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

COMPOUNDING COMMITTEE
MEETING MINUTES

DATE: September 5, 2019

LOCATION: University of Southern California
Orange County Center
2300 Michelson Drive
Irvine, CA 92612

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chairperson
Allen Schaad, Licensee Member, Vice Chairperson
Greg Lippe, Public Member, Acting President

STAFF MEMBERS PRESENT: Anne Sodergren, Interim Executive Officer
Christine Acosta, Supervising Inspector
Anna Kalantar, Supervising Inspector
Laura Freedman, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth, Administration Manager

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

Chairperson Serpa called the meeting to order and provided background on the committee's actions during the previous meetings. The committee determined and the full board agreed that regulations mirror the structure of the USP chapters, including separate requirements for the various types of compounding preparations. Rather than completing one rule making package that encompasses regulations for each USP Chapters, the Board will initiate the formal rulemaking process as regulations for each respective chapter are finalized. This will allow for more immediate transition to the new Chapters and regulations.

Dr. Serpa provided in July 2019, the committee discussed proposed regulations relating to nonsterile preparations, that may be necessary to implement, clarify or make more specific requirements related to USP Chapter 795 as well as to ensure safe compounding processes consistent with the board's consumer protection mandate. The committee's recommendation was considered by the board during the July 2019 board meeting. The board voted to initiate the rulemaking process, which is the first step in the promulgating the regulation. Dr. Serpa advised the rulemaking package was recently submitted to DCA counsel to complete pre-notice review. Upon completion of the pre-notice review by various control agencies, the board will release a notice and advise all interested parties about the proposed

changes and provide a 45-day comment period. Dr. Serpa suggested that anyone interested engage in the regulatory process during the comment period.

Dr. Serpa provided the focus of the meeting will be on proposed regulations for the compounding of sterile preparations to consider regulations that may be necessary to implement, clarify or make more specific requirements related to USP 797. Any such regulation should be consistent with the board's consumer protection mandate. Dr. Serpa noted if the committee is unable to complete the review at this meeting, a subsequent meeting will be convened on September 24th to continue the review. After completing this review on sterile compounding, the committee will move on to subsequent USP chapters 800 and 825 to consider additional regulations.

Chairperson Serpa called the meeting to order at 9:10 am. Board members present at the meeting were: Allen Schaad, Greg Lippe and Maria Serpa. 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. Discussion and Consideration of Proposed Regulations Related to Pharmaceutical Compounding of Sterile Preparations

Chairperson Serpa provided the committee will discuss each section one at a time with time for member and public discussion. Dr. Serpa advised the public if a delayed implementation is necessary for enhanced language in proposed California regulations to please include this in your comments. She noted, the proposed language will be projected so that live edits can be made with the consensus of the members. Dr. Serpa suggested that the committee consider a single motion to make a recommendation to the full board after completing its review of the proposal in its entirety. She advised the committee members and public that included in the meeting materials were draft proposed amendments to regulations that would rename Article 7 and repeal and replace Sections 1751-1751.10 with Sections 1751-1751.21. The second document included the same regulation language, but also included a brief explanation of the rationale and necessity for the proposed regulation.

Section 1751 Sterile Compounding in Licensed Pharmacies

The committee heard public comment on the proposed draft section 1751 (a) – (j).

Section 1751 (a)
The committee heard no comments on section 1751 (a).

Section 1751 (b)
The committee heard comments requesting allowing immediate use beyond the proposed limited situations where failure to administered could result in the loss of life or intense suffering. The committee and board staff explained the intent was to allow immediate use as an exception but in many hospitals, the exception became the practice. The commenter requested removing the labeling requirement of "for immediate use only" as this was redundant and represented additional

programming costs for labeling for each change to the label. The committee agreed and struck ‘ “for immediate use only” and’ from the second sentence of 1751 (b).

The committee heard comments requesting clarification if section 1751 (b) applied to all pharmacy personnel or personnel within the facility. Dr. Serpa clarified the board regulations are specific to the practice of pharmacy.

The committee heard comments about the unique identifier requesting clarification of the requirement during a code and if the unique identifier was specific to the CSP or patient. The committee clarified information on the code log would be sufficient documentation. The committee clarified the unique identifier was specific for the patient. The committee added “patient” before unique identifier in the last sentence of section 1751 (b).

