



Compounding Committee

Maria Serpa, Licensee Member, Chairperson
Allen Schaad, Licensee Member, Vice-Chairperson
Shirley Kim, Public Member
Victor Law, Licensee Member
Stanley Weisser, Licensee Member

The Compounding Committee met on February 20, March 13 and April 16, 2019. The focus of these first meetings has been the education of committee members on the proposed revisions to the compounding chapters. As part of each committee meeting, all present were advised of the USP process for updating chapters within the USP as well as the proposed revisions timeline.

The intended effective date for Chapters 795, 797, and 800 is December 1, 2019.

a. Summary of a Presentation on the Current Proposed Revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations

February 20, 2019, the committee convened its first meeting, focusing on education on the proposed revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations. The committee was provided with a general timeline for the development of the proposed chapter revisions, including a public comment period that ran from March 30, 2018 through July 31, 2018. USP's intended publication date for the revised chapter is June 1, 2019, with an intended official date of December 1, 2019.

The committee was presented with a summary of the minimum standards for each section within the chapter relating to nonsterile preparations including:

- Introduction and Scope
- Personnel Qualifications – Training, Evaluation, and Requalification
- Personal Hygiene and Garbing
- Buildings and Facilities
- Cleaning and Sanitizing
- Equipment and Components
- SOPs and Master Formulation and Compounding Records
- Release Testing
- Labeling
- Establishing Beyond-Use Dates
- Quality Assurance and Quality Control
- Compounded Nonsterile Preparation Handling, Packaging, Storage, and Transport

- Complaint Handling and Adverse Event Reporting
- Documentation

A copy of the approved minutes from this meeting is included in **Attachment 1**.

b. Summary of a Presentation on the Current Proposed Chapter Revisions to Pharmaceutical Compounding – Sterile Preparations, Chapter 797

March 13, 2019, the committee convened its second meeting, focusing on education on the proposed revisions to USP General Chapter 797, Regarding Pharmaceutical Compounding – Sterile Preparations (CSPs). The committee was provided with a general timeline for the development of the current proposed chapter revisions, including a public comment period that ran from July 27, 2018 through November 30, 2018. USP’s intended publication date for the revised chapter is June 1, 2019, with an intended official date of December 1, 2019.

The committee was presented with a summary of the minimum standards to be followed within each section within the chapter relating to sterile preparations including:

- Introduction and Scope
- Personnel Qualifications – Training, Evaluation, and Requalification
- Personal Hygiene and Garbing
- Facilities and Engineering Controls
- Microbial Air and Surface Monitoring
- Cleaning and Disinfecting Compounding Areas
- Equipment, Supplies, and Components
- Sterilization and Depyrogenation
- SOPs and Master Formulation and Compounding Records
- Release Testing
- Labeling
- Establishing Beyond-Use Dates
- Use of Conventionally Manufactured Products
- Use of CSPs as Components
- Quality Assurance and Quality Control
- CSPs Storage, Handling, Packaging, Shipping, and Transport
- Documentation
- Compounding Allergenic Extracts

A copy of the approved minutes from this meeting is included in **Attachment 2**.

c. Summary of a Presentation on the Proposed USP Chapter 800 – Hazardous Drugs – Handling in Healthcare Settings

April 16, 2019, the committee convened another meeting, focusing on education on the USP General Chapter 800, Hazardous Drugs (HDs) – Handling in Healthcare Settings. The

committee was provided with a general timeline for this chapter, including its original publication date of February 2016 and its intended official date of December 1, 2019.

The committee was advised that Chapter 800 covers all aspect of the handling of HDs in healthcare settings, including the compounding of such preparations. The committee was provided with an overview of the development of the National Institute for Occupational Safety and Health (NIOSH) and its relevance to the chapter. The committee was advised that the goal of the USP standard is to increase awareness, product uniform guidance to reduce the risk of managing HDs, and help reduce the risk posed to patient and healthcare workers.

The committee was presented with a summary of the minimum standards to be followed within each section of the chapter relating to HDs including:

- Introduction and Scope
- List of Hazardous Drugs
- Types of Exposure
- Responsibilities of Personnel Handling Hazardous Drugs
- Facilities and Engineering Controls
- Environmental Quality and Control
- Personal Protective Equipment
- Hazard Communication Program
- Personnel Training
- Receiving
- Labeling, Packaging, Transport, and Disposal
- Dispensing Final Dosage Forms
- Compounding
- Administering
- Deactivation, Decontaminating, Cleaning, and Disinfecting
- Spill Control
- Documentation and Standard Operating Procedures
- Medical Surveillance

A copy of the draft minutes from this meeting is included in **Attachment 3**.

d. Future Committee Meeting Dates

The 2019 Compounding Committee dates are providing below.

- June 4, 2019
- July 11, 2019
- August 29, 2019
- September 24, 2019
- October 16, 2019

Attachment 1



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



COMPOUNDING COMMITTEE MEETING MINUTES

DATE: February 20, 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

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Peg Panella-Spangler, Supervising Inspector
Anna Kalantar, Supervising Inspector
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Debbie Damoth, Administration Manager

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

Chairperson Serpa called the meeting to order at 10:05 am. Board members present: 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

Danny Martinez of the California Pharmacists Association commented on the availability of the meeting materials and requested meeting materials be provided in advance of the meeting.

Marie Cottman of Pacific Compounding requested the board consider adding to the agenda autologous serum eye drops that require both compounding and a biologics licenses.

3. Presentation on the Current Proposed Revisions to USP General Chapter 795, Regarding Pharmaceutical Compounding – Nonsterile Preparations

The committee heard a presentation on the current proposed revisions to USP General Chapter <795> regarding pharmaceutical compounding for nonsterile preparations by Supervising Inspectors Peg Panella-Spangler and Anna Kalantar.

Supervising Inspector Panella-Spangler provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and non-sterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Ms. Panella-Spangler updated the committee on the status of USP revising Chapter <795> and subsequent revisions.

