

Comments Received During 45-Day Comment Period (5/8/2015 - 6/22/2015) and at the Regulation Hearing on 6/25/2015.

Code Section	Commenter	Comment	Board Response
1735(b)	John Cronin Institute for Community Pharmacy	Dr. Cronin stated that the Board's definition of "Compounding" is more restrictive than the Federal definition found in 21 USC 353(a) as it does not include "mixing" in the definition. Mr. Cronin also recommended that the term "reconstiution" be defined within the regulation.	The Board rejected this comment. The Board determined that the addition of "mixing" was not appropriate as mixing is compounding. Additionally, "reconstitution" is an industry standard term and does not need to be defined for the regulated public to understand the meaning.
1735(b)	Doug O'Brien Kaiser Permanente	Dr. O'Brien indicted that the proposed language was incomplete and missing an important categories of products. Dr. O'Brien recommended adding some specific terms to reduce confusion to the list within the definition.	While the Board disagreed with Dr. O'Brien's statement that there are Ophthalmic products that require only reconstitution, after further reflection during a 15-day comment period, the Board elected to remove the list of products from the definition. The Board determined that the list was to restrictive and not was necessary for the regulated public to understand the definition.
1735.1	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein, providing comments together, recommended the addition for two new definitions to make references within other portion of the regulations more specific and clear. They recommended the addition of "Controlled area" or "designated area" and "Sterile compounding personnel".	The Board rejects this comment as it is not necessary to include these definitions. The terms "controlled area" and "designated area" are only used within the regulation text in a few places, all but one in existing text. In context, the uses are self explanatory and, if there were a question, the pharmacy, through the professional judgment of its pharmacist-in-charge, would be responsible to determine the appropriate controlled or designated areas. The term "sterile compounding personnel" is only used once in the regulation text and its use in context is self explanatory and, if there were to be questions about which personnel the regulation applied to, the pharmacy, through the professional judgment of its pharmacist-in-charge, would be responsible determine the application. As a result, additional definitions are unnecessary.

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1735.1	BJ Bartleson California Hospital Association	Ms. Bartleson recommended adding a definition for "Fully automated IV Robotics"	The Board rejects this comment as robots are an example of a Primary Engineering Control (PEC). As such, robots have been added to the definition of PEC with section 1735.1(ab). A separate definition is not necessary.
1735.1	Lynn Paulsen	Ms. Paulsen recommended adding a definition for "Robotics". Additionally, she was unclear why the biological safety cabinet did not have ventilation requirements. Finally, she requested delaying the regulation until USP 800 was finalized.	<p>The Board accepted Dr. Paulsen's first two comments and added reference to "Robots" to the definition of PEC. Additionally, the ventilation requirements were added to the definition of biological safety cabinet.</p> <p>The Board considered Dr. Paulsen's request to delay the regulation until USP 800 was finalized; however, the Board rejected this request. USP 800 is not expected to be finalized until sometime in 2017/2018 and the Board determined that continuing to wait for these regulations would not be in the best interest to public safety.</p>
1735.1(a)	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended modifying the definition of "Ante-area" to specify that "Sterile Compounding Personnel," rather than just "personnel" may perform hand hygiene and garbing, in order to clearly define the duties and requirements for those involved in sterile compounding.	The Board rejected this comment because personnel other than sterile compounding personnel may be in the ante-area. Those personnel within the ante-area may also perform hand hygiene and garbing for sterility.
1735.1(c)	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended modifying the definition of "Biological Safety Cabinet (BSC)" to include the phrase "Sterile Compounding Personnel" in order to clearly define the duties and requirements for those involved in sterile compounding.	The Board rejected this comment because the BSC protects all staff and not just sterile compounding personnel. The definition would not be accurate if the change was made.
1735.1(d)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended adopting the USP Chapter 797 definition for buffer area.	The Board rejects this comment, Based on several comments received, the Board determined that this definition was not necessary as it could be combined with "cleanroom." The definition of Buffer Area was removed from the regulation.

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1735.1(d)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended that the definition of "buffer area" be amended to to address different airflow issues and air quality.	The Board rejects this comment, Based on several comments received, the Board determined that this definition was not necessary as it could be combined with "cleanroom." The definition of Buffer Area was removed from the regulation.
1735.1(d)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval expressed concern about the restriction "for hazardous compounds, or for chemotherapy compounds" and recommended that the phrase be removed to allow for hazardous compounding in a buffer area.	The Board rejected this comment because USP 797 does not allow for hazardous compounding by displacement method. However, this definition has been remove from the regulation and combined with "Cleanroom" The cleanroom definition does allow for hazardous compounding with certain conditions.
1735.1(d)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane expressed concern about the definition of "Buffer area" and the ability to use displacement airflow. They recommended the addition of a water column to allow for hazardous compounding.	The Board agreed with this comment; however, applied it to the definition of "cleanroom" as the buffer area definition has been remove from the regulation and combined with "Cleanroom." The cleanroom definition does allow for hazardous compounding with certain conditions (including the water column).
1735.1(e)	Brian Warren California Pharmacist Association	Mr. Warren expressed concern about the definition of "Bulk drug substance" and recommended that "becomes" be changed to "is" because "an inactive ingredient does not become active."	The Board agreed with this comment and the definition was updated to change "becomes" to "is."
1735.1(f)	Doug O'Brien Kaiser Permanente	Dr. O'Brien expresse concern that this definition is misleading and inaccurate because it states that a cleanroom must provide ISO Class 7 or better air quality. Dr. O'Brien provided two examples of other acceptable configurations of cleanrooms. He recommended that the Board adopt the USP Chapter 797 definition for cleanroom.	The Board rejected this comment and it noted that both examples provided include by the commenter where for an ISO Class 7 or better (ISO Class 8) air quality. The definition allows for ISO Class 7 or ISO Class 8; the room does not need to have both areas.
1735.1(d) and (f)	University Compounding Pharmacy Joe Grasela	Mr. Grasela indicted that the definition for "Buffer area" and "Clean room" are used interchangeablyin USP 797. Additionally, he indicated that the definition of cleanroon was incomplete as it didn't address hazardous compounding and negative pressue (ISO Class 7).	The Board agreed with this comment. The definition of buffer area was removed and added to "cleanroom" definition. The revised definition of "cleanroom" includes the ISO class 7 requirements for hazardous compounding.

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1735.1(f)	Douglas Barcon Barcon & Associates	Dr. Barcon expressed concern about contamination in the airflow and recommended that the definition be changed to "A minimum differential positive pressure of 0.02-to 0.05-inch water column is required to segregate the room from the surrounding unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment."	The Board rejected the recommended language; however, the definition was changed "relative to all adjacent spaces" to address the contamination concerns.
1735.1(g)	Douglas Barcon Barcon & Associates	Dr. Barcon expressed concern that a CAI should not be used to compound antineoplastic hazardous drugs.	The Board agreed with this comment and modified the definition to add the term "non-hazardous" to definition.
1735.1(h)	Douglas Barcon Barcon & Associates	Dr. Barcon requested that "particle-generating, aerosol-producing, or sterile" be added after volatile to include USP 800 revisions.	The Board rejected this addition; however, the definition was changed to include the external venting necessary for hazardous compounding in USP 800. Additionally, the term "Volatile" was removed as all hazardous compounding can be done within a CACI.
1735.1(j)	Bruce Lepley Community Regional Pharmacy	Dr. Lepley requested that "or a range otherwise specified by the pharmaceutical manufacturer" be added to the language to address manufacturer storage temperature recommendations.	The Board rejected this comment as this language is already in the proposed approved text noticed for 45-day comment on May 8, 2015.
1735.1(j)	Douglas Barcon Barcon & Associates	Dr. Barcon indicated that there cannot be two definitions for "controlled freezer temperature." Use of "or" creates two definitions. He also indicated that "controlled freezer temperature" is not used in USP 797 (only freezer temperature is referenced). Dr. Barcon also expressed concern that items with a range below -25 degrees C could be comingled at the colder temperature in the same freezer with products that specify -20 degrees C.	The Board rejected this comment as it does not agree that there are two definitions. The compound needs to be stored within the listed temperatures unless the manufacturer states otherwise. The term is used within the regulation and needs to be defined accordingly. As these regulations are not an exact copy of USP 797, the term used in the regulation is slightly different. Additionally, "for that product" is added to address the possible comingle issue raised. Licensees will need to store the compounds within the appropriate temperature ranges to ensure the integrity of the product.

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1735.1(l)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested changing the definition to include an exemption for specific items from the definition of what is a copy or essentially a copy.	The Board rejected this comment as the list recommended is to specific. Adding an exemption would require that all possible items be included and the list is to extensive.
1735.1(m)	Lynn Paulsen	Ms. Paulsen recommended that the definition be updated to occur "every" day and not just when the pharmacy is open.	The Board agreed with this comment. The definition was revised to include the requirement of daily monitoring of temperatures when necessary.
1735.1(m)	BJ Bartleson California Hospital Association	Ms. Bartleson also expressed concern that pharmacies should check temperatures daily.	The Board agreed with this comment. The definition was revised to include the requirement of daily monitoring of temperatures when necessary.
1735.1(n)	Brian Warren California Pharmacist Association	Mr. Warren expressed concern that an exception to a rule is being placed in the definition section of the regulation. He recommended that it be moved to 1751.7(e).	The Board agreed with this comment as the regulated public may not look at the definition section with seeking clarification with the regulation. It is appropriate to have the exception in the requirements and not in the definition section. The exception was moved to 1751.7(e)(2)(A) and removed from definition.
1735.1(q)	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended that, in the definition of gloved fingertip sampling, "compounding personnel" be changed to "Sterile Compounding Personnel," for consistency.	The Board rejected with this comment, and believes the addition would be too specific. This section defines what gloved fingerip sampling is, and the requirements of "who" must perform the test are in other provisions (see, for example, sections 1735.7), but may include other compounding personnel.
1735.1(r)	Douglas Barcon Barcon & Associates	Dr. Barcon recommends changing the definition to include "and other hazardous drugs" as identified by the National Institute for Occupational Safety and Health (NIOSH).	The Board rejected this comment as repetitious. The Board determined that if the drug meets the NIOSH criteria for a hazardous drug, the definition applies without the addition suggested.
1735.1(s)	Lynn Paulsen	Ms. Paulsen indicated that she was unclear why both integrity and potency are defined separately.	The Board rejected this comment. Integrity and Potency have two different meanings and; therefore, need to be defined separately in the regulation for clarity.

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1735.1(t)	Doug O'Brien Kaiser Permanente	<p>Dr. O'Brien expressed concern that the definition is confusing and requires clarification.</p> <p>1. It could be interpreted to include different types of preparations that are prepared during one uninterrupted continuous cycle of compounding.</p> <p>2. It could be interpreted to mean a single type of drug preparation compounded during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).</p>	The Board rejected this comment and determined that the definition did not need to be clarified. It is one or more preparations compounded from one or more active ingredients during one uninterrupted cycle.
1735.1(t)	BJ Bartleson California Hospital Association	Ms. Bartleson recommended that the the "Lot" designation be limited to products made in anticipation of an order and cannot be tracked.	The Board rejected this comment as this is a patient safety issue. The possibility of contamination, even when the patients are known, can still occur.
1735.1(t)	William Stuart Hartley Medical	Mr. Stuart recommended that the definition of lot be changed to "two or more" to align the definition with the definition of non-sterile to sterile.	The Board rejected this comment because Lot and Non-Sterile to Sterile are defined differently. The term "lot" is used in the cleaning requirements and it is necessary to disinfect after each compound to prevent cross-contamination.
1735.1(t)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	<p>Dr. Palmer and Dr. Shane recommended the "Lot" definition be change to include only "non-sterile to sterile batch"compounding.</p> <p>OR</p> <p>They recommended changing definition of "lot" to "greater than one dose" in order to ensure timely preparation of compounded drugs to treat emergency patients' conditions where immediate administration of medications is essential.</p>	<p>The Board rejected this comment: Lot and Non-Sterile to Sterile are two separate items and are defined differently. The term "lot" is used in the cleaning requirements and it is necessary to disinfect after each compound to prevent cross-contamination.</p> <p>The second recommendation is also rejected. The definition of "lot" does not prevent preparing more than one dose, provided that it is done during one uninterupted cycle and is tested appropriately.</p>

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1735.1(u)	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended that "compounding personnel" be changed to <u>Sterile Compounding Personnel</u> .	The Board rejected the comment; however, the definition was changed and "compounding personnel" was removed. This section defines what a Media-fill test is and the requirements of "who" must perform the test are in 1751.7(b).
1735.1(u)	William Stuart Hartley Medical	Mr. Stuart recommend tha the definition be changed to remove "most routine" and only include "most challenging" procedures.	The Board agreed with this comment and changed the definition to remove "most routine" and remain consistent throughout regulation.
1735.1(w)	Lynn Paulsen	Ms. Paulsen inquired as to whether the definition included topical and recommended that the defintion be further refined.	The Board agreed with the comment and added a list of what it does not include. Additionally, after further reflection following the 15-day comment period, the Board removed the list of what it includes. The Board determined that it did not need to list what it includes if it listed what it didn't include.
1735.1(y)	Lynn Paulsen (The Board received 3 additional comments regarding this issue)	Ms. Paulsen expressed concern that the definition was too restrictive and did not address diluting of a commercial product.She indicated that commerical products are already +/-10% and then when diluted the resulting diluted product will exceed +/-10%.	The Board agreed with the comment. The definition of Potency was amended to address and exempt dilutions within a health care facility from commerical products.
1735.1(y)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that USP 797 does not describe potency in the manner used by the Board. Mr. Lepley recommended that the definition be removed.	The Board rejected this comment as the term is used within regulation and therefore needs to be defined accordingly; however, the definition of Potency was amended to address and exempt dilutions within a health care facility.
1735.1(ab)	Amy Gutierrez	Dr. Gutierrez recommended the addition for automated robots to the regulations.	The Board agreed with the comment and add automated robots to the PEC definition, as they are an example of a PEC.