The committee entertained a request to remove the compounded time from the requirements and specify records can be hard copy or electronic. The committee explained the compounded time is the documentation required to verify the product was used correctly.

The committee agreed to the following edits as a result of public comments:

> (b) Compounded sterile preparation (CSP) for immediate administration shall only be done in those limited situations where there is a need for immediate administration of a CSP and where failure to administer could result in loss of life or intense suffering. Any such CSP shall be labeled ~~“for immediate use only” and~~ with a beyond use date/time of 4 hours or less. The pharmacy shall maintain records of such CSPs shall at least include CSP made, compounded time, and patient name and patient unique identifier.

Section 1751 (c)
The committee heard no comments on section 1751 (c).

Section 1751 (d)
A member of the public expressed concern that section 1751 (d) required documentation from the physician. The committee and board staff advised the language is the same for sections 1735 pertaining to non-sterile compounding. Dr. Serpa directed board staff to confirm this information.

The committee heard public comments requesting section 1751 (d) be phrased in a more positive language so as not to be confusing. The commenter also requested the term “limited” to be defined and practice to be added to veterinarian for clarity. Board staff explained “limited” is current law and included in FDA guidance. Board staff indicated this could be included as an FAQ. The committee agreed to add “Except as identified below,” to the beginning of section 1751 (d) and remove “Notwithstanding this subdivision,” from section 1751 (d)(1). The committee agreed to add “practice” after veterinarian in section 1751 (d)(2).

The committee heard comments from pharmacists from large animal pharmacies. The pharmacists requested clarification if section 1751 (d)(2) referred to a single CSP or all CSPs. The committee clarified the requirement was for the specific CSP. To clarify the language, the committee agreed to change the last sentence of section 1751 (d)(2) to replace “additional CSPs” to “the same CSP” and will clarify additional products and frequency.

The committee heard a public comment requesting to have veterinary office dispensing added back into the section. The committee explained USP and current federal law does not allow for veterinary office dispensing. The committee attempted to find a balance to allow for continuance of care when needed without allowing for long-term dispensing from a veterinarian office.

The committee agreed to the following edits as a result of public comments:

> (d) Except as identified below, ~~No~~ no CSPs shall be compounded prior to receipt by a pharmacy of a valid patient specific prescription document. Where approval is given orally, that approval shall be noted on the prescription document prior to compounding.
>
> (1) ~~Notwithstanding this subdivision, a~~ A pharmacy may prepare and store a limited quantity of a CSP in advance of receipt of a patient specific prescription document.
>
> (2) Notwithstanding this subdivision, a pharmacy may prepare and provide a limited quantity of CSPs to veterinarians for animal patients based on a contract between the pharmacy and veterinarian for office use administration only. The pharmacy and veterinarian practice are jointly responsible for compliance with this section. The contract shall require the veterinarian to provide the pharmacy with the records documenting the dose administered to each patient or destruction record of CSPs. The pharmacy shall be prohibited from providing the same ~~additional~~ CSP~~s~~ to the veterinarian until the pharmacy has received and evaluate the records for compliance with this provision.

Section 1751 (e)

The committee heard comments that the language for section 1751 (e) should not refer to the compounding pharmacy. Chairperson Serpa clarified both the pharmacy license and pharmacist-in-charge are held responsible and accountable for the compounding done at the pharmacy.

The committee heard public comment requesting the time of dispensing be removed from section 1751 (e) (3) (A) as this shifted the burden of compounding to the pharmacy should the CSP be removed from the list during the compounding process. While the committee sympathized with the business decision, the committee must focus on the board's mandate of public protection.

Members of the public requested the committee specify human drugs in sections 1751 (e) (2) and (3) (A) and eliminate the duplicative wording in section 1751 (e) (3) (A). The committee removed "and at the time of compounding" in section 1751 (e) (3) (A).

The committee heard comments requesting clarification on section 1751 (e) (3) (A) and (B) which can be addressed in FAQs.

A member of the public requested clarification on section 1751 (e) (4). Board staff clarified raw materials should only be used for approved intended purposes. For example, raw materials for animal use should not be used for human use.