Supervising Inspector Panella-Spangler provided a synopsis of the proposed changes to the draft Chapter <795> to reflect new science and evidence based on updated guidance documents, best practices, and new learnings from investigations. The intent of the current draft is to respond to stakeholder input, clarify confusing topics and align with published Chapters <800> and revision efforts for Chapter <797>. The current Chapter <795> served as a template, and many of the summary statements were expanded to add clarity to requirements.

The committee was provided with a summary of the changes made in draft Chapter <795> based on the 14 sections.

Draft section Introduction and Scope added information on compounded nonsterile preparations (CNSP) and moved all hazardous drugs to General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings. A designated person was added and defined as one or more individuals responsible and accountable for the facility and personnel. Definitions for compounding and reconstituting were added.

Draft section Personnel Qualifications delineated training, competency and proficiency requirements prior to preparing CNSPs. Proficiency steps and minimum core competencies that must be demonstrated are noted.

Draft section Personal Hygiene and Garbing specified requirements prior to entering a designated compounding area and hand hygiene procedures. The draft section noted gloves are required and outlined appropriate garb.

Draft section Buildings and Facilities required a designated compounding area and outlined facility requirements (e.g., source of hot/cold water and accessible sink, etc.).

Draft section Cleaning and Sanitizing defined cleaning and sanitizing agent. Minimum frequencies for cleaning and sanitizing surfaces in nonsterile compounding areas were added.

Draft section Equipment and Components added the requirement for using a containment ventilated enclosure (CVE) for the weighing, measuring, or other manipulation of an active pharmaceutical ingredient (API). Minimum frequency for cleaning and sanitizing the CVE and equipment were defined. Certification requirements for the CVE were added. Requirements for components were added.

Draft section Standard Operating Procedures (SOP), Master Formulation and Compounding Records established the requirement for SOPs, master formulation records and compounding records.

Draft section Release Testing required visual inspection prior to release of any CNSPs and all checks/inspections for CNSPs detailed in SOPs.

Draft section Labeling defined and detailed requirements for labeling.

Draft section Establishing Beyond-Use Dates (BUD) defined and established parameters for BUDs. Maximum BUDs and package requirements were defined as well as the extension and shortening of the BUD. Microbial limit testing strategy for representative pharmaceutical and OTC drug products based on water activity was added to UPS <112>.

Draft section Quality Assurance and Quality Control defined quality assurance (QA) and quality control (QC) as well as outlined requirements for QA and QC.

Draft section CNSP Handling, Packaging, Storage and Transport outlined requirements for packaging materials, storage and shipping/transporting of CNSP.

Draft section Complaint Handling and Adverse Event Reporting detailed the requirements for developing and implementing SOPs for complaint receipt, acknowledgement and handling as well as defined the role of the designated person in the process.

Draft section Documentation defined the minimum requirements for electronic documentation for facilities where CNSPs are prepared.

Chairperson Serpa inquired about the labs used for stability testing for nonsterile compounding. Supervising Inspector Panella-Spangler provided that the same labs used for sterile compounding testing can be used for nonsterile compounding testing.

Committee Member Schaad confirmed the gloving and garbing requirement would be for any compounding. Supervising Inspector Panella-Spangler confirmed gloves are required and garbing is recommended at this time.

Joe Grasela of University Compounding Pharmacy recommended the board release the presentation to all compounders. Mr. Grasela confirmed that a study was not needed for a tablet as 180 days is the maximum. Mr. Grasela recommended the committee remove current compounding pharmacy law and replace with the USP when adopted.

DCA Counsel Freedman commented this meeting is for the educational purposes of the committee members. Chairperson Serpa encouraged Mr. Grasela to continue to attend the committee meetings to participate throughout the process.

Pharmacist Ranel Larsen commented on the quality of the presentation. Ms. Larsen noted there is a difference between water content and water activity. Ms. Larsen referred the committee to USP <659> for the temperature definitions.

Marie Cottman from Pacific Compounding Pharmacy shared she has no problem with the updated chapter and making changes to adhere to new requirements. Ms. Cottman shared her concern with the committee as an owner of a sterile compounding pharmacy about the fiscal impact of implementation. Ms. Cottman reminded the committee as a sterile compounding pharmacy, her pharmacy is inspected annually whereas pharmacies who do nonsterile compounding are not inspected annually. Ms. Cottman requested the committee consider this when developing implementation.

Board President and Committee Member Law confirmed it is the board's intent to ensure pharmacies are inspected every four years. Mr. Law advised the public the board can be notified if an inspection is needed or illegal activity is occurring at a pharmacy.

Mr. Grasela commented the out of state pharmacies will not be inspected. Mr. Grasela commented the committee may consider requiring accreditation to be licensed as a compounding pharmacy to ensure out of state pharmacies are inspected.

Clara Brown of Animal Solutions Pharmacy recommended and requested the committee to require pharmacists filling veterinary compounds know how to counsel and know species specific data of animals they are compounding for in order to reduce error rates. California Veterinary Medical Association and Veterinary Medical Association now requires counselling by a veterinarian when medication is provided to an animal. Ms. Brown requests the board protect animal patients as well as human patients. Ms. Brown expressed concern on the feasibility of implementation.

DCA Counsel Freedman reminded the committee and public this meeting is for the educational purposes of the committee members. Chairperson Serpa reminded the committee and public that board inspectors are inspecting to the current board regulation. The information presented today is draft USP <795> and not current board regulation.

Christine Versichele of Dynalabs commented to the committee that lab results completed by Dynalabs are provided online for customers for up to five years.

Chairperson Serpa inquired about testing for QA. Supervising Inspector Panella-Spangler provided her understanding was that testing was required to extend the BUD and not for routine QA. Interim Executive Officer Anne Sodergren indicated the committee could look at the release testing provisions in the chapter.

Jenny Partridge, a pharmacist and inspector for ACHC doing nonresident inspections for Texas, Louisiana and Florida and a surveyor for ACHC for specialty infusion sterile/nonsterile compounding

pharmacies, supports the adoption of draft USP <795> with consideration of comments to the cleaning, BUDs and garbing.

Paul Mahan of PETNET Solutions advised the committee he participated as a panel member on writing USP <825>. Mr. Mahan commented that USP <795> will not include nonsterile radiopharmaceuticals as it has been moved to USP <825>. Mr. Mahan reminded the committee that USP Chapters are the minimum standards that should be followed. Additionally, he commented that the audience of the USP Chapters extends beyond pharmacists/pharmacies.