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1735.1(ae)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman expressed concern that a master formula should not have to be changed if there is a one time deviation from the master formula due to the availability of an inactive ingredient.	The Board rejected this comment. The Board determined that there should be a master formula for each deviation in formulation. This is necessary so that there is appropriate documentation and uniform formulations should the same deviation occur again in the future. The Master Formula is the "recipe" of what's in the preparation.
1735.1(af)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended removing "non-hazardous" from the definition to allow compounding of hazardous drugs in a segregated compounding area within a CACI.	The Board initially rejected this comment; however, after further reflection following a 15-day comment period, the Board agreed with the comment and made recommended change.
1735.1(af) Same comment provided for 1751(b)(3)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the definition did not allow a CAI or CACI to be utilized in a segregated compounding area. Additionally, Mr. Lepley requested an exemption to allow for a sink within 3 feet of a ISO Class 5 PEC if its a CACI.	For comment 1, the Board agreed with the comment and modified the definition of segregated compounding area to add CAI and CACI requirements. For comment 2, the Board rejected the comment. The Board found no reliable data to support their belief and no reliable data was provided. The Board maintained it's position that there is a risk of contamination if there is a sink/drain within 3 feet of the compounding area.
1735.1(af)	Anonymous	An anonymous commentor indicated that some PEC manufactures do not require a 3 foot perimeter. They recommended that the regulation be modified to allow for compliance within manufacturers specifications.	The Board rejected this comment as not all manufacturers have the same standards and perform the same tests on their equipment. The Board would need to review and evaluate the recommendations of each manufacturer before it would be comfortable changing the language within the regulation.
1735.2	Lynn Paulsen	Ms. Paulsen indicated that some Hospitals still have not changed from expiration date to BUDs and the change cannot be done overnight due; therefore, she requested an implementation schedule over the next year or two.	The Board rejected this comment as these changes have been pending since 2013. Additionally, the implementation date has been set at January 2017, and this should sufficient to make the necessary changes.

Code Section	Commenter	Comment	Board Response
1735.2(c)(1)	Doug O'Brien Kaiser Permanente	Dr. O'Brien indicated that the term "fair market value" cannot practically apply to pharmacy-compounded items because there are no published prices that compounding pharmacies can use to determine that fair market value.	While the Board disagrees with the comment; this section has been modified and language was removed as pharmacies can no longer provide a non-patient specific 72-hour supply per the Federal 503b requirements.
1735.2(c)(1)	Brian Warren California Pharmacist Association (Also commented on at hearing by Tony Park)	Mr. Warren indicated that the proposed "fair market" requirement is arbitrary, difficult to enforce, and beyond the scope of the Board's mandate of protection of the public health and safety.	While the Board disagrees with the comment; this section has been modified and language was removed as pharmacies can no longer provide a non-patient specific 72-hour supply per the Federal 503b requirements.
1735.2(d)(3)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley recommended that "Manufacturer, Wholesaler, and/or Distributor acknowledge and provide documentation that the drug is in short supply" be added as many medications that are in short supply in "real time" may not be on the ASHP or FDA drug shortage list in a timely manner.	The Board rejected this comment. ASHP and FDA are the appropriate Federal sources for drug shortages. While one manufacturer/distributor may not be able to obtain the drug product, another may be able to. That manufacturer inability to obtain the drug does not equal a drug shortage.
1735.2(d)(3)	Michael Tou Providence Health	Mr. Tou expressed concern that the current wording of prohibits pharmacies from diluting a commercially-available drug product.	The Board rejected this comment as a dilution is not compounding. These these regulations would not apply to the dilutions. Additionally, reconstitution (adding water to a powder) is also not compounding and these regulations would not apply. The intent of this regulation is to not prevent the use of a sterile manufactured product to be used as directed by the manufacture to compound for patient administration.
1735.2(e)(5)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the language may be too broad. He recommended that the section be reworded to state "Specific and essential compounding steps used to prepare the drug"	The Board agreed with the comment and revised the section "and essential" added for specificity. This is eliminate the requirement to list non-essential steps.

Code Section	Commenter	Comment	Board Response
1735.3(a)(1)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman inquired about whether the master formula record must be kept with the compounding log or if it is a separate document. Additionally, Dr. Cottman identified that the records identified are called a "compounding log" in practice.	The Board agreed with both comments made. The section was modified to separate Master Formula and Compounding log, and specify that the compounding log is a single document" for clarity and to align the regulation with current practices. By separating the two documents, they do not have to be maintained together, as long as both items are maintained and accessible.
1735.3(a)(5)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman indicated that the term "component" is inconsistent with language in section 1735.2(e)(1) and 1735.2(e)(4) and recommended the term be changed to "ingredient."	The Board agreed with the comment and changed the term "component" to "ingredient."
1735.3(a)(6)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman indicated that the term "component" is inconsistent with language in section 1735.2(e)(1) and 1735.2(e)(4) and recommended the term be changed to "ingredient."	The Board agreed with the comment and changed the term "component" to "ingredient."
1735.3(a)(6)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommendation that ambulatory oncology clinic pharmacies be included in the seventy-two (72) hour exception language.	The Board agree with the comment and also agreed that not all "patients" are considered "inpatients" therefore, the language was changed from "an inpatient" to "a patient" in the exemption to address this issue.
1735.4(c)	Brian Warren California Pharmacist Association	Mr. Warren indicated that unit-dose containers are too small to comply with the labeling requirements of this section. He recommend an changing the label requirements for unit-dose containers because of size limitations.	The Board agreed with this comment. This entire section was rewritten following the 15-day comment period for clarity. The unit-dose exception requirements were added at 1735.4(d).
1735.5(a)	Brian Warren California Pharmacist Association (Also commented on at hearing by Tony Park)	Mr. Warren requested that "material" be added to this section to ensure that disciplinary action is not taken for minor irrelevant deviations from the policies and procedures. Additionally, he requested that "may" be added to allow the Board discretion over whether disciplinary action is actually taken.	The Board agreed with the addition of "material" to alleviate the concern raised by the commenter; however, the Board rejected the addition of "may" because the failure to follow the Policies and Procedures is a violation and constitutes a basis for discipline. The Board still has the authority to apply discretion over whether to take disciplinary action.

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1735.6(d)	Brian Warren California Pharmacist Association (Also commented on at hearing by Tony Park)	Mr. Warren recommended that the language be modified to require all compounding of hazardous drugs to be done in powder containment hoods to ensure pharmacist and pharmacy technician safety.	The Board rejected this comment. The Board disagrees the all hazardous compounding must be done in a powder containment hood. The exact requirements for hazardous compounding have been defined in new section 1735.6(e).
1735.8(c)	Doug O'Brien Kaiser Permanente	Dr. O'Brien indicated that the language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. As proposed the regulation would add major costs to hospital and other pharmacy-compounding.	The Board rejected this comment. This section specifies the requirements of a quality assurance plan. It does not state that "any and all" products be tested. The language in this section includes the frequency of testing and the testing schedule in the plan.
1735.8(e)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended changing "or" to "and", so the QA plan includes responding to out-of-range temperatures in the pharmacy and patient care areas versus one or the other.	The Board agreed with this comment and made the recommended change.
1751(b)(3)	Brian Warren California Pharmacist Association	Mr. Warren recommended that an exception be allowed for emergency eye wash stations as it is listed in 1735.1(af).	The Board agreed with this comment. The verbiage was removed in error from May 8, 2015 noticed language and has been added back into the text.
1751(b)(3)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed the same concern as Mr. Warren in regards to the emergency eye wash station.	The Board agreed with this comment. The verbiage was removed in error from May 8, 2015 noticed language and has been added back into the text.
1751.1	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended that "personnel" be changed to "sterile compounding personnel" throughout this section to make the requirements more specific.	The Board rejected this comment as it disagrees with the specification implied. This section addresses the documentation that a pharmacy engaged in sterile compounding must maintain. All employees will complete appropriate training as appropriate. The requirements of "who" must complete the competency evaluations are defined elsewhere (for example, section 1751.7(b)).

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1751.1	Michael Tou Providence Health	Mr. Tou recommended the addition of the following: Add: (4) Compounding (reconstitution and/or dilution) of FDA approved drug products is excluded from this restriction.	The Board rejected this comment. As indicated in previous comment responses "Reconstitution" and "dilution" is not compounding so these regulations would not apply these practices.
1751.1(a)(5)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley indicates that the word "sterile" was removed from the language and recommended that the word be added back in.	The Board rejected this comment. The language referenced was not removed and "sterile" remains in the approved proposed text posted May 8, 2015.
1751.1(a)(5)(c)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended that "controlled" be removed from the text as there is no definition of "controlled freezer temperature" in the USP.	The Board rejected this comment as the term is used within the regulation and is defined accordingly in 1735.1. Additionally, these regulations are not an exact copy of the USP.
1751.1(a)(7)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the regulation doesn't allow use of a continuous recording device.	The Board rejected this comment. The regulation language is not disallowing electronic monitoring as long as it is documented daily. It is up to the PIC to determine "how" the documentation is done.
1751.1(a)(10)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman expressed concern that the terms "preparation work sheet" and "master work sheet" are inconsistent with compounding record and master formula record used in other regulation sections.	The Board agreed with the comment and changed the language to master formula document and compounding log for clarity.
1751.2(b)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman requested clarifying information as to why inactive ingredients as well as the active ingredients need to be listed.	The Board agreed with this comment. The requirement to list inactive ingredients was removed. Additionally, the labeling requirements have been moved to 1735.4 as it applies to all compounded products, not just sterile.

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1751.2(b)	Michael Tou Providence Health	Mr. Tou requested clarification or guidance on the requirement for "each ingredient" as it conflicts with 1735.4.	The Board agreed with this comment: The requirement to list inactive ingredients was removed. Additionally, the labeling requirements have been moved to 1735.4 as it applies to all compounded products, not just sterile. Furthermore, the strength/volume/weight was modified to be consistent in 1735.4.
1751.3	Judith Brosz and Robert Stein	Dr. Brosz and Dr. Stein recommended that "staff" be changed to "sterile compounding personnel" as it may be subject to misinterpretation and lead to a universal practical testing requirement in a pharmacy. Additionally, in various sections of the proposed regulations, staff are referred to as "personnel," "staff," and "employees." We believe these terms are intended to refer to the same individuals and recommend using consistent terminology.	The Board rejected this comment. It believed the addition to be too specific. This section deals with the Policies and Procedures of a pharmacy engaged in sterile compounding. The P&P must address the training and competency of all staff that will have access to the area (including janitorial, for example), not just those involved in sterile compounding.
1751.3	Lynn Paulsen	Ms. Paulsen indicated that USP 797 requires identifying CFUs to genesis level to trigger action. She recommended this be included in the regulation.	The Board agreed with this comment and determined that the specific CFUs action level is to be determined by the PIC of the Pharmacy and included in the P&P.
1751.3(a)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman recommended sorting list by importance, sequence of events (Garbing and Gloving procedure should occur before fingertip testing), or alphabetically for clarity.	The Board agreed with this comment and alphabetized for clarity.
1751.3(b)(1)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman indicated that the term "compounding work sheets" is inconsistent with language in several other sections and recommended that the term be changed for consistency.	The Board agreed with this comment. The terms in this section were changed to "master formula document" and "compounding log" for clarity and consistency.
1751.4(d)	Eric and Kate	The commenter indicated that the cleaning section of the regulation was poorly written and misleading and provided recommended cleaning requirements.	The Board agreed with this comment. The cleaning section was rewritten and reorganized for clarity and consistency with USP 797.

