum standards for the preparation, compounding, dispensing, and repackaging of sterile and nonsterile radiopharmaceuticals for humans and animals that occur as part of state-licensed activities (e.g., the practice of pharmacy and the practice of medicine). He stated the standards apply to all radiopharmaceutical processing activities. Mr. Mahan provided for the activities the chapter does not apply.
- Nonsterile and Sterile Radiopharmaceuticals – Mr. Mahan explained the application of USP <825> to nonsterile and sterile radiopharmaceuticals.
- Radiation Safety Concerns – Mr. Mahan provided intent of worker safety and keeping exposure levels for workers involved as low as reasonably achievable (ALARA) practices as well as balancing aseptic handling practices with radiation safety concerns.
- Radiation Contamination Control – Mr. Mahan explained how USP <825> addresses radiation contamination control and the important concern for protection.
- Personnel Qualifications, Training and Hygiene – Mr. Mahan informed the committee personnel must be trained to work with radiopharmaceuticals according to policies and standard operating procedures.
- Aseptic Qualifications – Mr. Mahan reviewed for the committee gloved fingertip and thumb sampling and media-fill testing requirements.
- Re-Evaluation, Retraining and Requalification – Mr. Mahan provided the timing of re-evaluation and requalification. If personnel have not been working performing radiopharmaceutical processing in more than 6 months, the personnel must be requalified in all core competencies before resuming duties. Additionally, personnel who perform sterile compounding using nonsterile drug substance or components must be requalified in all core competencies every 6 months.
- Ancillary Personnel – Mr. Mahan explained only personnel who handle sterile preparations are required to complete training on media-fill testing. Visitors must adhere to garbing SOPs but not competencies.

- Facility Design and Environmental Controls – Mr. Mahan reviewed the temperature and humidity requirements as well as explained the temperature requirements apply to both processing and storage. Mr. Mahan also reviewed types of secondary engineering control and processing environment requirements specific to radiopharmaceuticals.
- Remote Aseptic Processing Involving a Hot-Cell – Mr. Mahan explained to the committee the unique requirements for the hot-cell device used with radiopharmaceuticals.
- Environmental Controls – Mr. Mahan provided an overview of environmental controls specific for radiopharmaceuticals.
- Microbiological Air and Surface Monitoring – Mr. Mahan reviewed requirements for air and surface monitoring procedures.
- General Monitoring Requirements – Mr. Mahan provided to the committee in addition to specific samplings described in the section, sampling is also required in certain circumstances (e.g., new or modification of facilities/equipment, in response to identified problems/trends, changes that could impact controlled area environments, etc.)
- Monitoring Air Quality for Viable Airborne Particulates: Viable Air Sampling: Timing and Locations – Mr. Mahan explained the frequency of required volumetric active air sampling in all classified areas.
- Monitoring Air Quality for Viable Airborne Particulates – Mr. Mahan explained requirements and required actions for measurements of viable air monitoring programs exceeding action levels. Investigations and corrective action required for measurements exceeding actions are consistent with USP <797>. A change was made requiring if levels exceed the action levels, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a qualified individual such as a microbiologist or industrial hygienist. This change is more consistent with California sterile compounding regulations.
- Monitoring Surfaces for Viable Particles: Surface Sampling: Timing and Locations – Mr. Mahan described the surface sampling is required at least monthly which is six times more stringent than previous requirements even though current USP <797> states periodically.
- Monitoring Surfaces for Viable Particles – Mr. Mahan noted the only change was for an ISO Class 8 levels dropped from greater than 100 to greater than 50.
- Cleaning and Disinfecting – Mr. Mahan reviewed the cleaning, disinfecting and sporicidal for various sites.
- Assigning BUD: Preparation Conditions – Mr. Mahan provided the different manipulations required for PECs, SECs, and BUD (h). Mr. Mahan noted they spend the most time on this section and brought in experts.
- Documentation – Mr. Mahan noted applicable hard-copy or electronic records including policies and SOPs must be maintained for all activities involved in repackaging, preparing, preparing with minor deviation, compounding, and dispensing radiopharmaceuticals. He reviewed the required documentation records.
- Master Formulation Record (MFR) – Mr. Mahan advised an MFR is required only for a preparation with minor deviations or compounding as described in USP Chapter <825>.
- Preparation Following Manufacturer Instructions: Nonsterile Preparations – Mr. Mahan reviewed the requirements for nonsterile preparations. He stated the area should be suitably clean and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical with a documented process. Mr. Mahan noted it is important between preparation cycles to make sure there is no contamination of other products.
- Preparation Following Manufacturer Instructions: Sterile Preparations – Mr. Mahan provided to follow instructions form the manufacturer while accounting for radiation safety, environmental controls, and aseptic handling to maintain sterility.