Marie Cottman commented that the draft USP <795> is written for a larger audience and shared her concern with adopting draft USP <795> in its entirety. Ms. Cottman expressed concerns on the requirement that certificates of analysis (COA) meet all of the requirements of USP monographs.

4. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for March 13, 2019, in Sacramento.

5. Adjournment

Chairperson Serpa adjourned the meeting at 11:31 am.

Attachment 2



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



**COMPOUNDING COMMITTEE
MEETING MINUTES**

DATE: March 13, 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
Stan Weisser, Licensee Member, Vice Chairperson
Victor Law, Licensee Member
Allen Schaad, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Shirley Kim, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Anna Kalantar, Supervising Inspector
MaryJo Tobola, Senior Enforcement 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 10:02 am. Board members present: Allen Schaad, Maria Serpa, Stan Weisser and Victor Law. A quorum was established.

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

Board President Victor Law suggested current issues affecting practitioners as a future agenda item. Board counsel Laura Freedman recommended that specific issues could be presented to the board during Public Comment and placed on future agenda.

3. Presentation on the Current Proposed Revisions to USP General Chapter 797, Regarding Pharmaceutical Compounding – Sterile Preparations

The committee heard a presentation on the current proposed revisions to USP General Chapter <797> regarding pharmaceutical compounding for sterile preparations by Supervising Inspector Anna Kalantar.

Supervising Inspector Kalantar provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and nonsterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Dr. Kalantar updated the committee on the status of USP revising Chapter <797> and subsequent revisions. The committee was provided with a summary of the changes made in draft Chapter <797> based on the 18 sections.

Dr. Kalantar noted that the draft section “Introduction and Scope,” describe the minimum standards to be followed when preparing compounded sterile human and animal drugs based on current scientific information and best practices for sterile compounding. The section defines sterile compounding as the process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug or bulk drug substance to create a sterile medication. The section also defines common terms including preparing, administration, reconstitution and repackaging. The draft section clarifies docking and activation of proprietary bag and vial systems in accordance with the manufacturer’s instructions for immediate administration to an individual patient is not considered compounding; however, the draft section specifies docking for future activation and administration is considered compounding.

Dr. Kalantar noted risk categories were eliminated as the risk categories (e.g., low, medium, or high) provided false security on sterility assurance as all sterile compounding has risk. Dr. Kalantar further explained the new model uses Category 1 and Category 2 based on conditions under which the compounded sterile preparations (CSP) are made including the probability for microbial growth and the time period for which they must be used.

Dr. Kalantar reviewed the draft section “Personnel Qualifications: Training, Evaluation and Requalification,” noting delineated personnel qualifications and core competencies based on Categories 1-2 rather than risk categories. Personnel qualifications for visual observation of hand hygiene and garbing, gloved fingertip and thumb sampling and media fill testing must be completed every six months regardless of the category. If any of these are failed, they must be passed before allowed to compound. Core competencies must be completed every 12 months and include written and hands-on proficiency. Core competencies are now extended to non-compounding staff such as cleaning crews to establish competencies to maintain the proper environment.

Dr. Kalantar reviewed the draft section “Personal Hygiene and Garbing,” which specify the minimum requirements that must be completed prior to entering a compounding area. The draft section notes acceptable hand hygiene methods and required hand hygiene procedures.

Dr. Kalanatar indicated that the order of garbing is to be determined by the facility and included in standard operating procedures (SOPS). Minimum garbing requirements to enter a buffer room or SCA are outlined. The draft chapter specifies if using RABS [compounding aseptic containment isolator (CACI) and compounding aseptic isolator (CAI)] disposable gloves either nonsterile or sterile are required inside of the gauntlet gloves and sterile gloves are required over the gauntlet gloves. Dr. Kalanatar noted gowns may no longer be reused once removed from the sterile compounding area.

Dr. Kalanatar reviewed the draft section “Facilities and Engineering Controls,” which defines a cleanroom suite as an ante-room and buffer room and provided requirements for each room. Dr. Kalanatar noted the HEPA filters are now required to be part of the ceiling and cannot be part of the HVAC systems. The draft section defined the Segregated Compounding Area (SCA) and provided the requirements. Dr. Kalanatar noted all surfaces should be smooth, non-shedding and resistant to damage. The draft chapter defined Primary Engineering Controls (PEC) and provides requirements for the PECs. Dr. Kalanatar noted smoke pattern tests must be performed initially and every 6 months. The draft chapter notes the minimum air exchange requirements based on the compounding area type. Dr. Kalanatar added the new requirement for ISO Class 8 rooms.

Dr. Kalanatar noted the certifications must be completed under dynamic conditions every six months in accordance with CETA guidelines or an equivalent guideline. Certifications required include airflow testing, HEPA filter integrity testing, total particle count testing and smoke visualization studies. The draft chapter notes when recertification is required.

Dr. Kalanatar reviewed the draft section “Microbiological Air and Surface Monitoring,” that requires the monitoring to be done under dynamic operating conditions. Further, the draft chapter specifies viable air sampling must be conducted initially and every 6 months and surface sampling must be completed initially and every monthly. Surface sampling will be increased to monthly as surface contamination poses the greatest risk. Monitoring functions must be completed again with new facility and equipment certification, after servicing of facilities/equipment and when problems are identified. Action levels are identified and if levels are exceeded, there must be an investigation and corrective action plan. The chapter no longer references highly pathogenic organisms and there is no need to identify every colony forming unit (CFU). If action levels are exceeded, the organism must be identified with the assistance of a microbiologist.

Dr. Kalanatar reviewed the draft section “Cleaning and Disinfecting Compounding Areas,” which defines cleaning, disinfecting and one-step disinfectant. Surfaces must be cleaned prior to disinfecting unless using EPA one-step disinfectant cleaner. Minimum requirements and frequencies for cleaning and disinfecting requirements are delineated as well as minimum requirements for cleaning supplies. If there is no daily compounding, these need to be initiated prior to compounding. Cleaning tools are only removed when disposed.