The committee received a request to allow for single exceptions to the requirements of section 1751 (e) (5).

The committee heard comment regarding 1751 (e)(6) requesting clarification if sterilization of product must be done in the pharmacy and cannot be completed outside of the pharmacy. Board staff confirmed the all steps to compounding including sterilization must be completed in the licensed compounding pharmacy.

The committee heard public comment regarding concern about limiting outsourced types of sterilization including gamma radiation, E-Beam and Ethylene Oxid (EtO) gas. The committee expressed concern about components of the compounding procedure leaving the licensed facility to an unlicensed facility and to an entity that should not be possessing dangerous drugs. The committee heard testimony that within the process is terminal sterilization. Once the product leaves the compounding licensed facility, the product is in a sealed vial/container. If tampered with, the product would not be used.

The committee heard testimony that USP 797 advocates for terminal sterilization. Public comment indicated gamma radiation and E-Beam sterilization is safer than autoclaving sterilization. Additional public comment indicated gamma radiation sterilization works better for some products. One commenter urged section 1751 (e)(6) be removed.

The committee understood the benefit of the terminal sterilization but acknowledged a change in statute is required if the board wanted to regulate the vendors that are not licensed.

The committee entertained a question about the authority to ship products via common carriers such as Fed Ex. Chairperson Serpa explained that is considered distribution to the end user and acceptable.

The committee heard public comment from an analytical lab representative who testified the company tests many compounds and sterile pellets with never having one fail. The representative testified the technique is viable and E-Beam sterilization is the most frequently used sterilization for medical devices. The commenter attested to the chain of custody used throughout the process.

Chairperson Serpa inquired about the opportunities to regulate vendors that are not licensed with the board. Interim Executive Officer Anne Sodergren advised a statutory change would be required.

The committee heard a comment concerning a hospital setting where autoclaving is part of central services. The commenter was concerned this wouldn't be allowed in the proposed draft language and requested the use of the term premise. Board staff advised the committee the definition includes within the licensed location and includes the entire hospital address.

The committee agreed to the following edits as a result of public comments:

(e) No pharmacy or pharmacist shall compound a CSP that:

(1) Is classified by the United States Food and Drug Administration (FDA) as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs which have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless

(A) that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding ~~and at the time of compounding~~ and at the time of dispense, or (B), the compounding of that CSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding.
The pharmacy shall retain a copy of the documentation of the shortage or the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(4) is made with any component not intended for use in a CSP for the intended patient population.

(5) Is made with a bulk drugs substance, as defined in Section 503A(b)(1)(A)(i), when there is an FDA approved sterile drug product that is available and appropriate for the intended CSP.

(6) cannot be sterilized within the licensed location ~~pharmacy~~.

Section 1751 (f)

The committee heard comment requesting clarification on when a self-assessment was required. The committee referred to section 1715 for clarification of self-assessment requirements.

Section 1751 (g)

The committee heard no comments on section 1751 (g).

Section 1751 (h)

A member of the public requested clarification on the definitions included in section 1751 (h). The committee agreed to the following edits as a result of public comments:

(h) Compounding with blood derived or other biological materials or blood components shall be done in compliance with Health and Safety Code section 1602.5.

Sections 1751 (i) and (j)

The committee received a request for the changes made to section 1751 (i) and (j). Board staff advised "and any board regulations" was added.

The committee took a break at approximately 11:03 am and returned at 11:21 am.

Chairperson Serpa advised to the audience that a decision had not yet been made about using a contracted sterilization company outside the licensed compounding facility. Dr. Serpa asked members of the public to email the board at and notify the board of any products that required being sterilized at a contracted sterilization company outside the licensed compounding facility. Dr. Serpa asked that the product requiring contracted sterilization be identified with an explanation why the contracted sterilization process is the only process that works for that product. Dr. Serpa advised the board will conduct further research on this issue. The email address compounding.pharmacy@dca.ca.gov was provided to the attendees. Supervising Inspector Christine Acosta requested names of outsourcing sterilization companies so the type of licensure can be identified for the companies.