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1751.4(d)	Doug O'Brien Kaiser Permanente	Dr. O'Brien expressed concern that under the current language, staff would need to clean and disinfect the PEC repeatedly within a short period of time. He indicated that the proposed language is confusion and increases cost. He recommended that the section be deleted.	The Board rejected this comment; however, the section was revised to separate "cleaning" versus "disinfecting." It is necessary to disinfect routinely to prevent accidental contamination when non-robotic PECs are being used.
1751.4(d)	William Stuart Hartley Medical	Mr. Stuart recommend that the language of this section be revised to be consistent with USP 797.	The Board agreed with this comment. The cleaning section was rewritten and reorganized for clarity and consistency with USP 797.
1751.4(d)(2)	BJ Bartleson California Hospital Association	Ms. Bartleson recommended that new language be added to address cleaning schedules of automated IV robots as repeated cleaning can result in contamination within robot.	The Board rejected this comment at this time. The automated compounder issue was addressed by adding "human staff" language to reduce the frequency of cleaning of robots. The Board will look futher at the issue of automated machines as they become more commonly used within the industry.
1751.4(d) & (e)	Lynn Paulsen	Ms. Paulsen recommended adding language for self cleaning robots as a self-contained robot is not cleaned after every preparation. She indicated that contamination comes from hands and arms.	The Board rejected this comment at this time. Manufacturer cleaning instructions of each robot need to be evaluated before adding this language to a regulation because they are not all consistent. The Board did modify the language to reduce the frequency of cleaning for robots by adding in the "human staff" language.
1751.4(d)(2)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval expressed concern that cleaning AND disinfecting surfaces of the ISO Class 5 PEC may not be feasible depending on the scale of operations. She recommended that the Board adopting USP 797s minimum frequency of cleaning and disinfecting the PEC.	The Board agreed with this comment. The cleaning section was rewritten and reorganized for clarity and consistency with USP 797.
1751.4(d)(2)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the regulation was not consistant with USP 797 and it requires cleaning every 30 minutes during continuous compounding. He also expressed concern that, as written, the language would impact the timeliness of the compounding. He recommended removal of "before and after each lot" and replace with "every 30 minutes during continuous compounding."	The Board rejected this specific recommendations within the comment. However, the section was modified to remove "and After" and leave the language as "Before each lot" and "30 minutes" has been added for compounding with human staff to address the continuous compounding issue.

Code Section	Commenter	Comment	Board Response
1751.4(d)(4)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman recommended that the language be modified to only require cleaning when the cleanroom is used as not all facilities access there cleanroom everyday.	The Board rejected this comment. The Board determined that cleaning is necessary even if the cleanroom is not used as it is possible for someone to still enter the cleanroom and contamination may occur.
1751.4(e)	BJ Bartleson California Hospital Association	Ms. Bartleson expressed concern that the use of disinfectants and germicidal detergent overlap significantly in the proposed text.	The Board agreed with this comment. The section was revised to separate cleaning and disinfecting into different subdivisions.
1751.4(e)	Michael Tou Providence Health	Mr. Tou echoed concerns expressed by Ms. Bartleson. However, Mr. Tou indicates that water is not required for floor cleaning.	The Board rejected this comment. Water is necessary to rinse the floor of the detergent. The section was revised to separate cleaning and disinfecting into different subdivisions.
1751.4(e)	Lynn Paulsen	Ms. Paulsen recommended that the Board identify the difference between germicidal cleaner and a disinfectant. She indicated that USP 797 requires a germicidal cleaner followed by water and not an additional disinfectant.	The Board agreed with this comment. The section was revised to separate cleaning and disinfecting into different subdivisions.
1751.4(f)	Douglas Barcon Barcon & Associates	Dr. Barcon requested that this section be modified to include manufacturer certification that the PEC meets performance standards. Dr. Barcon also expressed concern the section (f) conflicts with section (h).	<p>The Board rejected this comment. While the manufacturer can state that the PEC is designed to meet those standards, the manufacture cannot ensure the CAI/CACI is performing at the requirements. The unit needs to be routinely checked and certified to meet the requirements. It is possible for machines to fail.</p> <p>The Board disagrees that the two sections conflict. Section (f) addresses the certification requirements of the PEC and Section (h) addresses the placement of the PEC.</p>
1751.4(g)	Brian Warren California Pharmacist Association	Mr. Warren indicated that garbing requirements should not be necessary when compounding within an aseptic containment isolators.	The Board rejected this comment. The Board determined that garbing is required for patient safety to prevent accidental contamination.

Code Section	Commenter	Comment	Board Response
1751.4(g)	BJ Bartleson California Hospital Association	Ms. Bartleson requested that last sentence that states, "where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply" be removed. She indicated that a manufacturer should not have the ability to eliminate the requirement for protective garbing.	The Board agreed with this comment and removed the exemption from the language.
1751.4(g)	University Compounding Pharmacy Joe Grasela	Mr. Grasela requested that the double glove requirement be removed from the regulation as USP 800 doesn't require or propose a double glove when working with hazardous compounds.	The Board rejected this comment and disagrees with the commenter. USP 800 does require double gloves and refers to section 6.1 Hazardous Drugs (Gloves).
1751.4(i)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern about the frequency of testing. He recommended that the viable surface sampling requirement be reduced to every six months to coincide with other sampling that will be performed by qualified outside vendors. Mr. Lepley indicated that USP 797 regulations states that viable surface sampling be done periodically.	The Board agreed with this comment. The sampling schedule was changed to "six months" for sterile-to-sterile and "quarterly" for non-sterile-to-sterile. The Board determined the non-sterile-to-sterile should be tested more frequently do to contamination risks.
1751.4(j)	Brian Warren California Pharmacist Association	Mr. Warren recommended that specific temperatures be removed and only require "comfortable" work conditions.	The Board rejected this comment. The Board determined that "comfortable" was too broad and needed additional clarity. The temperature settings were modified to allow for a temperature range. The temperature range must be specified to keep the room cool and prevent sweating by staff and possible contamination.
1751.4(j)	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein recommended that "compounding personnel" be changed to <u>Sterile Compounding Personnel</u> .	The Board rejected this comment as it is too specific. Comfortable working conditions apply to all personnel in the area. The temperature range must be specified to keep the room cool and prevent sweating by staff and possible contamination.

Code Section	Commenter	Comment	Board Response
1751.4(j)	Anonymous	This commenter stated that the Board should not be regulating what is a comfortable temperature. Staff should be allowed to decide.	The Board rejected this comment. The temperature settings were modified to allow for a temperature range. The temperature range must be specified to keep the room cool and prevent sweating by staff and possible contamination. While staff may want the room warmer, patient safety should come first.
1751.4(j)	Lynn Paulsen	Ms. Paulsen expressed concern that some Hospitals do not have air conditioners or may keep an area cool, but not at or below 68 degrees. She recommended eliminating the temperature or changing the wording.	The Board agree with this comment. The temperature settings were modified to allow for a temperature range. The temperature range must be specified to keep the room cool and prevent sweating by staff and possible contamination.
1751.4(j)	BJ Bartleson California Hospital Association	Ms. Bartleson recommended that the temperature requirement be removed. She indicated that some hospital pharmacies are challenged with precision temperature control, however can continue to maintain a comfortable temperature for employees. The exact temperature stated in this section cannot be supported by evidence and is not required by Cal/OSHA.	The Board rejected this comment. The temperature settings were modified to allow for a temperature range. The Board determined that a temperature range must be specified to keep the room cool and prevent sweating by staff and possible contamination. The temperature range selected is in alliance with the recommended temperature range for registered nurses (Guideline for a safe environment of care, part 2. In: Guidelines for perioperative practice. Dever, CO: AORN, Inc").
1751.4(j)	Douglas Barcon Barcon & Associates	Dr. Barcon expressed concern that the temperature in this section should apply to the sterile compounding area only per USP.	The Board agreed with this comment. "Sterile compounding area" was added and the temperature settings were modified to allow for a temperature range.
1751.5(a)(4)	Judith Brosz and Robert Stein	Dr. Brosz and Dr. Stein recommended that "compounding personnel" be changed to <u>Sterile Compounding Personnel</u> .	The Board rejected this comment as the Board determined that further specificity is not necessary as the section is "Sterile Compounding Attire," and the introduction in subdivision (a) makes it clear when and to whom the requirement applies.

Code Section	Commenter	Comment	Board Response
1751.5(a)(6)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that "exposed" be added before rashes and cosmetics" as there is no risk to patients unless the specified conditions are exposed.	The Board agreed with a part of this comment and added exposed before rashes; however, the Board disagreed and rejected the addition before cosmetics. Cosmetics are not allowed as can flake and are a potential contamination risk.
1751.5(a)(6)	Dennis Lau	Mr. Lau inquired about specifying only certain cosmetics are not allowed and allow others. He also requested that the Board allow the use of face shields or cosmetics sealers.	The Board rejected this comment. Allowing some products and not others would require both Board Inspectors and employers to be experts on whether the makeup their employee is wearing is acceptable. Additionally, cosmetics of any kind pose a contamination risk. Patient safety is the priority.
1751.5(a)(6)	BJ Bartleson California Hospital Association	Ms. Bartleson recommended adding gel nails and nail polish as not allowed. She also recommended adding that eyelash extensions are not prohibited.	The Board agreed with the addition of nail polish and artificial nails. The Board rejected the addition of listing eyelash extensions because the list of what is not prohibited is too encumbering. The Board cannot list just one item.
1751.6	Judith Brosz and Robert Stein	Dr. Brosz and Dr. Stein recommended changing all staff/personnel references to <u>Sterile Compounding Personnel</u> .	The Board rejected this comment as the Board determined that further specificity is not necessary and may be too restrictive. In order to ensure that sterile compounding is done in a sterile and safe environment, the pharmacy's training requirements may apply to other staff that may be in the environment, not just those performing the actual compounding.
1751.7(b)	Judith Brosz and Robert Stein	Dr. Brosz and Dr. Stein recommended changing all staff/personnel references to <u>Sterile Compounding Personnel</u> .	The Board rejected this comment as the Board determined that further specificity is not necessary and may be too restrictive from the existing language. Because the risk to consumers is so high particularly if the sterility of the preparation is compromised, the section applies to all those involved in the sterile compounding process, not just those performing the actual compounding. This section was, however, later revised to address clarity on the manner of determining competency.

Code Section	Commenter	Comment	Board Response
1751.7(c)	Judith Brosz and Robert Stein	Dr. Brosz and Dr. Stein recommended that "compounding personnel" be changed to Sterile Compounding Personnel.	The Board accepted this comment for clarity, though not the specific proposed language. The language of the second sentence was changed to add "each individual who may be required to do so in practice" in place of "compounding personnel."
1751.7(e)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane expressed concern about the need for immediate dispensing of compounded preparations without testing. They identified two examples that may need immediate dispensing.	The Board rejected this comment. The regulation does not permit immediate dispensing of Non-Sterile Compounded Preparations. The examples provided could be obtained from a 503b pharmacy.
1751.7(e)	Marie Cottman Pacific Compounding Pharmacy	Dr. Cottman expressed concern that the regulation is in conflict with USP <797>, <85> and <771> by requiring testing of ALL sterile products. USP <797> specifically exempts ophthalmic drops and inhalations from testing for pyrogens.	The Board agreed with this comment. The language was modified to exempt Ophthalmic and Inhalation preparations from pyrogen testing with limits placed on the amount of supply that can be provided without testing.
1751.7(e)	Brian Warren California Pharmacist Association (Also commented on at hearing by Tony Park)	Mr. Warren expressed concern the language proposed will impact patient safety. He recommended that language be modified to allow for the immediate dispensing on ophthalmic and inhalation products. Additionally, he requested that products compounded in a batch of 25 or fewer doses, those for emergency situations, and those with low chemical stability be exempted from testing.	<p>The Board agreed with and incorporated one of the recommendations (30 day Ophthalmic). Additionally, the Board included 5 days for inhalation to allow for emergency treatment while the product is obtained from another source.</p> <p>During a few Board meetings, the Board asked for examples of when the recommendations the other exemptions being requested would be applied and the commenter was unable to provide examples of these situations. The Board disagrees and without examples, rejected the requested exemptions.</p> <p>Patient safety is jeopardized without testing Non-Sterile preparations.</p>

Code Section	Commenter	Comment	Board Response
1751.7(f) - Add	Judith Brosz / Robert Stein	Dr. Brosz and Dr. Stein requested that a new section be added to the regulation to clarify that staff not performing the actual sterile compounding, but verifying the sterility remotely should not have identical training requirements to those performing the actual compounding. Specific text was recommended.	The Board accepted this comment in part, but rejected the recommended text. The training and competency requirements were modified in section 1751.7(b) and (c) to address the concerns raised by this comment. The policies and procedures must address how the pharmacy will train its staff and evaluate competency to ensure the safety of the public and the sterility of the preparations. The regulation does not specify that the policies and procedures must provide that each staff person demonstrate skills in each function.
1751.8	Lauren Berton CVS Health	Dr. Berton recommended removing the section and only including the reference to USP 797 to avoid having to rewrite the regulation everytime USP 797 is updated.	The Board rejected this comment. USP 797 is too large to include in the actual CCR for California. As USP 797 is incorporated by reference, this year/edition verbiage is required per the Administrative Procedure Act.
1751.8	Douglas Barcon Barcon & Associates	Dr. Barcon recommended deleting "a more" and replace with "an" for clarity.	The Board agreed with this comment and incorporated recommended change.
1751.8	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended adding specific language stating that the BUDs defined in sections (a) through (d) may be utilized for preparations compounded in CAIs or CACIs that meet the requirements delineated in 1751.4(f)	The Board agrees with this comment and added CAI to section. CACI is used for Hazardous and shouldn't be included. The Board understands that while you can use a CACI for Non-Hazardous, it would be being utilized as a CAI.
1751.8	Douglas Barcon Barcon & Associates	Dr. Barcon recommended that the wording be changed in this section to solid frozen state to incorporate the reference in USP 797.	The Board agreed with this comment and revised the entire section to "Solid Frozen State" for clarity and reduce confusion with the previous use of "Controlled freezer temperature"
1751.8(a)	University Compounding Pharmacy Joe Grasela	Dr. Grasela requested clarification about the differences between section (a) and section (b). He inquired if section (a) is also applicable to multiple patients and multi-use container.	The Board rejected this comment. The BUD for single-dose and Multi-dose containers is defined in section 1751.9 for clarity.