Dr. Kalanatar reviewed the draft section “Equipment, Supplies and Components,” defines the restricted-access barrier system (RABS); CACI; and CAI but specifies CAI and CACI are not isolators. Component and Active Pharmaceutical Ingredient (API) are defined. APIs must be

obtained from an FDA-registered facility; must comply with *USP-NF* monograph, if one exists; and must be accompanied by a certificate of analysis (COA). COA must demonstrate the specifications, test results and demonstrate the API meets the specifications of the *USP-NF*, if one exists.

Dr. Kalantar reviewed the draft section “Sterilization and Depyrogenation,” which delineates the sterilization methods. Dr. Kalantar clarified that sterilized products may be compounded from sterile or nonsterile ingredients. When compounding from sterile ingredients, the sterility of the ingredients must be maintained. When compounding from nonsterile ingredients, the sterility must be achieved. The two methods for achieving sterilization are defined as aseptic preparation and terminal sterilization. Terminal sterility is preferred because it can achieve sterility assurance level of 10^{-6} .

Dr. Kalantar reviewed the draft section “Standard Operating Procedures, Master Formulation and Compounding Records,” which establish the requirement for SOPs, master formulation records and compounding records. Dr. Kalantar clarified that a master formulation records is required if the CSP is prepared for a batch greater than one patient and the CSP is prepared from nonsterile ingredients. She noted that the chapter defines batch as more than one unit of CSP prepared in a single process. Dr. Kalantar stated compounding records are required for all CSPs. The compounding record form is not specified as long as the requirements are met. The record may be stored electronically but must be retrievable.

Dr. Kalantar reviewed the draft section “Release Testing,” which requires visual inspection prior to release of any Category 1 and 2 CSPs. Sterility testing is required for Category 2 to extend the BUD. Sterility testing must be completed according to USP <71>. Bacterial endotoxin testing is excluded for inhalations and topical ophthalmics but is required for Category 2 CSPs if made from one or more nonsterile ingredients/components and if assigned Beyond Use Date (BUD) requires sterility testing.

Dr. Kalantar reviewed the draft sections “Labeling,” “Establishing Beyond Use Dates (BUD),” Use of Conventionally Manufactured Products,” and “Use of CSPs as Components” which detail the requirements for labeling, provide that compounders must consider stability factors and sterility factors when establishing BUDs. Dr. Kalantar noted that BUDs for Category 1 and 2 are included in the proposed chapter and that multi-dose containers are defined and must be prepared as a Category 2 CSP. Further Dr. Kalantar noted that the proposed chapter details the time within which a product must be used based on the type of container and the appropriate storage requirements related to BUDs.

Dr. Kalantar highlighted the draft section “Quality Assurance (QA) and Quality Control (QC),” including the required elements: recall SOP procedures; complaint handling; and adverse event reporting.

Dr. Kalantar discussed the draft “CSP Storage, Handling, Packaging, Shipping and Transporting,” which outline requirements for packaging materials, storage and shipping/transporting of CSP as well as the draft section “Documentation,” establishing the minimum requirements for when CSPs are prepared.

Board President Law inquired how inspectors verify documentation of all requirements. Dr. Kalantar advised that inspectors request documentation from the licensee at the time of inspection that is reviewed by board inspectors. Dr. Kalantar noted that typically, licensees have information ready for board inspectors. If additional information is required, the licensee retrieves it for the inspector.

Chairperson Serpa inquired about docking for future activation and administration being considered compounding. Dr. Serpa indicated this is a change in practice and asked Dr. Kalantar for additional comment. Dr. Kalantar responded it may be performed outside of ISO 5 but aseptic technique must be followed. If it is docked for future activation, under the proposed chapter, would be compounding, and this chapter will apply. Dr. Serpa indicated this will be a large area for education as it occurs in multiple environments and implications in some acute care settings like nursing homes.

Chairperson Serpa commented that another issue will be the temperature ranges and will be discussed in the future. Dr. Kalantar provided the chapter states what the temperatures should be rather than must be required.

Chairperson Serpa inquired about the components mentioned in the presentation and if that included supplies such as syringes, bags, shields, devices etc.. Dr. Kalantar indicated that was how she interpreted it as well. Dr. Kalantar indicated it was not discussed during the open mic but may be included in the future by the providers.

The committee took a break and returned at 11:47 am.

BJ Bartleson of the California Hospital Association referred to an educational tool put together by some of the associations. Dr. Serpa commented that the tool would have to be re-written to incorporate the changes to the USP compounding chapters. Discussion noted that updating the educational tool would be most beneficial after the proposed changes to the various chapters are finalized. Ms. Bartleson indicated the concern for the 430+ hospitals undergoing major construction based on what they think will happen and to stay on track with deadlines. Ms. Bartleson indicated she would appreciate continued collaboration. Ms. Bartleson commented with AB 973 would change regulations and USP standards and the hospitals will be looking forward to that change.

Paul Mahan of PETNET Solutions advised the committee he participated as a panel member on writing USP <825> and nondisclosure agreements are required for participants, so the participants are unable to comment.

Pharmacist Holly Strom commented and inquired how the presentation was compiled. Dr. Kalantar said it was based on the USP September 5th open mic and added to the information provided. Ms. Strom inquired about the definition for components and the comment “must be evaluated when received and before use.” Ms. Strom asked what the inspectors would be looking for during inspections for proof this was completed. Dr. Kalantar responded all components must be evaluated when received and before use. Interim Executive Officer Anne Sodergren added that these items would be clarified at the time the board pursues regulations and referred Ms. Strom to the documentation section of the draft USP <797>. DCA Counsel added comments can be added to USP as well.

Ms. Strom also inquired about packaging of materials and reference to shaking of the materials. Dr. Kalantar responded the draft chapter states the pharmacy will need to consider the shaking. Ms. Strom mentioned use of 3PLs should be considered with the development of the board's regulations.

Christine Versichele of Dynalabs provided an overview of what is provided to a customer who requests a stability study for an extended BUD.