Section 1751.1 Compounding Definitions

The committee heard public comment on the proposed draft section 1751.1 (a) – (l).

Section 1751.1 (a)
The committee heard comments requesting clarification and further definition of compounding personnel. Specifically, the committee was asked if environmental services, printing labels, washing equipment, and messengers to floors were included as part of compounding personnel. Board staff provided this section was intended to include all personnel involved in the compounding process. A member of the public requested this be addressed with FAQs. Dr. Serpa added this will be addressed in 1751.2.

Section 1751.1 (b)

The committee received comments on section 1751.1 (b) requesting clarification if IV admixture is no longer considered a CSP if made by manufacturer instructions. Dr. Serpa and Dr. Acosta clarified the board's proposed regulations further clarify USP 797 in specifying FDA approved labeling by product manufacturer. Dr. Serpa further clarified reconstituting must be done according to the manufacturer's insert. If reconstituting deviates from the manufacturer's insert, that is considered compounding.

A member of the public stated they appreciated "FDA approved" was clarified in this section and requested reconstituting and mixing be clarified as being exempt from compounding provided the approved labeling is being followed. Dr. Acosta stated it is included in USP 797 and this is part the preparation and not the process. Dr. Serpa clarified the board's proposed regulations are to clarify items that are not clear in USP 797.

Section 1751.1 (c) – (e)
The committee heard no comments on section 1751.1 (c) - (e).

Section 1751.1 (f)
The committee heard comments requesting clarification of "in process material" and the meaning of this term. DCA Counsel Freedman provided this was an effort to clarify a confusing definition but the board will continue to refine the language.

The committee heard comments requesting removal of "the" or "all" in the last sentence of Section 1751.1 (f). The committee agreed to the following edits as a result of public comments:

> (f) "In process material or in process preparation or stock solution" means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the CSP. For purposes of this article, "in process material" shall refer to ~~the~~ all terms used in this subdivision.

Section 1751.1 (g) – (l)
The committee heard no comments on section 1751.1 (g) - (l).

Section 1751.2 Personnel Training and Evaluation

The committee heard public comment on the proposed draft section 1751.2(a) – (f).

Section 1751.2 (a)
The committee heard no comments on section 1751.2 (a).

Section 1751.2 (b)
The committee heard comments indicating there was confusion if required semiannual or annually and requested adding "at least annually." Dr. Acosta advised the frequency is included in USP 797.

Section 1751.2 (c)
The committee heard comments requesting definitions for primary engineering controls. The committee agreed to the following edits as a result of public comments:

> (c) Aseptic manipulation evaluation and requalification documentation shall include the PEC's (Primary Engineering Control) unique identifier used during the evaluation. Aseptic manipulation evaluation and requalification shall be performed using same personnel, procedures, type of equipment, and materials used in compounding drug preparations.

Section 1751.2 (d)
The committee received comments requesting reference to the action levels in USP and clarification on what levels require action. The committee expressed concern on limiting action to only the tables referenced in USP and explained USP action tables are the minimum requirements. Some standard operating procedures identify any contamination requiring action. The committee expressed concern for limiting those who want to exceed USP standards. The committee heard comments requesting definitions for standard operating procedures. The committee agreed to the following edits as a result of public comments:

> (d) Requalification in hand hygiene, garbing and aseptic manipulation shall occur each time the quality assurance program yields an unacceptable result as defined in the Standard Operating Procedure (SOP)s that may indicate microbial contamination of CSPs. Requalification procedures shall be defined in the pharmacy's SOPs.

Section 1751.2 (e)
The committee heard no comments on section 1751.2 (e).

Section 1751.2 (f)
The committee received comments requesting clarification on what training is required for people working on the floors. Chairperson Serpa advised all personnel involved in compounding would have to have a measure or competency that would prove they are following hospital standard operating procedures. Dr. Acosta advised USP 797 in 1.5 specifies they are subject to the following not listed in categories 1 and 2 such as training, competency testing and personal hygiene for personnel are applicable to all compounding personnel.

Section 1751.3 Personnel Hygiene and Garbing

The committee heard public comment on the proposed draft section 1751.3 (a) – (f).