Code Section	Commenter	Comment	Board Response
1751.8(a)(1) & (b)(1)	Michael Tou Providence Health	Mr. Tou recommended that addition of a CAI or CACI to this section if it meets the requirements of 1751.4(f) for BUD.	The Board agree with this comment and added CAI to section. CACI is used for Hazardous and shouldn't be included. The Board understands that while you can use a CACI for Non-Hazardous, it would be being utilized as a CAI.
1751.8(c)	William Stuart Hartley Medical	Mr. Stuart recommended that the clause, "or where the sterile compounded drug preparation lacks effective antimicrobial preservatives" be removed as it is not referenced in USP <797>.	The Board agreed with this comment. The sentence was removed from the regulation text.
1751.8(e)(1)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley requested that the labeling for "immediate use only" be replaced with the hour BUD to avoid confusion with other regulatory agencies. He also requested that the section be reword to use "a delay could harm the patient" to avoid confusion. Additionally, Mr. Lepley asked if the regulation applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.	The Board rejected this comment as the Board determined that the additional language is not needed. Depending on the hospital, "Immediate use" does not necessarily mean what the commenter is requesting to change it to. These regulations apply to all sterile compounding as defined by CCR 1751. It applies to Pharmacy compounding, but does not apply to those not licensed by the Board.
1751.9(a), (b), (c)	Two commenters on CSTD	Dr. O'Brien and Dr.Palmer suggested that the language be modified to include the use of proven technologies with quality assurance procedures (for example, Closed System Transfer Devices) allowing for extension of BUD for single-dose vials.	The Board rejected this comment. The Board disagrees with the commenters rationale and notes that no data was provided to support argument. Closed System Transfer Devices are not completely effective and can still contaminate the vials because the outside of the vial is still handled by humans. The Board requested that the commenters provide data that supports the argument.
General Comment	University Compounding Pharmacy Joe Grasela	Mr. Grasela suggestioned that the Board use USP 797 and 795 and 71 and 800 instead of drafting it's own regulations.	The Board rejected this comment. While these regulations are aligned with the USP, CA regulations are more detailed in an effort to provide greater clarity and address the specific needs to CA licensees and consumers.
General Comment	Michael Tou Providence Health	Mr. Tou requested that that board clarify the intent of the language in section 1735.2(d)(3) and 1751.2(b).	The Board agreed with this comment. The regulation language has been edited for clarity.

Code Section	Commenter	Comment	Board Response
General Comment	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane requested the ability to provide emergency therapy to patients and provide chemotherapy to patients using technology withch preserves medication vials.	The Board rejected this comment. The Board determined that emergency therapy drugs can be obtained from a 503b and not compounded by the pharmacy. Additionally, the Board could find no reliable data that CSTD eliminate contamination. The Board requested the commenter provide data that supports this argument.

Comments Received During First 15-Day Comment Period (7/31/2015 - 8/15/2015)

Code Section	Commenter	Comment	Board Response
1735(b)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that the language in this section be modified to indicate that the list is not all inclusive and specifically list the categories of "ophthalmic" and "otic" to the list of products where "Compounding" does not include "reconstitution". He indicated that the proposed language is missing some very common and important categories of products.	While the topic of this comment is outside the scope of 15-Day comment period, the Board agreed with the comment and modified that language to address it. Instead of continuing to add to the list of products, the Board elected to remove the list. The Board determined that the list was too restrictive and not was necessary for the regulated public to understand the definition.
1735.1(a)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that the definition of "Ante-area" be modified to further align with USP 797. Specifically, Dr. O'Brien pointed out that an ISO Class 8 Ante-area is inappropriate for a negative pressure buffer area.	The Board agreed with this comment. The language of this section was updated to include the requirement for an ISO Class 7 or better air quality in a negative pressure room.
1735.1(c)	Jeffrey Nehira Dignity Health	Dr. Nehira recommended removing the added text related to where hazardous drugs are prepared. He indicated that this requirement is not part of USP<797> and is not part of evidenced based practice.	The Board rejected this comment. This requirement is included in USP 800 and the Board determined that it was proper venting is essential for patient safety and the safety of compounding staff.
1735.1(c)	Michael Tou Providence Health	Mr. Tou requested that the Board issue exemptions to hospital pharmacies which are unable to immediately comply with the ventilation requirements of section 1735.1(c).	The Board agreed with this comment. The Board will allow licensees to submit notice of intent to comply with regulations and approval will be granted on a case-by-case basis. The Board will allow facilities time to make the necessary improvements in order to comply. The waiver request requirements was added to the regulation at section 1735.6(f).
1735.1(d)	Jeffrey Nehira Dignity Health	Dr. Nehira recommended using the USP<797> definition for buffer area.	The Board rejected this comment because the term and definition for buffer area has been removed from the regulation.
1735.1(d)	Jeffrey Nehira Dignity Health	Dr. Nehira recommended using the USP<797> definition and include reference to the container of a sterile preparation.	The Board rejected this comment. The Board determined that adding a container definition would be confusing to the regulated public. This definition refers specifically to specific components in the compounding of drug preparations and not the container which encompasses the bulk drug substance.
1735.1(e)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane indicated that the definition was not consistent with 1735.6. The recommended that the number of air changes be changed to 12 for consistency.	The Board rejected this comment. The Board did agree that the language was not consistent, but instead of changing the definition to 12, the Board elected to change 1735.6(e)(1) & (2) to 30 for consistency.
1735.1(e)	Jeffrey Nehira Dignity Health	Dr. Nehira recommended removing the requirement for HEPA-filtered air as the requirement is not in USP<797>.	The Board rejected this comment. The Board disagreed that this requirement is not in USP 797 and refers the commenter to page 12 of USP 797.

Code Section	Commenter	Comment	Board Response
1735.1(e)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that the Board use the USP 797 definitions for buffer area and cleanroom. Additionally, Dr. O'Brien requested that displacement airflow method be allowed for positive pressure buffer areas, Finally, he requested a delay in implementation of the requirementd for a negative pressure buffer area for compounding hazardous drugs until USP Chapter 800 is finalized.	The Board rejected this comment as the term buffer area and cleanroom have been combined and no longer hold alternative meanings within the regulation. The Board will allow licensees to submit notice of intent to comply with regulations and approval will be granted on a case-by-case basis. The Board will allow facilities time to make the necessary improvements in order to comply. The waiver request requirements was added to the regulation at section 1735.6(f).
1735.1(e)(1)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that it is confusing to refer to buffer area within the clean room definition. Additionally, he stated that the differential positive pressure of 0.02 to 0.05 inch is not standard practice and should be removed.	The Board rejected this comment. Buffer Area and Cleanroom mean the same thing as used in the regulation. The Board is not defining them as separate spaces. Additionally, the pressure range references are directly from USP 797, "For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required."
1735.1(e)(1) & (2)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty expressed concern that the use of a range of pressure implies that anything outside of the range is not allowed. Additionally, they expressed concern that the cleanroom definition does not reference sterile preparations.	The Board rejected this comment. The Board determined that the range references are from USP 797 and USP 800 and it is appropriate to list them. Additionally, the Board determined that referencing sterile preparations was not necessary as the language was modeled from USP 797 and USP 800.
1735.1(e)(2)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that the requirements for this section do not meet CETA engineering requirements when compared with USP<797>.	The Board rejected this comment. The requirements in this section are direct references from USP 797 and USP 800. Additionally, the commenter appears to be misunderstanding CETA. Board staff contacted CETA and the FDA and confirmed that the requirements within the regulation do not conflict with CETA.
1735.1(e)(2)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that USP 797 makes the stipulation of 12 air changes per hour for compounding hazardous drugs. He recommended this section be modified for consistency with section 1735.6 (e) (1).	The Board rejected this comment. Section 1735.6(e)(1) & (2) was modified for consistency and adds in the 12 air change exception when specific requirements are met as outlined in USP 800.

Code Section	Commenter	Comment	Board Response
1735.1(e)(2)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval requested that the Board consider using USP 800 for alternative ACPH requirements. Additionally, Dr. Sandoval requested that the Board consider reasonable timelines and expectations for compliance so that patient care is not impacted.	The Board rejected this comment for this section; however, the Board did modify section 1735.6(e)(1) & (2) to add in the 12 air change exception when specific requirements are met as outlined in USP 800. The Board will allow licensees to submit notice of intent to comply with regulations and approval will be granted on a case-by-case basis. The Board will allow facilities time to make the necessary improvements in order to comply. The waiver request requirements was added to the regulation at section 1735.6(f).
1735.1(f)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that the requirements for this section do not meet CETA engineering requirements when compared with USP<797>.	The Board rejected this comment. The requirements in this section are direct references from USP 800. Additionally, the commenter appears to be misunderstanding CETA. Board staff contacted CETA and the FDA and confirmed that the requirements within the regulation do not conflict with CETA.
1735.1(f)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding unidirectional HEPA-filtered airflow between "unidirectional" and "compounding" and strengthening the language to ensure that the exhaust air be externally vented.	The Board agreed with this comment. The language was modified to add HEPA-filtered. Additionally, "should" was changed to "shall" to ensure proper venting.
1735.1(g)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding unidirectional HEPA-filtered airflow between "unidirectional" and "air"	The Board agreed with this comment. The language was modified to add HEPA-filtered.
1735.1(i)	Jeffrey Nehira Dignity Health	Mr. Grasela indicated that the calculation of C to F does not take into account significant figures.	The Board agreed with this comment and corrected the temperature conversions.
1735.1(l)	University Compounding Pharmacy Joe Grasela	Mr. Grasela expressed concern that the definition is not consistent with 503a of Federal law. He indicates the "significantly different" and "clinically different" are two different things and the pharmacist will not know if something is clinically different.	The Board rejected this comment. The Board determined that "significantly" different was vague and needed further clarification. The intent of the language is to prevent pharmacies from manufacturing compounds for non-patient specific populations. The Board intends the purpose for compounding of a specific compound for a specific patient for a specific need.
1735.1(m)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that the definition of daily was unclear. He indicated that defining it as every 24 hours is not correct and will provide future problems with definitions which conflict with national standards.	The Board rejected this comment. Daily is clearly defined as "every day that a pharmacy is operating" and "24 hours" is limited to the monitoring of Fridge and Freezer temps (which can be accomplished with standard automated recorders).