A sterile compounding pharmacist inquired about the intention of the education for the board. Dr. Serpa commented there is a series of educational meetings regarding the future of USP and to determine what regulatory changes may be needed for our state. The pharmacist inquired about the fingertip testing. Dr. Kalantar provided the intent of the process is for the person to demonstrate they can go through the process without adding contamination to their hand. DCA Counsel referred the pharmacist to the USP for commenting on draft USP <797>.

4. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next educational meeting is scheduled for April 16, 2019, in Sacramento.

5. Adjournment

Chairperson Serpa adjourned the meeting at 12:17 pm.

Attachment 3



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



DRAFT
COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: April 16, 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
Stan Weisser, Licensee Member, Vice Chairperson
Victor Law, Licensee Member
Allen Schaad, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Shirley Kim, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Julia Ansel, Chief of Enforcement
Christine Acosta, Supervising Inspector
Laura Hendricks, Staff Analyst
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 10:05 am. Board members present: Allen Schaad, Maria Serpa, Stan Weisser 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 800 – Hazardous Drugs – Handling in Healthcare Settings

The committee heard a presentation on the current proposed revisions to USP General Chapter 800 regarding the handling of hazardous drugs by Supervising Inspector Christine Acosta.

Supervising Inspector Acosta provided an overview of the United States Pharmacopeia (USP) 2015-2020 Council of Experts including Healthcare Quality Standards Collaborative Group which includes compounding. USP maintains resolutions to work with stakeholders in the development and maintenance of practice and quality standards in sterile and nonsterile compounding. USP includes General Chapters: <795> – Pharmaceutical Compounding – Nonsterile Products; <797> – Pharmaceutical Compounding – Sterile Preparations; <800> – Hazardous Drugs – Handling in Healthcare Settings; and <825> – Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging. Dr. Acosta updated the committee on the status of USP revising Chapter <797> and subsequent revisions. The committee was provided with a summary of the changes made in draft Chapter <797> based on the 18 sections.

Dr. Acosta stated that the National Institute for Occupational Safety and Health (NIOSH) is a division of Center for Disease Control and Prevention (CDC). She explained that NIOSH developed a list of antineoplastic and other hazardous drugs in healthcare settings. Dr. Acosta noted that the list has not been updated in 2016, but an updated list is expected to be released soon (typically it is updated every two years).

Dr. Acosta reviewed the following six characteristics that are used by NIOSH to determine if a drug is hazardous in humans or animals.

- Carcinogenicity
- Teratogenicity or fertility impairment
- Reproductive toxicity
- Organ toxicity
- Genotoxicity
- Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous

Dr. Acosta explained that NIOSH organizes hazardous drugs into categories which are commonly referred to as “tables.” Dr. Acosta summarized the characteristics of each of the tables as provided below.

Table 1. Group 1: Antineoplastic drugs

- One or more of the NIOSH criteria for a hazardous drug.
- Many of these drugs are cytotoxic.
- Represent an occupational hazard to healthcare workers and should always be handled with use of recommended engineering controls and personal protective equipment (PPE), regardless of their formulation.

Table 2. Group 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug

- Some of these drugs may represent an occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, because they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational exposure risk as injectable drugs, which usually require extensive preparation.

Table 3. Group 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

- NIOSH criteria for reproductive hazards.
- Represent a potential occupational hazard to males or females who are actively trying to conceive, women who are pregnant or may become pregnant, and women who are breast feeding, as they may be present in breast milk.
- Unopened, intact tablets and capsules may not pose the same degree of occupational risk as injectable drugs that usually require extensive preparation.

Table 4

- Contains drugs that were deleted from the 2014 NIOSH hazardous drug list for the 2016 update; however, there are no deletions to report.

Table 5

- Provides general guidance for some of the possible scenarios that may be encountered in healthcare settings where hazardous drugs are handled.

Dr. Acosta explained that NIOSH defines the criteria and identifies hazardous drugs (HD), while USP develops the standards for handling these HDs to minimize the risk to public health. Dr. Acosta stated that the goals of the USP standards are to help increase awareness, provide uniform guidance to reduce the risk of managing HD, and help reduce the risk posed to patients and the healthcare workforce. Dr. Acosta noted that healthcare workers will become patients if they are exposed to these HDs without the proper precautions.

Dr. Acosta stated that there has been a delay in releasing the updated USP 800 due to the number of comments and stakeholders involved; however, it is expected that the updated USP 800 will be released and become enforceable on December 1, 2019.

Dr. Acosta recommended that interested parties visit the frequently asked questions section of USP's website because it contains a wealth of information broken down in an easy to search format.

Dr. Acosta reported that USP 800 is broken down into the following 18 sections. She noted that her presentation would also be broken down into these sections.

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling Hazardous Drugs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding

14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and Standard Operating Procedures
18. Medical Surveillance

Section 2. List of Hazardous Drugs

Dr. Acosta explained that NIOSH maintains a list of antineoplastic and other HDs used in healthcare. The entity must maintain a list of HDs, which must include any items on the current NIOSH list that the entity handles. Dr. Acosta added that the list must be reviewed at least every 12 months and whenever a new agent or dosage form is used.

Dr. Acosta explained that section two contains the criteria that can be used by pharmacists to determine if containment requirements in USP 800 must be followed or when an “assessment of risk” can be conducted to determine alternative containment strategies.

Dr. Acosta explained that any HD active pharmaceutical ingredient (API) must follow the requirements in the chapter. She also provided the following definition of API: “any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.” Dr. Acosta stated that any antineoplastic requiring HD manipulation must also follow all of the requirements of the chapter.

Dr. Acosta explained that drugs on the NIOSH list that do not have to follow all of the containment requirements of this chapter if an assessment of risk (AOR) is performed and implemented include: final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer). Dr. Acosta stated that for dosage forms of other HDs on the NIOSH list, the entity may perform an assessment of risk to determine alternative containment strategies and work practices.

Dr. Acosta reported that an AOR must document what alternative containment strategies and/or work practices are being employed for dosage forms to minimize occupational exposure. She added that it must be reviewed at least every 12 months and the review must be documented. Dr. Acosta also stated that the AOR must, at a minimum, consider the following:

- Type of HD (e.g., antineoplastic, non-antineoplastic, reproductive risk only)
- Dosage form
- Risk of exposure
- Packaging
- Manipulation

Dr. Acosta explained that an assessment of risk (AOR) may be performed for dosage forms to determine alternative containment strategies and/or work practices.