- Preparation with Minor Deviations – Mr. Mahan provided examples of minor deviations.
- Preparation of Radiolabeled Blood Components – Mr. Mahan noted the 6 hours after blood sample is obtained from the patient or blood bank. Mr. Mahan provided if the blood samples are taken, there is a high risk that the blood has an infection. Proper precautions must be followed to ensure the safety of the patients and workers.
- Compounding Nonsterile Radiopharmaceuticals – Mr. Mahan reviewed the requirements for the committee.
- Sterile Compounding – Mr. Mahan reviewed the requirements for sterile compounding and indicated the designated person is held accountable for all activities.
- Sterile Compounding Using a Nonsterile Drug Substance or Components – Mr. Mahan reviewed the requirements as well as when testing described in Chapter <85> must be performed .
- Dispensing and Radioassay – Mr. Mahan noted except for an unopened manufactured container, the final dose or ordered amount must be radioassayed.
- Labeling – Mr. Mahan noted the minimum labeling requirements are noted. If a blood product or therapeutic product, the patient name must be added.
- Repackaging – Mr. Mahan reviewed the definition of repackaging.
- Quality Assurance and Quality Control – Mr. Mahan differentiated the differences in definitions for quality assurance and quality control.
- Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals – Mr. Mahan reviewed the steps to take should such an event occur to immediately notify the prescriber and determine if a recall is necessary.
- Complaint Handling – Mr. Mahan provided a system must be in place to receive complaints customers who will be using the radiopharmaceuticals including facilities and patients.

Committee member Schaad inquired about the occasion of therapeutic use of nonsterile radiopharmaceuticals. Mr. Mahan provided there is occasion.

Board President Law inquired about the types of complaints received. Mr. Mahan provided the most common complaint for PETNET is that doses are late based on the contractual agreement. Board President Law thanked Mr. Mahan for the site tour provided to board members and staff the previous day.

Supervising Inspector Acosta asked if kit splitting was considered repackaging. Mr. Mahan responded it is considered compounding.

Chairperson Serpa thanked Mr. Mahan for the tours provided to board members and staff the previous day.

Chairperson Serpa inquired what is the role of the board for regulating the use of radiopharmaceuticals in licensed pharmacies where non-pharmacy personnel are doing activities in the licensed care environment but are not staff by pharmacy personnel. Mr. Mahan provided that is a difficult area as physicians are using it in the practice of medicine. Chairperson Serpa indicated this may be the purview of the board to inspect radiopharmaceuticals outside of the licensed pharmacy. Massachusetts has statutory authority. DCA Counsel Freedman added the board is working with the Medical Board. Interim Executive Officer Sodergren added that both entities have defined jurisdiction. At the staff level, the board will be looking at the Massachusetts model should the committee desire. Chairperson Serpa added even if it is not under the purview or scope of the board, it is still under the purview of

pharmacy leadership and other regulators (e.g., Joint Commission, CDPH) to hold the pharmacy accountable for all compounding including radiopharmaceuticals.

A member of the public inquired if the board will be forwarding the blood labeling process to the agency that accredits laboratories for CLIA certification. Chairperson Serpa provided it has not been discussed at the committee level as there are multiple regulators in the area.

4. Approval of the April 16, 2019, Meeting Minutes

Chairperson Serpa requested delay of the April 16, 2019, meeting minutes until the committee had time to review the minutes.

5. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for July 11, 2019, in Sacramento. Chairperson Serpa noted that the board's website has been updated to reflect the future meeting date.

6. Adjournment

Chairperson Serpa adjourned the meeting at 11:30 am.

Presentation on the Proposed USP Chapter 825 – Radiopharmaceutical – Preparation, Compounding, Dispensing, and Repackaging by Paul B. Mahan, RPh., BCNP, Senior Regulatory Affairs Specialist with PETNET Solutions/Siemens Corporation

A copy of these documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.