Code Section	Commenter	Comment	Board Response
1735.1(m)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson expressed concern that the 24 hours requirement implies that measurements must be taken within the hour of the exact same time each day.	The Board rejected this comment. Daily is clearly defined as "every day that a pharmacy is operating" and "24 hours" is limited to the monitoring of Fridge and Freezer temps (which can be accomplished with standard automated recorders). Additionally, the regulation does not state that the temperatures must be recorded at the same time every day, only that they be recorded once every 24 hours. To ensure patient safety, daily monitoring of these systems, either by electronic monitoring or a manual temperature log is necessary.
1735.1(n)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval recommended that hazardous compounding requirements be removed from this section as it will take time to modify systems to comply. If the language cannot be removed, she requested that the Board allow timelines for compliance. She further recommended that the definition be removed completely as it is not used anywhere in the regulation.	The Board rejected this comment. Displacement airflow method is used in the compounding of hazardous compounds would potentially present an occupational hazard and contradict requirements in 1735.1(e)(2) for hazardous compounding. The Board will allow licensees to submit notice of intent to comply with regulations and approval will be granted on a case-by-case basis. The Board will allow facilities time to make the necessary improvements in order to comply. The waiver request requirements was added to the regulation at section 1735.6(f).
1735.1(n)	Doug O'Brien Kaiser Permanente	Dr. O'Brien expressed concern that USP 797 allows for the compounding of low volumes of hazardous drugs within a positive pressure buffer area with the displacement airflow method of design, with appropriate primary engineering controls.	The Board rejected this comment. While the low volume exception is in USP 797, it has been excluded from USP 800. The Board determined that the exception should not be allowed.
1735.1(s)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding "or NIOSH" at end after "pharmacist-in-charge."	This comment was also submitted during the 45-day comment period. It was rejected at that time and is rejected again as repetitious. The Board determined that if the drug meets the NIOSH criteria for a hazardous drug, the definition applies without the addition suggested.
1735.1(u)	Doug O'Brien Kaiser Permanente	Dr. O'Brien expressed concern that the definition is confusing and requires clarification. 1. It could be interpreted to include different types of preparations that are prepared during one uninterrupted continuous cycle of compounding. 2. It could be interpreted to mean a single type of drug preparation compounded during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).	This comment was also submitted during the 45-day comment period. It was rejected at that time and is rejected again. The Board determined that the definition did not need to be clarified. It is one or more preparations compounded from one or more active ingredients during one uninterrupted cycle.

Code Section	Commenter	Comment	Board Response
1735.1(u)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane recommended the "Lot" definition be change to include only "non-sterile to sterile batch"compounding. OR They recommended changing definition of "lot" to "greater than one dose" in order to ensure timely preparation of compounded drugs to treat emergency patients' conditions where immediate administration of medications is essential.	This comment was also submitted during the 45-day comment period. It was rejected at that time and is rejected again. Lot and Non-Sterile to Sterile are two separate items and are defined differently. The term "lot" is used in the cleaning requirements and it is necessary to disinfect after each compound to prevent cross-contamination. The second recommendation is also rejected. The definition of "lot" does not prevent preparing more than one dose, provided that it is done during one uninterrupted cycle and is tested appropriately.
1735.1(v)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson inquired about updated their processed on an annual basis based on what they determine to be complex and error prone.	The Board rejected this comment. There was no recommendation made, so the Board was unclear on what they were stating. The Media-fill testing can be defined in the Polices and Procedures.
1735.1(x)	Jeffrey Nehira Dignity Health	Dr. Nehira suggested redefining the term "parenteral" and removing the specific list.	The Board agreed with this comment. The definition has been updated to remove incomplete list.
1735.1(x)	Rachel Taggs Shauna Doherty Precision Pharmacies	Dr. Taggs and Dr. Doherty expressed concern about the phrase "administration into the eye" as it can include ophthalmic drops. They recommended the phrase be changed.	The Board agreed with this comment. The definition has been updated to remove incomplete list.
1735.1(z)	Jeffrey Nehira Dignity Health	Dr. Nehira suggested adding an appendix of USP34-NG32, 37th Revision for easier referencing of the USP version required in CA Pharmacy Law.	The Board rejected this comment. The Board determined that an appendix was not necessary as the terms are defined in the regulation text.
1735.1(z)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that all pharmacies with sterile compounding permits benefit from the dilution exemption.	The Board rejected this comment. The Board does not agree that "all" pharmacies need the exemption as not "all" pharmacies will be compounding soley from commerical products.
1735.1(z)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern over the definition of "potency" as it is used differently in USP 797. He requested that the definition be removed.	The Board rejected this comment. The term "Potency" is used within regulation and needs to be defined for clarity.
1735.1(ab)	Doug O'Brien Kaiser Permanente	Dr. O'Brien expressed concern about the definition of "Prescriber's Office". He indicated that the definition allows Licensed Clinics and small hospitals (99 beds or less) o compound without a pharmacy or pharmacist which would result in compounding by less qualified personnel or deferral of the care provided by pharmacist-compounded products.	The Board rejected this comment. Clinics and Small Hospitals are still licensed by the Board and would still be bound by the same regulations as large hospitals. Additionally, this comment is outside the scope of the 15-Day Comment Period.
1735.1(ac)	Jeffrey Nehira Dignity Health	Dr. Nehira recommend removing "through the use of unidirectional HEPA filtered first air" as he indicates that while it is implied, it is not a requirement of USP 797.	The Board rejected this comment. The Board agrees that it is implied in the USP 797; however, the language in included for clarity in the regulation.

Code Section	Commenter	Comment	Board Response
1735.1(ac)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that automated robots needed to be placed in an ISO Class 5 or better air environment. He indicated that these robots are made to be simply put or placed in the appropriate air environment (ISO Class air).	The Board rejected this comment. The Board determined that the language was appropriate as automated robots require a class 5 or better environment in USP 797. The Board disagrees that the robots can be placed in any environment.
1735.1(ag)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that the definition within USP 797 is different than the Board's definition. He indicates the proposed language does not match the standard of practice.	The Board rejected this comment. The definition is descriptive for improved clarity. The Board disagrees that the BUD is limited to 12 hours or less. When a CAI or CACI is utilized with the segregated compounding area, the BUD can be longer.
1735.1(ag)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that hazardous drug compounding be allowed in a segregated compounding area within a CACI. Additionally, he indicated that 1735.6(e) allows hazardous drug compounding within a segregated compounding area with the appropriate engineering controls.	The Board agreed with this comment and the language was modified to remove "Non-hazardous" as a CACI can be utilized with a segregated compounding area
1735.1(ag)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended that hazardous sterile preparations in a segregated compounding area and this is also permitted in the current draft of USP 800. Additionally, he indicated that the BUD should not be restrictive to 12 hours and recommended that hazardous drug preparation compounding be permitted in a CACI with manufacturer compliance with USP 797 when located in a segregated sterile compounding area provided the area is negative pressure, externally vented, and has at least 12 ACPH.	The Board agreed with this comment. The regulation text was modified to allow for hazardous compounding in the segregated compounding area. Additionally, the BUD can be assigned for greater than 12 hours if the PEC meets specific criteria.
1735.1(ag)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley requested an exemption to allow for a sink within 3 feet of a ISO Class 5 PEC if its a CACI.	The Board rejected this comment. The Commenter provided the same comment previously and it was rejected at that time as well. The Board has found no reliable data to support their belief that it is safe for a sink to be placed near a CACI and no reliable data was provided. The Board maintained it's position that there is a risk of contamination if there is a sink/drain within 3 feet of the compounding area.
1735.1(ah)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended that the paragraph be relabeled as (ah) because the previous paragraph is labeled (ag).	The Board agreed with this comment. The sections have been renumbered accordingly to address additions and deletions within the language.
1735.2(c)(1)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson expressed concern about the word Paid For as physicians do not pay for medication directly in health systems. They are paid for by University accounts or other systems.	The Board agreed with this comment. The language was updated to remove "Paid for" from regulation text.
1735.2(c)(1)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty also expressed concern about the phrase "and paid for by the prescriber" as many prescribers belong to a practice and the business entity pays for the purchases.	The Board agreed with this comment. The language was updated to remove "Paid for" from regulation text.

Code Section	Commenter	Comment	Board Response
1735.2(c)(1) & 1735.2(c)(3)	Doug O'Brien Kaiser Permanente	Dr. O'Brien requested clarification that the prescriber does not have to personally pay for the medication. Additionally, he recommended that the Board not eliminate the ability of pharmacies to compound for prescriber's office use. He indicated that not allowing compounding for office use will hinder safe therapy and result in a waste of medication as prescribers would need to dispose of unused medication instead of dispensing it to the patient.	<p>The Board agreed with the first comment regarding "paid for" and the regulation text was modified to allow for someone other than the prescriber to pay for medication.</p> <p>The Board rejected this second comment. The type of dispensing the commenter referenced needs to be covered by a prescription or purchasing from a 503B facility. The regulation is permitting "office use" compounding; however, "office dispensing" is not permitted.</p> <p>Kaiser asked for specific examples at the Board meeting. No specific examples were provided with their comments. In the example cited at the Board meeting (autologous ophthalmic drops), the prescriber should request a patient-specific prescription from the pharmacy at the initial ordering. This is particularly important given that the patient's own blood is used for admixture. Kaiser could provide no additional examples as to when this may be an issue for the Board to consider.</p>
1735.2(d)(2)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty expressed concern that this subdivision would not allow veterinary preparations to be compounded when the drugs have been removed from human use, but are not necessarily unsafe or not effective for veterinary use.	The Board rejected this comment. The Board determined that comment was outside the scope of 15-Day Comment Period. The Board determined that pharmacies should not be compounding with drugs removed from the Market.
1735.2(d)(3)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms Taggs and Ms. Doherty expressed concern that the ASHP and FDA lists are not updated on a regular bases. There is no other formal list of short supply or backordered veterinary drugs.	The Board rejected this comment. The Board determined that comment was outside the scope of 15-Day Comment Period. Additionally, the Board determined that while one manufacturer or wholesaler may not have the drug, others may have it. The lack of availability to one wholesaler does not make it a drug shortage.
1735.2(i)	University Compounding Pharmacy Joe Grasela	Mr. Grasela recommended that the BUD definition should be changed to include the ability to use stability studies to support a later date. He expressed concern that the wording removes pharmacist judgment and is unnecessarily restrictive to the patient, affecting continuity of therapy.	The Board agreed with this comment and added extended the using specific test. Additionally, the BUD requirements in regulations are what is recommended by USP <795>.
1735.2(i)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty expressed concern about the use of the word "identical" to support a later BUD as it is extremely limiting.	The Board rejected this comment. Specifying "Identical" is necessary if BUD is to be extended beyond USP 795 recommendations. If the ingredients are not identical, testing would be needed, as the result could be altered by using different ingredients.
1735.2(i)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that CSP's (e.g. reconstituted vials) will have BUDs that exceed the limitations in this section when made following a manufacturer's directions Additionally, he indicated that stability studies will not be provided by the manufacturer.	The Board rejected this comment. The Board determined that the commenter is referring to "sterile" preparations. This section specifically addresses "nonsterile" preparations and the commenters comment would not apply. The specific BUD for sterile preparations is found in 1751.8.

Code Section	Commenter	Comment	Board Response
1735.3(a)(2)(E)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty expressed concern that requiring documentation of receive date if an expiration date is not provided by the manufacturer and limiting when items can be used in (k) will create confusion and inconsistent record keeping.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. Additionally, the Board does not agree (k) specifically states "after date of receipt in pharmacy." If the pharmacy does not record the date of receipt, the Pharmacy will not know the expiration date and Board inspectors will not be able to determine how old the ingredients are during inspections.
1735.3(a)(2)(E)(i)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that ambulatory oncology clinic pharmacies be included in the seventy-two (72) hour exception language.	The Board rejected this comment. The Board determined that ambulatory oncology clinics are licensed under HS section 1250, so the exemption would already apply to them.
1735.3(a)(2)(H)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson expressed concern that drugs are stored according to USP or manufacturer recommendations and that they do not record the storage of each drug and it would be labor intensive.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the recording of the quantity/amount compounded is not a new requirement.
1735.3(c)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty expressed concern that the term "supplier" implies "wholesaler" and excludes manufacturers.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees. Supplier would include "manufacturer" if they are registered with the FDA.
1735.4(b)	Douglas Barcon Barcon & Associates	Dr. Barcon expressed concern that the regulations exclude a centralized hospital packaging pharmacy (CHP).	The Board rejected this comment. CHPs are already included in regulation as they are licensed by the Board.
1735.4(c)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that it is impracticable to include the the names of the compounding pharmacy and the dispensing pharmacy, if different, on the label.	The Board rejected this comment. The Board determined that labeling of preparations with both pharmacies is important for traceability and accountability of medication, especially, should a recall be necessary.
1735.4(e)	Candace Fong Clara Evans Dignity Health	Dr. Fong and Ms. Evans requested that a new section be added to address the alternate cleaning schedules that may be submitted to the Board for fully automated robots	The Board rejected this comment. Once the Board has additional information about the different cleaning methods/ requirements for robots, the Board can approve exemptions and seek a regulation change at that time to address the robots. Currently robots are not routinely used and the Board cannot provide clear cleaning schedules necessary for regulation language.