Section 1751.3 (a)
The committee heard public comment that USP doesn't specify rashes or sores not exposed are restrictive to go into the IV room and how would a pharmacist know without a search. The committee advised this is included under the accommodation section, CCR 1751.3(f). Dr. Acosta provided the discretion from the designated person has been removed in the board's proposed regulations.

Section 1751.3 (b)
The committee heard no comments on section 1751.3 (b).

Section 1751.3 (c)
The committee received a comment requesting clarification if this is referring to hazardous. Chairperson Serpa indicated this would be addressed in the next section at a different meeting.

The committee heard comments requesting to revert to USPs suggestion that donning and doffing do not occur in the ante room rather than making it compulsory. Dr. Serpa advised the intent was to imply in most situations, this should not be done but added the process is required if done.

DCA Counsel Freedman clarified that discussions occurred between Dr. Serpa and staff but not Dr. Serpa and other committee members. Dr. Serpa clarified she worked with staff to provide input and kept up to date on proposed drafts.

Section 1751.3 (d) – (f)
The committee heard no comments on Section 1751.3 (d) – (f).

Section 1751.4 Facilities and Engineering Controls

Committee Member Lippe indicated this would be a good section to define PEC as primary engineering control.

The committee heard public comment on the proposed draft section 1751.4 (a) – (h).

Section 1751.4 (a)
The committee did not hear comments on section 1751.4 (a).

Section 1751.4 (b)
The committee heard a comment requesting reusable equipment and utensils that cannot be sterilized be required to be rinsed with sterile water for injection or sterile water for irrigation as USP does not define pyrogen free water. Dr. Acosta added sterile water for injection or sterile water for irrigation are pyrogen free. The committee agreed to reference applicable USP chapters and agreed to the following edits as a result of public comments:

> (b) Reusable equipment and utensils which ~~have~~ cannot ~~not~~ be sterilized and depyrogenated, and that will come in direct contact with compounding components must be rinsed with either sterile water for injection or sterile water for irrigation, ~~, pyrogen free water~~.

Section 1751.4 (c)

The committee did not hear comments on section 1751.4 (c).

Section 1751.4 (d)

A commenter asked why USP 797 was restated in this section. Dr. Acosta provided this language is to eliminate a plan with an ante room and cleanroom but later the site determines higher volume is needed so a PEC is put in the ante room where the cleanroom is no longer the cleanroom. Dr Acosta continued if the anteroom is used as a SEC then the cleanroom that follows this anteroom is no longer a cleanroom, but is now a SCA.

Section 1751.4 (e)

The committee heard a comment requested removal of section 1751.4 (e)(1) and (e)(2) as it is included in USP and redundant. Dr. Serpa provided temperatures are regulated differently by different regulators. She stated it was the committee's intent with the proposed language to find the best language for the comfort and safety of personnel. The language of "should" from USP was not enforceable which is why the language was changed to "shall" with the allowance of adding "typically." The SCA is added to the language. This will also be added to the FAQs. Dr. Serpa encouraged the public to use ask.inspector@dca.ca.gov for questions about specific sites. The committee also heard comment that this language should be stricter and should be "shall."

The committee heard a comment requesting any deviation to be documented. Dr. Acosta provided that requirement for documentation was already included in USP.

The committee heard a comment requesting the allowance for using non-sterile components in the sterile preparation process provided the process is validated. The commenter requested water for injection produced at the facility to be allowed. Dr. Acosta expressed concern writing law for one business practice and was not aware of other sites that created their own water.

Section 1751.4 (f)

The committee heard a comment that new CA building codes effective 1/1/20 will not allow for a pass through between the hazardous drug buffer room and any unclassified area. The committee also heard a comment requesting the effective date of this requirement to be two years from the effective date of the regulation. The committee agreed to reference applicable USP chapters and agreed to the following edits as a result of public comments:

> (f) Where a pass-through is installed in a secondary engineering control, SOPs must address how both doors will not be opened at the same time. Effective ~~January 1, 2020,~~ [two years from the effective date of the regulation], all pass-throughs must be interlocking. ~~A pass-through used to access a negative-pressure ISO 7 or better space from a non-classified space, must be a HEPA-filtered purge pass-through.~~

Section 1751.4 (g) – (h)

The committee did not hear comments on section 1751.4 (g) and (h).