Section 3. Types of Exposure

Dr. Acosta highlighted the potential opportunities of exposure based on activity as provided in Section 3. For example, the risk of exposure that can occur while transporting HDs within a healthcare setting.

Section 4. Responsibility of Personnel Handling Hazardous Drugs

Dr. Acosta explained that each facility must have a designated person who:

- is qualified and trained to be responsible for developing and implementing appropriate procedures;
- oversees compliance with this chapter and other applicable laws, regulations, and standards;
- ensures competency of personnel;
- ensures environmental control of the storage and compounding areas.
- thoroughly understands:
 - rationale for risk-prevention policies,
 - risks to themselves and others,
 - risks of noncompliance that may compromise safety,
 - the responsibility to report potentially hazardous situations to the management team.
- Is responsible for the oversight of monitoring the facility and maintaining reports of testing/sampling performed in facilities and acting on the results.

Section 5. Facilities and Engineering Controls

Dr. Acosta stated that HDs must be handled under conditions that promote patient safety, worker safety, and environmental protection. Signs designating the hazard must be prominently displayed before the entrance to the HD handling areas. She explained that access to areas where HDs are handled must be restricted to authorized personnel to protect persons not involved in HD handling.

Dr. Acosta also reported that HD handling areas must be located away from breakrooms and refreshment areas for personnel, patients, or visitors to reduce risk of exposure. There must be designated areas available for: receipt and unpacking, storage of HDs, nonsterile HD compounding, and sterile HD compounding. Dr. Acosta reviewed the following criteria for the designated areas.

- Designated areas:
 - Receipt and unpacking: (Antineoplastic HDs and all HD APIs)
 - neutral/normal or negative pressure relative to the surrounding areas.
- Storage of HDs:
 - Not on floor

- Antineoplastic HDs (requiring manipulation) and all HD APIs:
 - stored separately from non-HDs
 - stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH).
- Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs:
 - may be stored with other inventory if permitted by entity policy.
- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH.

Dr. Acosta explained that a containment primary engineering control (C-PEC) is a ventilated device to minimize worker and environmental HD exposure and it must operate continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.

Dr. Acosta stated that a containment secondary engineering control (C-SEC) is the room in which the C-PEC is placed and must:

- be externally vented,
- be physically separated (a different room from other areas),
- have an appropriate air exchange (ACPH); and
- have a negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas.

Dr. Acosta reported that supplemental engineering controls (closed-system drug-transfer device (CSTD)) are adjunct controls to offer additional levels of protection.

Dr. Acosta noted that a sink must be available for hand washing and the water source and drain must be located at least one-meter way from the C-PEC.

Dr. Acosta explained that C-PECs must be placed in separate rooms, unless the C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. She added that if they are in the same room they must be placed at least one-meter apart and particle-generating activity must not be performed when sterile compounding is in process.

Dr. Acosta stated that nonsterile HD compounding must be performed in a C-PEC within a C-SEC. she added that the C-SEC surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the nonsterile compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding.

Dr. Acosta reviewed the following requirements for C-PECs (Class II or III Biological Safety cabinet or compounding aseptic containment isolator):

- must be externally vented
- must provide an ISO Class 5 or better air quality
- must not be used for the preparation of a non-HD unless:

- non-HD is placed into a protective outer wrapper during removal from the C-PEC and is labeled to require PPE handling precautions.
- must be located in a C-SEC

Dr. Acosta explained that in the HD cleanroom suite the C-SEC (clean/buffer room) must have:

- fixed walls,
- minimum of 30 ACPH of HEPA-filtered supply air,
- air quality of ISO Class 7 or better; and
- negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas

Dr. Acosta also explained that the C-SEC (Anteroom) must have:

- Fixed walls,
- Minimum of 30 ACPH of HEPA-filtered supply air
- Positive pressure of at **least** 0.02 inches of water column relative to all adjacent unclassified areas
- Air quality of ISO Class 7 or better
- Hand-washing sink **must** be placed in the ante-room at least 1 meter from the entrance to the HD buffer room

Dr. Acosta stated that if the HD buffer room is entered through the positive-pressure non-HD buffer room, the following is also required: (Not a recommended facility design)

- Line of demarcation must be defined within the negative-pressure buffer room for donning and doffing PPE
- Method to transport HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room to minimize the spread of HD contamination.
 - If using a pass-through chamber (buffer area and adjacent space).
 - must be included in the facility's certification (particles and pressure)
 - refrigerator pass-through must not be used.

Dr. Acosta reported that containment segregated compounding areas (C-SCA) must have:

- Fixed walls,
- Negative pressure **between** 0.01 and 0.03 inches of water column relative to all adjacent areas,
- 12 ACPH
- Externally vented
- hand-washing sink must be placed at least 1 meter from C-PEC
 - either inside the C-SCA or directly outside the C-SCA.
- Only low-and medium-risk HD CSPs may be prepared in a C-SCA.

Dr. Acosta explained that a closed-system drug-transfer device (CSTD) may limit the potential of generating aerosols during compounding. She also stated that it must not be used as a substitute for a C-PEC when compounding. Dr. Acosta explained that a CSTD should be used when compounding HDs when the dosage form allows and when administering antineoplastic HDs when the dosage form allows.

Section 6. Environmental Quality and Control

Dr. Acosta stated that environmental wipe sampling for HD surface residue should be performed routinely.

Dr. Acosta explained that surface wipe sampling should include:

- Interior of the C-PEC and equipment contained in it
- Pass-through chambers
- Surfaces in staging or work areas near C-PEC
- Areas adjacent to C-PECs (floors, staging, and dispensing area)
- Areas immediately outside the HD buffer room or the C-SCA
- Patient administration areas

Dr. Acosta stated that if any measurable contamination is found, the designated person **must** identify, document, and contain the cause of contamination.

Section 7. Personal Protective Equipment (PPE)

Dr. Acosta reviewed the types of personal protective equipment must be used by the staff.