Code Section	Commenter	Comment	Board Response
1735.4(e)	BJ Bartleson California Hospital Association	Ms. Bartleson echoed the comments provided by Dr. Fong and Ms. Evans.	The Board rejected this comment. Once the Board has additional information about the different cleaning methods/ requirements for robots, the Board can approve exemptions and seek a regulation change at that time to address the robots. Currently robots are not routinely used and the Board cannot provide clear cleaning schedules necessary for regulation language.
1735.5(a)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson recommended that "shall" be changed to "may" or eliminate the statement altogether as unnecessary. The regulations give the Board authority to take disciplinary actions.	The Board rejected this comment. The failure to follow the Policies and Procedures is a violation and constitutes a basis for discipline. The Board still has the authority to apply discretion.
1735.5(a)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested defining "material" and "material failure."	The Board rejected this comment as it determined that the definitions are not necessary. The Board determined that these are commonly understood terms to a pharmacist in context. The pharmacist would exercise his or her professional judgment in making such determinations.
1735.5(c)(4)	Jeffrey Nehira Dignity Health	Dr. Nehira requested that "facility (physical plant) used for compounding" be defined in the definition section of the regulation.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that a definition is necessary. While the specific cleaning is defined in the regulation, this section calls for the procedures of "how" the cleaning is to be completed.
1735.5(c)(7-8)	Jeffrey Nehira Dignity Health	Dr. Nehira requested removal of the requirement for an annual review of the policies and procedures. He indicates that although it is current policy, it differs from other regulatory body requirements for hospitals. Additionally, he requested that electronic signatures be included.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that annual review is not necessary. It is crucial to be sure that policies and procedures are current and being followed. The regulation does not state that electronic signatures are not allowed.
1735.5(c)(9)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding: "and as specified in 1735.8 (e) for health care facilities" for continuity	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that the additional language is necessary as it does not improve the clarity of the regulation.
1735.5(c)(9)	Jeffrey Nehira Dignity Health	Dr. Nehira requested clarification regarding room temperature storage as there is currently no requirement for daily monitoring of room temperature. Dr. Nehira requested an extended implementation date to implement this in hospital settings.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. The Board will allow facilities time to make the necessary improvements in order to comply.

Code Section	Commenter	Comment	Board Response
1735.5(c)(10)	Jeffrey Nehira Dignity Health	Dr. Nehira suggest an exemption for health care settings with a facility services policy regarding appropriate function of refrigeration devices.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees with the exemption. The temperatures need to be monitored for patient safety.
1735.5(c)(10)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding: "and as specified in 1735.8 (e) for health care facilities" for continuity	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that the additional language is necessary as it does not improve the clarity of the regulation.
1735.6(e)	Rachel Taggs Shauna Doherty Precision Pharmacies	Ms. Taggs and Ms. Doherty requested that Subdivision (e), sections (1), (2) and (3), be removed until USP 800 is in place.	The Board rejected this comment. USP 800 is not anticipated to be finalized until 2017/2018 and the Board determined that continuing to wait for these regulations would not be in the best interest to public safety. Modifications to the text were made to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
1735.6(e)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that a physically separate room for low risk, low volume hazardous compounding is not required in USP 797 and does not agree with CETA engineering requirements.	The Board rejected this comment. Low volume hazardous compounding in positive pressure with displacement airflow is no longer allowed with the implementation of USP 800.
1735.6(e)	Brian Warren California Pharmacist Association	Mr. Warren requested an implementation date of January 1, 2020 . He indicated that given the extensive changes necessary, time will be needed for compliance.	The Board initially rejected this comment; however, the Board later amended the regulation to allow facilities a process to seek an extension to make the necessary improvements in order to comply.
1735.6(e)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson recommended a lead time of a minimum of 3-5 years to implementation given space and cost considerations and extent of mechanical systems to handle the venting and negative pressure requirements.	The Board rejected this comment; however, modifications to the text were made to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.

Code Section	Commenter	Comment	Board Response
1735.6(e)	Doug O'Brien Kaiser Permanente	Dr. O'Brien requested that implementation be delayed until USP 800 is finalized or the Board allow an adequate period for the phase-in of this design. Additionally, he indicated that the wording of 1735.6(e)(3) is confusing.	The Board rejected the delay for USP 800. USP 800 is not anticipated to be finalized until 2017/2018 and the Board determined that continuing to wait for these regulations would not be in the best interest to public safety. The Board did, however, modify the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply. The Board agreed with the wording issue of (e)(3) and modifications were made to the regulation text for clarity.
1735.6(e)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested that a new section be added to include the proposed requirement in USP 800 for the room to be externally vented and the PEC to be externally vented.	The Board agreed with this comment. Modifications were made to the regulation text to include PEC venting.
1735.6(e)(1)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval suggested that this section appears to conflict with 1735.1(e)(2).	The Board agreed with this comment. Modifications were made to the regulation text to correct the "12" and "30" air change conflict.
1735.6(e)(2)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval requested that the Board strike the words within the parenthesis or provide guidance on how the pressure differential is to be monitored between the negative pressure room and the ceiling above it.	The Board rejected this comment. The Board determined that it is up to the licensee to determine how to monitor the space (i.e. Pressure cages: Magnehelic, Pressura, etc.).
1735.6(e)(3)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval pointed out a typographical error to change the word "with" to "within"	The Board agreed with this comment and modifications were made to the regulation text to address it.
1735.6(e)(1-3)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval requested that that Board consider establishing reasonable timelines and expectations for compliance so as not to severely limit patient access to compounded medications.	The Board agreed with this comment. The Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
1735.6(e)(1)	Michael Tou Providence Health	Mr. Tou requested that the Board issue exemptions to hospital pharmacies which are unable to immediately comply with the requirements of section 1735.6(e)(1)(2)(3).	The Board agreed with this comment in part. The Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply. It is not, however, specific to hospital pharmacies.
1735.6(e)(1-3)	Lauren Berton CVS Health	Dr. Berton requested that this section be removed until USP 800 is finalized as USP 800 could still be modified and then the Board regs will not align with USP 800.	The Board rejected this comment. USP 800 is not anticipated to be finalized until 2017/2018 and the Board determined that continuing to wait for these regulations would not be in the best interest to public safety. Additionally, the Board does not anticipate conflicting changes occurring to USP 800. Should a conflict arise, the Board will take immediate steps to address it.

Code Section	Commenter	Comment	Board Response
1735.7	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that a time frame for the record keeping is not specified. Additionally, he requested an exemption from training requirements for institutions with contracts for environmental cleaning services.	The Board rejected this comment. The Board determined that the pharmacy needs to take responsibility for any and all personnel who enter and clean any environment and/or room encompassed by the HSP, LSC, and/or PHY licensures. The Board determined that the documentation always needs to be retained, as such, a time frame is not provided.
1735.8(c)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the language in this section is not specific enough and appears to imply that all products compounded by a pharmacy must be tested for integrity, potency, quality and labeled strength at least annually.	The Board agreed with this comment. The language was modified to add "specified" for clarity. The Pharmacy will determine the "specific" preparation and include that in the quality assurance plan.
1735.8(c)	Doug O'Brien Kaiser Permanente	Dr. O'Brien indicated that the language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. As proposed the regulation would add major costs to hospital and other pharmacy-compounding.	The Board rejected this comment. The same comment was submitted during the 45-day comment period and rejected. This section specifies the requirements of a quality assurance plan. It does not state that "any and all" products be tested. The language in this section includes the frequency of testing and the testing schedule in the plan.
1735.8(e)	Jeffrey Nehira Dignity Health	Dr. Nehira suggest an exemption for health care settings with a facility services policy regarding appropriate function of refrigeration devices.	The Board rejected this comment. Refrigeration is important and a plan to correct for out-of-range variations is necessary for patient safety.
1735.8(e)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson states that agree with the comment provided by Doug O'Brien of Kaiser during the 45 Comment document. Additionally could create a push for increased use of 503B facility produced products due to the substantial increase in cost for implementing this onerous of a program as defined and left to interpretation by inspectors.	The Board rejected this comment. This section specifies the requirements of a quality assurance plan. It does not state that "any and all" products be tested. The language in this section includes the frequency of testing and the testing schedule in the plan.
1751(b)	Jeffrey Nehira Dignity Health	Dr. Nehira request exemption for the venting requirements for Dignity Health and rural hospitals. Additionally, he requested referencing this code of regulations as an appendix in the CA law book.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that an exemption to venting should be allowed. The Board agrees that Title 24 chapter could change; however, if it changes, the Board would need to update the regulation with the revised chapter.

Code Section	Commenter	Comment	Board Response
1751(b)(3)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley requested an exemption to allow for a sink within 3 feet of a ISO Class 5 PEC if its a CACI.	The Board rejected this comment. The Commenter provided the same comment previously and it was rejected at that time as well. The Board has found no reliable data to support their belief that it is safe for a sink to be placed near a CACI and no reliable data was provided. The Board maintained it's position that there is a risk of contamination if there is a sink/drain within 3 feet of the compounding area.
1751(b)(3)(A)	Douglas Barcon Barcon & Associates	Dr. Barcon expressed concern that the proposed text does not include manufacturer documentation of Chapter 797, USP-38 NF-33, 38th Revision, Effective May 1, 2015 compliance in air quality worse than ISO Class 7.	The Board rejected this comment. The Board determined that that addition is not necessary as it would be duplicative. The information requested is already specified in 1751.4(f).
1751(b)(4)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding: "products or" before "compounded drug preparations"	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagrees that the additional language is necessary as it does not improve the clarity of the regulation.
1751.1(a)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson requested that the Board amend length of time within the pharmacy versus outside of the department or at an offsite storage location.	The Board rejected this comment. As the entire facility is licensed by Board, the records can be stored anywhere within the facility. Additionally, facilities can submit an offsite storage request for approval if space is an issue.
1751.1(a)(5)	Jeffrey Nehira Dignity Health	Dr. Nehira requested clarification regarding room temperature storage as there is currently no requirement for daily monitoring of room temperature. Dr. Nehira requested an extended implementation date to implement this in hospital settings.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. The Board did, however, modify the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
1751.1(a)(7)	Jeffrey Nehira Dignity Health	Dr. Nehira states that current technology does not exist for mobile isolation chambers and barrier isolators to measure the pressure differential of the ISO class 7 area. Only the pressure associated with the ISO class 5 compounding area can be measured. He recommended removing the requirement for MICs/Barrier Isolators and changing the requirement for testing to every 6 months for room compliance.	<p>The Board rejected this comment. The disagrees with the commenter statement that current technology doesn't permit the required measuring. Current CACIs allow for the required measurement to be taken and it needs to be done for safety. MIC units are not allowed under proposed regulations/= as CACI's can be used.</p> <p>It is required to measure pressure differentials to ensure they are positive or negative were required. It is a standard of practice to ensure pressure is appropriate for the compounded product and the safety of the compounding staff.</p>

Code Section	Commenter	Comment	Board Response
1751.1(a)(7)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that the regulation doesn't allow use of a continuous recording device.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the regulation language is not disallowing electronic monitoring as long as it is documented daily. It is up to the PIC to determine "how" the documentation is done.
1751.1(b)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding: "license type" before or after "license number" and shifting placement of "and."	The Board agreed with this comment. Modifications were made to regulation text and "license type" was added.
1751.2(c)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding protection from light at end to read of this section.	The Board rejected this comment. The Board determined that the comment was outside the scope of 15-Day Comment Period. However, the Board determined that the additional language was not necessary and did not improve clarity.
1751.2(d)	Douglas Barcon Barcon & Associates	Dr. Barcone suggested adding "and non-hazardous preparations compounded in a PEC that is also used for compounding hazardous preparations" to bring into harmony with 1751.4(g).	The Board rejected this comment. The Board determined that the comment was outside the scope of 15-Day Comment Period. However, the Board determined that the additional language was not necessary and did not improve clarity.
1751.2(a)(2) Incorrect Section listed. Should be 1751.2(d)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern that cytotoxic and caazardous drugs have very specific definitions not interchangeable. He recommended that "if applicable" be left in the language.	The Board rejected this comment. The Board determined that the comment was outside the scope of 15-Day Comment Period. However, the Board determined that the additional language was not necessary and did not improve clarity.
1751.3	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson recommended that "shall" be changed to "may" or eliminate the statement altogether as unnecessary. The regulations give the Board authority to take disciplinary actions.	The Board rejected this comment. The failure to follow the Policies and Procedures is a violation and constitutes a basis for discipline. The Board still has the authority to apply discretion.
1751.3(a)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested defining "material" and "material failure."	The Board rejected this comment as it determined that the definitions are not necessary. These terms are commonly understood in context by pharmacists exercising their professional judgement.