The committee took a break for lunch at 12:36 pm and returned from lunch at 1:22 pm.

Section 1751.5 Certification and Recertification

The committee heard public comment on the proposed draft section 1751.5 (a) – (c).

Section 1751.5 (a)

The committee heard concerns about referencing CETA guidelines with a specific reference to a version of the guidelines when the guidelines are expected to change in the future. DCA Counsel Freedman provided the Office of Administrative Law will require a version to be specified. Ms. Freedman provided if new guidelines come out during the regulation process, the proposed regulation text can be amended.

The committee heard comment requesting to change "certify" to "certification" in section 1751.5 (a)(2). Based on public comment, the committee agreed to the following change in section 1751.5 (a)(2):

> (2) CAG standard(s) used to perform ~~certify~~ certification testing in all classified areas to shall be recorded on certification report.

Section 1751.5 (b) – (c)
The committee did not hear comments on section 1751.5 (b)-(c).

Section 1751.6 Microbiological Air and Surface Monitoring

The committee heard public comment on the proposed draft section 1751.6 (a) – (e).

Section 1751.6 (a)
The committee heard no comment on section 1751.6 (a).

Section 1751.6 (b)
The committee heard comments concerning the term organism of concern. Dr. Serpa clarified this section is referring to air and surface monitoring. Dr. Kalantar advised the purpose is to have the pharmacies identify the organisms of higher concern and pointed pharmacies to consult a microbiologist to help create the list.

The committee heard comments requesting (b) and (c) reference SOPs and action levels associated with USP 797. Dr. Serpa provided the intent of this requirement is to require the pharmacy to at least biannually know what is growing in the environment even if the levels are below the action levels required by USP.

The board heard comment agreeing with the organism of concern and requesting the board post information on the board's website. The committee advised this is to be handled by the pharmacy and included in the SOPs which will also address geographic differences. The commenter requested removing the organism of concern from the regulation and added to the self-assessment. Board staff and DCA Counsel indicated it needs to be in regulation to clarify in law for the regulated public.

The committee heard a comment requesting removing "species" and replacing with "level" and requesting the change shall be identified "by a qualified microbiologist" to provide reassurance of the biannual testing and the level of species to see if it is an organism of concern.

The committee heard comments requesting specification to the genus level for cfu counts below ISO classification action levels and within the facility's historical trend as being questionable to patient safety and representing increased cost for the patients. The commenter requested reconsideration of moving away from organisms of concern.

The committee heard comment requesting the removal of the last sentence and requested adding to the SOPs identification of organisms of concern. Any time there is growth in the hospital setting, administrators want to know the law. As written now, organisms of concerns include molds or yeast. Dr. Serpa recommended using an adjective or qualifier for molds or yeast.

The committee heard comment that section 1751.6 (b) was beyond the scope of practice for a pharmacist who is not a microbiologist specialist. Dr. Serpa appreciated that it may be above the pharmacist-in-charge, but the pharmacist-in-charge needs to have the general idea and microbiologists are available for consultation.

Based on public comment received, the committee agreed to the following changes in section 1751.6 (b):

> (b) During biannual recertification, all microorganism recovered (growth) shall be identified by a qualified microbiologist, at least to the genus ~~species~~ level, regardless of the cfu count. When identification of an organism of concern, action shall be taken. Organisms of concern shall be identified by the PIC or designated person and shall be documented in a SOP. Some possible organisms of concern ~~would~~ may, but need not, include ~~be~~ gram-negative rods, coagulase positive staphylococcus, and certain molds and yeasts.

Section 1751.6 (c)

The committee heard comments that whenever growth is identified in (a) or (b), resampling has to be redone. The committee indicated the intent was not to require continuous resampling for (b). The intent is only when action levels are exceeded or during biannual testing. The committee made edits to remove "growth is identified" and replace with "cfu action levels are exceeded or an organism of concern is identified."