- Gloves:
 - Must meet American Society for Testing and Materials (ASTM) standard D6978
 - worn for handling all HDs
 - must be powder-free
 - must be inspected for physical defects before use.
 - for sterile compounding: two pairs required
 - the outer chemotherapy gloves must be sterile
 - changed every 30 minutes
 - must be changed when torn, punctured, or contaminated
- Gowns:
 - must be disposable and shown to resist permeability by HDs
 - must be selected based on the HDs handled
 - must close in the back (i.e., no open front), be long sleeved, and have closed cuffs that are elastic or knit
 - must not have seams or closures
 - must be changed per the manufacturer's information for permeation of the gown. If none every 2–3 hours
 - must not be worn to other areas
- Respiratory Protection:
 - Surgical masks must not be used when respiratory protection is required.
 - For most activities, a fit-tested NIOSH-certified N95 or more is sufficient to protect against airborne particles.
 - no protection against gases and vapors and little protection against direct liquid splashes

- Appropriate full-facepiece, chemical cartridge-type respirator or powered air-purifying respirator (PAPR) should be worn when there is a risk of respiratory exposure to HDs, including when:
 - Attending to HD spills larger than what can be contained with a spill kit
 - Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
 - There is a known or suspected airborne exposure to powders or vapors
- Disposal of Used Personal Protective Equipment:
 - All PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs.
 - All PPE worn be disposed of in the proper waste container before leaving the C-SEC.
 - Chemotherapy gloves and sleeve covers worn during compounding must be carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.

Section 8. Hazard Communication Program

Dr. Acosta reviewed the requirements for hazard communication programs as provided below.

- Required to establish P&Ps that ensure worker safety during all aspects of HD handling.
- Must develop SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of the HDs and use of Safety Data Sheets (SDS), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).
- Elements of the hazard communication program plan must include:
 - Written plan that describes how the standard will be implemented
 - All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
 - must have an SDS for each hazardous chemical they use (29 CFR 1910.1200)
 - must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
 - Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
 - Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs

Section 9. Personnel Training

Dr. Acosta informed the committee that all personnel must be trained based on their job functions. She added that the training must occur before the employee handles any HDs and each employee must demonstrate the effectiveness of the training. Dr. Acosta stated that the training must include at least the following:

- Overview of entity's list of HDs and their risks
- Review of the entity's SOPs related to handling of HDs
- Proper use of PPE

- Proper use of equipment and devices (e.g., engineering controls)
- Response to known or suspected HD exposure
- Spill management
- Proper disposal of HDs and trace-contaminated materials

Dr. Acosta explained that all training must be documented and must be reassessed every 12 months.

Section 10. Receiving

Dr. Acosta provided the following requirements for receiving of HD products.

- HD products should be received from the supplier in impervious plastic to segregate them from other drugs.
- HD products must be delivered to the HD storage area immediately after unpacking.
- PPE, including chemotherapy gloves, must be worn when unpacking HDs.
- A spill kit must be accessible in the receiving area.
- The entity must enforce policies that include a tiered approach, starting with visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass).
- Damaged shipping containers: transported to a C-PEC designated for nonsterile compounding.
 - Damaged containers are considered spills and must be reported to the designated person and managed.

Section 11. Labeling, Packaging, Transport and Disposal

Dr. Acosta provided a summary of each section as provided below.

- Labeling
 - HDs identified must be clearly labeled at all times during their transport.
 - Personnel must ensure that the labeling processes for compounded preparations do not introduce contamination into the non-HD handling areas.
- Packaging
 - must select and use packaging containers and materials that will maintain physical integrity, stability, and sterility (if needed) of the HDs during transport.
 - must protect the HD from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs.
 - must have written SOPs to describe appropriate shipping containers and insulating materials.
- Transport
 - must be labeled, stored, and handled in accordance with applicable federal, state, and local regulations.
 - must be in containers that minimize the risk of breakage or leakage.
 - must ensure that labels and accessory labeling for the HDs include storage instructions, disposal instructions, and HD category information in a format that is consistent with the carrier's policies.
- Disposal

- All personnel performing custodial waste removal and cleaning activities must be trained in appropriate procedures.
- Disposal of all HD waste, including, but not limited to, unused HDs and trace-contaminated PPE and other materials, must comply with all applicable federal, state, and local regulations.

Section 12. Dispensing Final Dosage Forms

Dr. Acosta explained that HDs that do not require any further manipulation, other than counting or repackaging of final dosage forms, may be prepared for dispensing without any further requirements for containment unless required by the manufacturer or if visual indicators of HD exposure hazards are present (e.g., HD dust or leakage). She added that clean equipment should be dedicated for use with HDs and should be decontaminated after every use. Dr. Acosta also noted that tablet and capsule forms of antineoplastic HDs must not be placed in automated counting or packaging machines.

Section 13. Compounding

Dr. Acosta stated that all compounding must be compliant with the appropriate USP standards for compounding including <795> and <797> and must be done in proper engineering controls.

Dr. Acosta explained that when compounding HD preparations in a C-PEC, a plastic-backed preparation mat should be placed on the work surface of the C-PEC and the back should be changed immediately if a spill occurs and regularly during use and should be discarded at the end of the daily compounding activity.

Dr. Acosta reported that bulk containers of liquid and API HD must be handled carefully to avoid spills. She also explained that APIs or other powdered HDs must be handled in a C-PEC to protect against occupational exposure, especially during particle-generating activities

Section 14. Administering

Dr. Acosta explained that HDs must be administered safely using protective medical devices and techniques and appropriate PPE must be worn. She added that PPE must be removed and disposed of in a waste container approved for trace contaminated HD waste at the site of drug administration.

Dr. Acosta stated that equipment (such as tubing and needles) and packaging materials must be disposed of properly, such as in HD waste containers, after administration.

Dr. Acosta explained that If HD dosage forms do require manipulation such as crushing tablet(s) or opening capsule(s) for a single dose, personnel **must** don appropriate PPE and use a plastic pouch to contain any dust or particles generated.

Section 15. Deactivating, Decontaminating, Cleaning and Disinfecting

Dr. Acosta explained that all areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned. She noted that sterile

compounding areas and devices must be subsequently disinfected.