Code Section	Commenter	Comment	Board Response
1751.3(a)(2)	Jeffrey Nehira Dignity Health	Dr. Nehira states that current technology does not exist for mobile isolation chambers and barrier isolators to measure the pressure differential of the ISO class 7 area. Only the pressure associated with the ISO class 5 compounding area can be measured. He recommended removing the requirement for MICs/Barrier Isolators and changing the requirement for testing to every 6 months for room compliance.	<p>The Board rejected this comment. The disagrees with the commenter statement that current technology doesn't permit the required measuring. Current CACIs allow for the required measurement to be taken and it needs to be done for safety. MIC units are not allowed under proposed regulations/= as CACI's can be used.</p> <p>It is required to measure pressure differentials to ensure they are positive or negative were required. It is a standard of practice to ensure pressure is appropriate for the compounded product and the safety of the compounding staff.</p>
1751.3(a)(7)	Jeffrey Nehira Dignity Health	Dr. Nehira suggested that the language should state, "Cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4." as the frequency is specified elsewhere regulations.	The Board rejected this comment. The Board determined that the comment was outside the scope of 15-Day Comment Period. However, the Board determined that the additional language was not necessary and did not improve clarity.
1751.3(a)(9)	Jeffrey Nehira Dignity Health	Dr. Nehira indicated the language should be changed to ass "if applicable" because the purge time for some CACI's is indicated by an LED light or lockout mechanism.	The Board rejected this comment. The Board determined that the manufacturer still indicates a purge time regardless if an LED light or lockout mechanism is utilized in case those mechanisms fail.
1751.3(a)(16)	Jeffrey Nehira Dignity Health	Dr. Nehira requested an exemption for institutions with infection control policies. Additionally, he suggested that most pharmacies do not handle infectious materials; so "if applicable" should be added.	The Board rejected this comment. Pharmacies must have policies and procedures for handling and disposing of infectious materials, even if they rarely handle them. If an institution has a infection control policies, it can be printed and placed into a BOP binder for inspector review to satisfy regulation.
1751.3(a)(20)	Jeffrey Nehira Dignity Health	Dr. Nehira requested clarification regarding room temperature storage as there is currently no requirement for daily monitoring of room temperature. Dr. Nehira requested an extended implementation date to implement this in hospital settings. He further states daily monitoring is impractical and does not correspond to current industry practice.	The Board rejected this comment. The Board disagrees the daily monitoring of temperatures is impractical. There are numerous devices made that electronically record it if the pharmacy cannot manually record it. The Board did however, modify the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
1751.3(c)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested that the text be changed to "section 1735.5 and 1751.3(a)" to "section 1735.5, 1751.3(a), and 1751.7(e) for accuracy.	The Board agreed with this comment. The reference sections were modified for accuracy within the regulation.

Code Section	Commenter	Comment	Board Response
1751.3(e)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson requested that the regulation be amend to allow for electronic capture.	The Board rejected this comment. The Board determined that the comment was outside scope of 15-Day comment period; however, the regulation does not restrict the ability to use electronic tracking.
1751.3(e)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that all personnel must review all changes to all compounding policies and procedures, even if they do not directly impact their job duties in a material fashion. Additionally, he states a signature and date should only be required if there is a significant practice change being implemented as a result of any changes in policies and procedures.	The Board rejected this comment. The Board determined that all staff need to have an understanding of the policies and procedures for safety of all employees and the public. Additionally, the signature and date requirement is to ensure that all staff read and understand the policies and procedures.
1751.4(d)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley states that USP 797 does not make any stipulation or requirement of mandatory use of a sterilizing agentand only makes the stipulation of sanitizing and disinfecting. He recommends the removal of the requirement to use a sporicidal agent monthly. If the requirement is not removed, specifies that it is for the cleaning of floors.	The Board rejected this comment. The oversight of this issue is in USP 797. Additionally, refer to USP 1072 (Disinfectant and Antiseptics).
1751.4(d)(1-2)	Jeffrey Nehira Dignity Health	Use of a sporicidal agent is not required or standard of practice for surfaces other than ISO-5 environments in institutional settings, and is not mentioned in USP<797>. This regulation implies that a sporicidal agent is used on all surfaces and floors daily, which is not based on practice or evidenced based infection control practices. Frequency of cleaning also goes beyond/contradicts the requirements of weekly cleaning as specified in earlier regulation. Recommend removing this requirement of, "work table surfaces, carts, counters, and the clean room floor" as well as "walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment." Fungal contamination takes weeks of incubation, and through monitoring of surface sampling and standard infection control practices risk is minimal.	Reject: Cleaning is necessary for patient safety. Refer to USP 1072. Guidance can be provided if necessary.
1751.4(d)(4)	Jeffrey Nehira Dignity Health	Dr. Nehira requested an exemption for institutions regarding the storage of cleaning supplies in a clean room or ante-area. He indicates there are conflicting regulatory requirements for the storage of cleaning products under safety and environment of care.	The Board rejected this comment. The Board determined that this language is a direct reference from USP 797, page 16.
1751.4(e)	Jeffrey Nehira Dignity Health	Dr. Nehira states that the requirement in this section is not listed in USP<797> and not based in evidence practice. He states it would severely compromise the integrity of the pharmacy profession.	The Board rejected this comment. The Board determined that this is a direct reference from USP 797, page 15.
1751.4(e)	William Stuart Hartley Medical	Mr. Stuart expressed concern that as written, the language would require cleaning in the middle of compounding if the lot required more than 30 minutes to complete. Additionally, he recommend introducing the definition of a "batch" to differentiate between patient specific prescriptions and larger quantity compounded preparations.	The Board rejected this comment. The Board does not believe the language requires, nor would it expect, a person to stop compounding in the middle of a lot to disinfect. They would need to disinfect following completion of that lot. However, modifications were made to the regulation text to address the use of robots during compounding.

Code Section	Commenter	Comment	Board Response
1751.4(e)	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended that section 1751.4(e)(2) be deleted as it could result in unnecessary cleaning and/or disinfection.	The Board rejected this comment. The Board determined that the language is the recommended disinfection requirements of USP 797.
1751.4(e)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval requested that the Board insert the verbiage "when ongoing compounding activities are occurring" after the word "minutes" to be more consistent with USP Chapter <797>.	The Board agreed with this comment. The language was modified to include "when compounding with human staff" to address this concern and the use of robots for compounding.
1751.4(e)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern over the use of the words "using a suitable sterile agent" to "using a suitable disinfecting agent" to mitigate the risk of confusion that the use of a sterilizing agent is required to disinfect the PEC. There could be confusion if these two words are used in the same sentence. Mr. Lepley also requested that the 30 minute and before/after each lot disinfection requirements be removed as it would impair the ability to effectively use the PEC.	The Board rejected this comment. The verbiage within the regulation is clear and from USP 797/USP 1072. Disinfection is necessary for patient safety to prevent accidental contamination.
1751.4(f)	Jeffrey Nehira Dignity Health	Dr. Nehira indicated the barrier isolators are self-contained by definition and manufacturer specification and should not require recertification if moved.	The Board rejected this comment. The Board determined that all PECs must be recertified if moved as the unit could be damaged when moved.
1751.4(f)(1)	Jeffrey Nehira Dignity Health	Dr. Nehira requested an exemption should be made for Barrier Isolators from the requirement as airflow displacement is different than laminar flow hoods.	The Board rejected this comment. The Board determined that this comment was outside scope of 15-Day comment period.
1751.4(f)(2)	Jeffrey Nehira Dignity Health	Dr. Nehira requested clarification if Barrier Isolators require testing during material transfer as, he states it is impractical and not part of testing for recertification of the hoods.	The Board rejected this comment. The Board determined that this comment was outside scope of 15-Day comment period.
1751.4(f)(3)	Jeffrey Nehira Dignity Health	Dr. Nehira requested clarification of this requirement. He recommended that the regulation should defer to manufacturer specifications.	The Board rejected this comment. The Board determined that not all PECs are the same. The Board would need to review the manufacturer specifications for each PEC prior to granting an exemption from the requirement.
1751.4(g)	Jeffrey Nehira Dignity Health	Dr. Nehira requested an exemption of the labeling requirement for DSH hospitals and rural hospitals as this places a tremendous cost on the organization/facility. Also he states that two layers of gloves contradicts some manufacturer's recommendations.	The Board rejected this comment. The Board determined that the labeling of preparations with both pharmacies is important for traceability and accountability of medication. Additionally, personal Protective Equipment must be worn when operating CACI and hazardous compounds. The double glove requirement is included in USP 800.

Code Section	Commenter	Comment	Board Response
1751.4(g)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern about the definition of hazardous. He recommended that the definition be modified to "hazardous" to mean "all anti-neoplastic agents used to treat neoplasms identified by the National Institute for Occupational Safety (NIOSH)....."	The Board rejected this comment. The Board does not agree that hazardous only applies to those used to treat neoplasms. The intent of regulation is for any compounded preparation prepared in PEC used to compound "hazardous" compounds will be labeled as "hazardous" regardless if the medication is not defined as "hazardous." This is because cross-contamination can occur.
1751.4(g)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. SHane requested tha the external venting requirement be removed or include a timeframe (ex.5 years) to allow facility changes to be made for external venting of PEC before enforcing.	The Board rejected this comment; however, the Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
1751.4(g)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern that USP 797 does not required that CACI's used to compound hazardous drugs to be externally vented. He recommends that a stipulation ne added that a PEC does not have to be externally vented unless environmental sampling cannot be provided.	The Board rejected this comment. CACIs need to be externally vented because of hazardous compounding. It is necessary for patient and employee safety. Re-circulating the air is not safe as it does not remove the contaminates from the air.
1751.4(g-l)	University Compounding Pharmacy Joe Grasela	Mr. Grasela expressed that it is unnecessary to have a gown that closes in the back so long as the employee is fully covered, front closure with zippers or snaps should be allowed. Additionally, he states double gloving should not be required unless working with hazardous compounds.	The Board rejected this comment. The gown closure in the back is required for occupational hazard control and is a requirement of USP 800. Additionally, double gloving reduces occupational hazard to employees.
1751.4(h)	Jeffrey Nehira Dignity Health	Dr. Nehira expressed concern about the double glove requirement. He indicated that two layers of gloves is not consistent with most PEC operational guidelines and deviates from manufacturer recommendations.	The Board rejected this comment. The Board determined that this comment was outside scope of 15-Day comment period. Additionally, the Board determined that the double grove requirement was appropriate for employee safety and is required for hazardous compounding in UPS 800.
1751.4(h)	Ernest Pieper Glenn Medical Center	Mr. Pieper also expressed concern about the double glove requirement. He indicated that there is no need or evidence to support donning sterile gloves over intact, sanitized isolator gloves. Additionally, he states that the packaging for sterile gloves might introduce potentially harmful particulate matter into the compounding area.	The Board rejected this comment. The Board determined that this comment was outside scope of 15-Day comment period. Additionally, the Board determined that the double grove requirement was appropriate for employee safety and is required for hazardous compounding in UPS 800.
1751.4(h)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested that a CACI should be included in this section to allow its use.	The Board rejected this comment. The Board determined that this comment was outside the scope of the 15-Day comment period. Additionally, the Board did address the use of a CACI by adding setion (i) to the regulation language.
1751.4(k)	Brian Warren California Pharmacist Association	Mr. Warren recommended that the typo be corrected (is to of) and the Celsius to Fahrenheit conversion error be corrected.	The Board agreed with this comment. The language was modified and the temperature conversion corrected.

Code Section	Commenter	Comment	Board Response
1751.4(k)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested that the language be changed from "is" to "in"	The Board agreed with this comment. The language was modified to make this correction.
1751.4(k)	Jeffrey Nehira Dignity Health	Dr. Nehira requested that the temperature requirement puts undo burden on pharmacies with a narrow temperature range smaller than the definition of controlled room temperature defined above.	The Board rejected this comment. The controlled room temperature is for storage of the compounded drugs. The temperatures in this section are the room temperature where the sterile compounding is occurring. Additionally, reference of temperature to 68 - 75 is from Guideline for a safe environment of care, part 2. In: Guidelines for perioperative practice. Denver, CO: AORN, Inc.
1751.4(k)	BJ Bartleson California Hospital Association	Ms. Bartleson indicated that the temperature conversion between Celsius and Fahrenheit was incorrect. Additionally, she suggested that since the range mirrors the controlled room temperature, it would be appropriate to eliminate the specific temperature range.	The Board rejected this comment. The Board determined that the temperature range is necessary to ensure proper working temperatures for staff to prevent accidental contamination. The Board agreed with the temperature conversion comment and it was corrected in the regulation.
1751.4(k)	Candace Fong Clara Evans Dignity Health	Dr. Fong and Ms. Evans echoed the comments provided by Ms. Bartleson regarding the temperature issue.	The Board rejected this comment. The Board determined that the temperature range is necessary to ensure proper working temperatures for staff to prevent accidental contamination. The Board agreed with the temperature conversion comment and it was corrected in the regulation.
1751.4(k)	University Compounding Pharmacy Joe Grasela	Mr. Grasela requested that the Board correct the Celsius to Fahrenheit conversion error.	The Board agreed with this comment. The language was modified and the temperature conversion corrected.
1751.5(a)(1)	Jeffrey Nehira Dignity Health	Dr. Nehira recommend removal of the statement allowing a manufacturer to provide evidence that personal protective equipment is not necessary. He indicated that manufacturers would not take on the liability of the product since it is dependent on the environment they are used.	The Board agreed with this comment. The Board determined that personal protective equipment should be worn and a manufacturer should not have the ability to eliminate that need.
1751.5(a)(4)	Jeffrey Nehira Dignity Health	Dr. Nehira requested the addition of the statement, "If jewelry cannot be removed, then it must be thoroughly cleaned and covered."	The Board rejected this comment. The Board referenced USP 797: "shall remove all hand, wrist, and other visible jewelry that can interfere with the effectiveness of Personal Protective Equipment."
1751.5(a)(5)	Jeffrey Nehira Dignity Health	Dr. Nehira recommend removing the first word, "sterile". He states that sterile gloves will be immediately contaminated when products are picked up and would require disinfection regardless of the original sterility of the glove.	The Board rejected this comment. The Board determined that sterile gloves are a requirement of USP 797, page 15.