Based on public comment received, the committee agreed to the following changes in section 1751.6 (c):

> (c)Whenever ~~growth is identified~~ cfu action levels are exceeded or an organism of concern is identified as specified in (a) or (b), required action shall include at a minimum, an investigation of (1) cleaning and compounding operations, (2) sampling, (3) personnel training, (4) incubator functionality, (5) facility management, and (6) resampling. Consultation with a competent microbiologist, infection control professional, or industrial hygienist is required when resampling results in growth of an organism of concern or when action levels are exceeded, regardless of count. All actions taken shall be documented.

Section 1751.6 (d) – (e)

The committee did not hear comments on section 1751.6 (d) or (e).

Section 1751.7 Cleaning, Disinfecting, and Applying Sporicidal Agents in Compounding Areas

The committee heard public comment on the proposed draft section 1751.7 (a) – (b).

Section 1751.7 (a)
The committee heard comment that this was duplication of USP. Dr. Acosta clarified it has to be written in the SOPs for clarity.

The committee received a comment requesting clarification if the disinfectant has to be sterile. Dr. Acosta clarified USP does not specify.

Section 1751.7 (b)
The committee did not hear comment on section 1751.7 (b).

Section 1751.8 Introducing Items into the SEC and PEC

The committee heard public comment on the proposed draft section 1751.8 (a).

Section 1751.8 (a)
The committee heard a comment requesting to change "this" to "these." Based on the comment from the public, the committee agreed to the following change:

> The requirements of this section apply in addition to the requirements in USP Chapter 797**.**
>
> (a) SOPs shall define the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the ante-room, entering a PEC, and entering the SCA. ~~This~~ These SOPs will define at a minimum, what product is to be used, the dwell time required, and how dwell time will be monitored and documented.

Section 1751.9 Equipment, Supplies, and Components

The committee heard public comment on the proposed draft section 1751.9 (a) – (f).

Section 1751.9 (a) – (b)
The committee did not hear comment on section 1751.9 (a) – (b).

Section 1751.9 (c)
The committee heard comments requesting if the board was moving to making FDA guidance documents a regulatory requirement. Dr. Serpa clarified they should be considered. The commenter requested it be added as a separate item. Dr. Serpa requested Section 1735 be considered.

After hearing public comment, the committee agreed to the following changes with the possible rephrasing:

(c) Any component used to compound a CSP shall be used and stored <u>(1) considering issued Guidance Documents and Alerts (2)</u> in accordance with all industry standards including the following:

(~~1~~ <u>A</u>) United States Pharmacopeia (USP) – National Formulary (NF),

(~~2~~ <u>B</u>) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,

(~~3~~ <u>C</u>) Food Drug Administration (FDA) requirements and ~~considering issued Guidance Documents and Alerts~~, and

(~~4~~ <u>D</u>) Manufacturers' specifications and requirements.

<u>*Section 1751.9 (d)*</u>

The committee heard comments expressing concern enforcing USP chapters over 1000 as the chapters are meant to be informational purposes only. The recommendation was made to reference any USP chapter over 1000 rather than requiring it. DCA Counsel Freedman confirmed as proposed in the draft, the requirement is established for USP 1080.

<u>*Section 1751.9 (e)*</u>

The committee heard comment regarding concern about dietary supplement standards as written would negatively impact patient access. Dr. Serpa provided it is not the board's purpose to get in the way of patient treatment where it is safe for patients, but this was included because there are unsafe practices occurring. Dr. Acosta provided the intent of the language is to prevent people from taking inappropriately graded raw materials and preparing to make injectables and use materials that are graded for injectables. Dr. Serpa indicated human consumption grade need to be considered when selecting raw materials for injections.

Dr. Serpa encouraged the public to provide information via the email address for specific examples that are known that would be impacted by this language.

The committee heard comments that guidance is needed for what is acceptable and standard for injections. Dr. Acosta provided a USP monograph is not required. A USP monograph is one of the acceptable methods but there are other acceptable methods.

The committee heard a comment from a veterinary pharmacist that there several APIs that do not have USP monographs but have the COA. If there are no guidelines, they use what the manufacturer usually tests. They also use vendors that set their own standards. Dr. Serpa requested a list indicated as veterinary use.

The committee heard a comment inquiring about investigational drugs. Dr. Acosta provided investigational drugs are regulated by CDPH and FDA. The FDA makes allowance for FDA-approved products.