Dr. Acosta stated that policies and procedures for cleaning must include procedures, agents used, dilutions (if used), frequency, and documentation requirements.

Dr. Acosta described appropriate PPE as follows:

- resistant to the cleaning agents used,
- two pairs of chemotherapy gloves
- impermeable disposable gowns
- eye protection and face shields must if splashing is likely
- respiratory protection must be used, if warranted

Dr. Acosta explained that agents used for deactivation, decontamination, and cleaning should be applied through the use of wipes wetted with appropriate solution and all disposable materials must be discarded to meet EPA regulations and the entity's policies.

Dr. Acosta also reminded that committee that all cleaning must be performed in areas that are sufficiently ventilated.

Dr. Acosta provided the committee with the following definitions of deactivating, decontaminating, cleaning and disinfecting.

- Deactivation
 - renders a compound inert or inactive.
 - Residue must be removed by decontaminating the surface.
 - There is no one proven method for deactivating all compounds. (EPA-registered oxidizing agents that are appropriate for the intended use)
- Decontamination
 - inactivating, neutralizing, or physically removing HD residue and transferring it to absorbent, disposable materials (e.g., wipes, pads, or towels) appropriate to the area being cleaned.
 - The work surface of the C-PEC must be decontaminated between compounding of different HDs.
 - The C-PEC must be decontaminated at least daily, any time a spill occurs, before and after certification, any time voluntary interruption occurs, and if the ventilation tool is moved.
 - areas under the work tray must be deactivated, decontaminated, and cleaned at least monthly
- Cleaning
 - a process that results in the removal of contaminants (e.g., soil, microbial contamination, HD residue) from objects and surfaces using water, detergents, surfactants, solvents, and/or other chemicals.
 - Cleaning agents used on compounding equipment should not introduce microbial contamination.
- Disinfection
 - a process of inhibiting or destroying microorganisms.
 - must be done for areas intended to be sterile, including the sterile compounding areas.

Section 16. Spill Control

Dr. Acosta provided the committee with the following information regarding spill control.

- personnel must receive proper training in spill management and the use of PPE and NIOSH-certified respirators
- Spills must be contained and cleaned immediately by qualified personnel with appropriate PPE.
- Qualified personnel must be available at all times while HDs are being handled.
- Signs must be available for restricting access to the spill area.
- Spill kits must be readily available in all areas where HDs are handled.
- All spill materials must be disposed of as hazardous waste.
- The circumstances and management of spills must be documented.
- Personnel potentially exposed during the spill or spill cleanup or who have direct skin or eye contact with HDs require immediate evaluation.
- Non-employees exposed to an HD spill should follow entity policy, which may include reporting to the designated emergency service for initial evaluation and completion of an incident report or exposure form.
- SOPs must:
 - be developed to prevent spills and to direct the cleanup of HD spills.
 - address the size and scope of the spill and specify who is responsible for spill management and the type of PPE required.
 - address the location of spill kits and clean-up materials as well as the capacity of the spill kit.

Section 17. Documentation and Standard Operating Procedures (SOP)

Dr. Acosta explained that standard operating procedures must be reviewed (and documented) at least every 12 months and should include:

- Hazard communication program
- Occupational safety program
- Designation of HD areas
- Receipt
- Storage
- Compounding
- Use and maintenance of proper engineering controls
- Hand hygiene and use of PPE based on activity
- Deactivation, decontamination, cleaning, and disinfection
- Dispensing
- Transport
- Administering
- Environmental monitoring
- Disposal
- Spill control
- Medical surveillance

Dr. Acosta stated that personnel who transport, compound, or administer HDs must document their training according to OSHA standards (OSHA Standard 1910.120) and other applicable laws and regulations.

Section 18. Medical Surveillance

Dr. Acosta explained that Medical surveillance is part of a comprehensive exposure control program complementing engineering controls, safe work processes, and use of PPE. She added that healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program.

The committee thanked Dr. Acosta for her presentation and asked for public comments.

A pharmacist that compounds exclusively for veterinary practices asked if the board would be creating an exception that would allow certain veterinary HD products to be handled in a room that is not USP 800 compliant. Dr. Acosta recommended contacting the CDC as they create the NIOSH list which is used to determine how HD products must be handled.

A member of the public asked if the committee could make Dr. Acosta's slides available in an electronic format or in larger printed sizes. Chairperson Serpa reminded the public that it is the responsibility of the PIC and designated staff to review the USP standards, the slides are only a high-level review of the standards.

A compounding pharmacist asked if a pharmacy that provides patient specific HDs to a hospital is responsible to make sure that the HDs are handled appropriately by hospital staff when it is administered (i.e. wearing proper PPE and proper disposal). Chairperson Serpa responded that in some healthcare systems the pharmacy is responsible to oversee the HDs from compounding to administration; however, an independent pharmacy would have different requirements. DCA legal counsel Laura Freedman stated that this question goes beyond the agenda item and should be placed on a future agenda for future discussion.

Interim Executive Officer Anne Sodergren reminded the committee that there is pending legislation that will set the relevant USP chapters as the floor for the board's compounding regulations. After the floor is set the board will have the opportunity to develop additional regulations if necessary.

4. Approval of the February 20, 2019 Meeting Minutes

Chairperson Serpa noted that in both the February and March minutes on page 2 the term "<825> – Preparation" should be corrected to read "<825> – Radiopharmaceuticals Preparation."

The committee agreed with the changes to both minutes.

Motion: Approve the February 20, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Weisser/Law

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			
Serpa	x			
Weisser	x			

5. Approval of the March 13, 2019 Meeting Minutes

Motion: Approve the March 13, 2019, committee meeting minutes with the correction noted by Chairperson Serpa.

M/S: Schaad/Weisser

Support: 4 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Kim				x
Law	x			
Schaad	x			
Serpa	x			
Weisser	x			

6. Future Committee Meeting Dates

Chairperson Serpa announced the committee’s next meeting is scheduled for June 4, 2019, in Sacramento. She added that the July meeting has been rescheduled to July 11, 2019, in Sacramento. Chairperson Serpa noted that the board’s website has been updated to reflect the new meeting date.

7. Adjournment

Chairperson Serpa adjourned the meeting at 11:25 a.m.