<u>*Section 1751.9 (f)*</u>

The committee heard a comment requesting clarification if section 1751.9 (f) prohibits use of pre-sterilized or pre-pyrogenized components. Dr. Acosta provided it speaks to what is done in the pharmacy.

Section 1751.10 Sterilization and Depyrogenation

The committee heard public comment on the proposed draft section 1751.10 (a) – (f).

Section 1751.10 (a) – (f)
The committee heard public comment that the inclusion of gamma radiation and x-ray should be included in section 1751.9 (f). Dr. Serpa provided as the committee looks to radiation in the previous section, the committee will include corresponding changes to this section. The public is invited to submit comments.

Section 1751.11 Master Formulation and Compounding Records

The committee heard public comment on the proposed draft section 1751.11 (a) – (c).

Section 1751.11 (a)
The committee heard a comment to remove "at least volume" from section 1751.11 (a)(2). Dr. Acosta advised it was removed from nonsterile but kept for sterile.

Section 1751.11 (b)
The committee received a comment requesting clarification of the definition for "routinely" and there is no provision in USP 797 to put the master formula on the prescription itself. There is a provision to put the record of compounding on the prescription. Dr. Acosta clarified it was left in the proposed draft to allow for one offs to not have to change practice. The requirements are the same as USP but need to be on one document.

Section 1751.11 (c)
The committee received an inquiry why section 1751.11 (c)(2) has removed the internal ID number for lots or orders and now it is only for these compounded drug preparations. Dr. Serpa provided this is current process. Dr. Acosta clarified USP does not require unique number and the proposed draft regulations specify the unique number.

The committee received an inquiry why section 1751.11 (c)(3) requirements are for only CSP for more than one patient and from CSP from nonsterile ingredients. Dr. Serpa and Dr. Acosta provided this is current practice.

The committee heard a comment requesting clarification if there was an exemption for lot compounding. Dr. Acosta confirmed the exemption currently allows for a loophole that prevented processing of recalls and unable to determine if the product used was expired at the time of the use. It has been an exemption for inpatient practices but is not beneficial to the consumers. This exemption is not maintained in the proposed regulation.

The committee was asked why the number of units is required to be documented if assigned a unique identification number in section 1751.11 (c)(4). The committee explained the board needs to know how many products share in the batch made.

Dr. Serpa thanked the public for the participation and great discussion through section 1751.11. Dr. Serpa advised the continued review of section 1751 will recommence at the next committee meeting on September 24, 2019.

4. Approval of the June 4, 2019, Meeting Minutes

Motion: Approve the June 4, 2019, committee meeting minutes with the following edits:

- On page 4 of 5 of the meeting minutes in the last paragraph, amend the first sentence to remove "in licensed pharmacies" to read "Chairperson Serpa inquired what is the role of the board for regulating the use of radiopharmaceuticals where non-pharmacy personnel are doing activities in the licensed care environment."
- On page 4 of 5 of the meeting minutes in the last paragraph, delete the third sentence.
- On page 4 and 5 of 5 of the meeting minutes in the last paragraph on page 4, amend the last sentence of the last paragraph to add "in these organizations and" after pharmacy leadership to read "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 in these organizations and other regulators (e.g., Joint Commission, CDPH) to hold the pharmacy accountable for all compounding including radiopharmaceuticals."

M/S: Schaad/Serpa

Support: 2 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Schaad	x			
Serpa	x			
Lippe			x	

5. Approval of the July 11, 2019, Meeting Minutes

Motion: Approve the July 11, 2019, committee meeting minutes with the following edits:

- On page 3 of 11 of the meeting minutes in the third paragraph, amend the last sentence to add "and she will contact USP for further clarification" to read "Inspector Christine Acosta stated the USP 795 committee intended for the inclusion of a flavoring agent to be considered compounding and she will contact USP for further clarification."

M/S: Lippe/Schaad

Support: 3 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Schaad	x			
Serpa	x			
Lippe	x			

6. Future Committee Meeting Dates

Chairperson Serpa announced the committee's next meeting is scheduled for September 24, 2019, in Sacramento.

7. Adjournment

Chairperson Serpa adjourned the meeting at 2:50 pm.