Code Section	Commenter	Comment	Board Response
1751.5(a)(6)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley expressed concern about prohibiting the use of nail polish in an ISO Class 5 or 7 area as USP 797 only restricts artificial nails or extenders.	The Board rejected this comment. The Board determined that nail polish can chip and contaminate a preparation. The Board found no reliable scientific studies to show otherwise and the commenter provided no studies.
1751.5(b)	Rheta Sandoval Kaweah Delta Health Care	Dr. Sandoval requested clarification as to the section being cited in this section.	The Board agreed with this comment. The exception was removed from the regulation text.
1751.6(e)	Douglas Barcon Barcon & Associates	Dr. Barcon indicated that was a space issue and a line feed was necessary to shift (e) to next line.	The Board agreed with the comment and made the correction.
1751.6(e)(1)(E)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley recommended that the statement "which contain the same amount or greater of volume transferred during the selected manipulations" be removed because it implies that the media-fill test performed by personnel must involve a volume transfer.	The Board rejected this comment. The Board determined that in order to adequately assess compounding steps and aseptic manipulations the same volume as that being compounded is necessary. Simulation of media fill is not a true simulation if the same volumes are not used. The volume is very important to guard against worker fatigue.
1751.6(e)(1)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding "Hazardous and non-hazardous spills and knowledge of MSDS information" to this section.	The Board rejected this comment. The Board determined that this comment was outside the scope of the 15-Day comment period. Additionally, the Board determined that the suggested language was not necessary as it did not improve the clarity of the regulation.
1751.7(b)	P. Kim Peterson University of California, Davis Medical Center	Dr. Peterson expressed concern that materials could imply the drugs and diluents and recommended the Board use language that would separate those preparing (technicians) from those checking (pharmacists) in completing this hands on testing.	The Board agreed that additional clarity was needed to address the competency and validation process of personnel, as such, this entire section was rewritten.
1751.7(e)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended the addition of "s" to "preparation." He also recommended that the (1) be deleted following the (e) for number purposes.	The Board agreed with the comment and the language was corrected accordingly.
1751.7(e)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane expressed concern about the need for immediate dispensing of compounded preparations without testing. They identified two examples that may be need immediate dispensing.	The Board rejected this comment. This same comment was submitted during the 45 day comment period and was rejected at that time as well. The regulation does not permit immediate dispensing of Non-Sterile Compounded Preparations except for ophthalmic and inhalation. The risk to the patient exceeds the possible benefit. Formalin is a hazardous compound and must be tested.

Code Section	Commenter	Comment	Board Response
1751.7(e)	Brian Warren California Pharmacist Association	Mr. Warren expressed concern the language proposed will impact patient safety. He recommended that language be modified to allow for the immediate dispensing of inhalation products for 14 days. Additionally, he requested that products compounded in a batch of 25 or fewer doses, those for emergency situations, and those with low chemical stability be exempted from testing.	The Board rejected this comment. This same comment was submitted during the 45 day comment period and was rejected at that time as well. 503B facilities produce the examples provided and the preparations can be obtained directly from a 503B. Patient safety is jeopardized without testing Non-Sterile preparations.
1751.7(e)(1)	Michael Tou Providence Health	Mr. Tou recommended that the paragraph be renumbered (1) and (2) for clarity.	The Board agreed with this comment and modifications to the regulation text were made to address comment.
1751.7(f)	Judith Brosz	Dr. Brosz recommended that a section be added to address the training requirement of staff may vary if not involved in the actual production of sterile compounding.	The Board rejected this specific addition, however, the Board agreed that additional clarity was needed to address the competency and validation process of personnel. As such, 1751.7(b) was rewritten.
1751.8	Doug O'Brien Kaiser Permanente	Dr. O'Brien recommended an BUD exemption for allergen extracts.	The Board agreed with this comment. The language was modified to address Allergen extracts in 1751.8(f).
1751.8	Jeffrey Nehira Dignity Health	Dr. Nehira recommended using verbiage straight from USP797 to eliminate confusion.	The Board rejected this comment. While similar, the Board is not duplicating verbiage from USP 797 for regulation. Additionally, Low, Medium, High risk terminology is being removed from USP 800.
1751.8(a)(1)	Douglas Barcon Barcon & Associates	Dr. Barcon suggested adding a reference to USP 797 to ensure compliance.	The Board rejected this comment. The Board determined that a direct reference to USP 797 would not be appropriate at this location. USP 797 is referenced in the initial paragraph.
1751.8(a)(3)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended allowing the use of spiked transfer devices.	The Board agreed with this comment. The language was modified and spiked transfer was added to allow use of these devices.
1751.8(e)	Douglas Barcon Barcon & Associates	Dr. Barcon recommended adding "or within a segregated compounding area" because a compounded product may be given either a 12-hour BUD or an immediate use BUD depending on compounding staff choice.	The Board rejected this comment and determined that the addition was not necessary for clarity. This section only applies when sections 1751.8(a)-(d) do not apply; therefore there is no need for it to be in a Segregated compounding area because that is referred to in 1751.8(d).

Code Section	Commenter	Comment	Board Response
1751.8(e)	Bruce Lepley Community Regional Pharmacy	Mr. Lepley requested that the labeling for "immediate use only" be replaced with the hour BUD to avoid confusion with other regulatory agencies. He also requested that the section be reword to use "a delay could harm the patient" to avoid confusion. Additionally, Mr. Lepley asked if the regulation applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.	The Board rejected this comment. This same comment was submitted during the 45 day comment period and was rejected at that time as well. The Board rejected this comment as the Board determined that the additional language is not needed. Depending on the hospital, "Immediate use" does not necessarily mean what the commenter is requesting to change it to. These regulations apply to all sterile compounding as defined by CCR 1751. It applies to Pharmacy compounding, but does not apply to those not licensed by the Board.
1751.9(a)	Jeffrey Nehira Dignity Health	Dr. Nehira requested an exemption be made for single-dose ampules used during a procedure as most are used in the sterile operating room.	The Board rejected this comment. The Board determined that the comment was outside the scope of 15-Day comment period. However, the Board disagrees that a single dose ampule can be used more than once. Once a needle is inserted, the contents are no longer sterile.
1751.9(b)	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane requested the ability to use Closed system transfer devices (CTSD) to extend the beyond use date of single dose vials of chemotherapy to 24 hours or use through the end of the shift, whichever is shorter.	The Board rejected this comment. The Board disagrees with the commenters rationale. Closed System Transfer Devices are not completely effective and can still contaminate the vials because the outside of the vial is still handled by humans. Additionally, CTSD use is not presently supported by the FDA for the extension of the BUD.
1751.9(a)(b)(c)	Doug O'Brien Kaiser Permanente	Dr. O'Brien echoed the comment by Dr. Palmer and Dr. Shane and requested the ability to use CTSDs to extend the BUD.	The Board rejected this comment. The Board disagrees with the commenters rationale. Closed System Transfer Devices are not completely effective and can still contaminate the vials because the outside of the vial is still handled by humans. Additionally, CTSD use is not presently supported by the FDA for the extension of the BUD.
Overall Comment	Michael Tou Providence Health	Mr. Tou requested that the Board allow exemptions from compliance to allow time for construction.	The Board accepted this comment. The Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
Overall Comment	Judith Brosz	Dr. Brosz indicated that the regulations are indiscriminate in the use of "employees," "personnel" "staff," "compounding personnel, and "sterile compounding personnel." She indicated that the broad range of terms leaves too much room for interpretation.	The Board rejected this comment. Similar comments were submitted and rejected in response to the initially noticed text. The language was chosen to apply to the appropriate groups of people in each context. The board does not believe the terms are confusing, and in context can be readily understood.

Code Section	Commenter	Comment	Board Response
Overall Comment	BJ Bartleson California Hospital Association	Ms. Bartleson requested that a program waiver be considered based on the development of a detailed plan of correction and corresponding timeline of planned implementation, and full completion of updated requirements as determined in the plan of correction.	The Board agreed with this comment. The Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
Overall Comment	Candace Fong Clara Evans Dignity Health	Dr. Fong and Ms. Evans requests the Board to provide program flexibility to allow hospitals to assess, plan and implement venting requirements and room construction, and time to move those changes through the complicated Office of Statewide Health Planning and Development (OSHPD) approval process.	The Board agreed with this comment. The Board modified the text to permit licensees to seek extensions on a case-by-case basis that will allow facilities time to make the necessary improvements in order to comply.
Overall Comment	Katherine Palmer Rita Shane Cedars-Sinai Medical Center	Dr. Palmer and Dr. Shane requested the ability to provide emergency therapy to patients and provide chemotherapy to patients using technology which preserves medication vials.	The Board rejected this comment. The same comment was previously submitted during the 45 day comment period and was rejected. The Board determined that emergency therapy drugs can be obtained from a 503b and not compounded by the pharmacy. Closed System Transfer Devices are not completely effective and can still contaminate the vials because the outside of the vial is still handled by humans. Additionally, CTSD use is not presently supported by the FDA for the extension of the BUD.
Overall Comment	University Compounding Pharmacy Joe Grasela	Mr. Grasela requested that the Board wait until the language in USP 800 is finalized prior to making it law.	The Board rejected this comment. With the implementation is SB 294, the Board cannot wait for USP 800 to finalize regulations. USP 800 is not expected to be finalized until sometime in 2017/2018 and the Board determined that continuing to wait for these regulations would not be in the best interest to public safety. If changes are necessary once USP 800 is implemented, the Board will seek to amend the regulation.

Comments Received During 15-Day Comment Period (11/20/2015 - 12/5/2015)

Code Section	Commenter	Comment	Board Response
1735.1(e)(1)	Rheta Sandoval & James McNulty	Dr. Sandoval and Dr. McNulty expressed concern about deleting the word "minimum" as they feel it creates a pressure requirement that is different than current and proposed USP Chapter <797>.	The Board rejected this comment. The Board determined that while the Board is utilizing USP 797 for several areas, these regulations are not an exact replica. While the intent is similar, the Board is using a range for positive pressure.
1735.1(e)(1)	Bruce Lepley	Mr. Lepley expressed concern that USP 797 requires 12 air changes per hour when compounding hazardous drugs. In addition, he states there is a contradiction in section 1735.6 (e) (1).	The Board rejected this comment. The Board determined that USP 800 states 30 ACPH is required for an ISO Class 7 buffer room and a USP 797 BUD. The commenter seems to misunderstand the exemption in 1735.6(e)(1), which establishes a BUD of 12 hours or less.
1735.1(f)	Douglas Barcon	Dr. Barcon suggested a spelling correction to "recirculated." Additionally, he requested that clarification be added to the language to address issues with poor design and improper placement of the PEC.	The Board agreed with the spelling correction; however, the Board reject the additional language. The Board determined that that language addition does not improve regulation and clarification is not necessary to address poor design or improper placement of CACI. The Board believes that the regulation cannot be written to address all potential problems a pharmacy may encounter.
1735.1(f) & (g)	Douglas Barcon	Dr. Barcon also requested clarificatin regarding the whether the regulation is addressing static, dynamic, or both air conditions of operation?	The Board rejected this comment. The Board determined that the critical site should be bathed with non-turbulent first air. Additionally, the intent of the regulation is the recirculation and turbulent air resulting within the CACI, as some PECs employ.
1735.1(k)	Brian Warren	Mr. Warren requested that the Board define "essentially a copy" and "clinically significant difference". Additionally, he requested clarification where "high particulate matter" can be done where "sterile compounding" is required to be done?	The Board reject this comment. The Board determined that both terms have been defined in the regulations already in this section. Additionally, "high particulate-generating activities," which include staging, preparation, etc are designated to the "Ante-area" (see 1735.1(a)) Finally, "sterile compounding" is to be compounded in an ISO Class 5 or better air quality (See 1735.1(ab)).
1735.1(k)	Brian Warren	Mr. Warren requested clarification if the use of a different base, oil, or filler is considered a clinically significant difference. He recommended that the Board use the verbiage for the 503a defintion to reduce confusion with other states.	The Board reject this comment. The Board determined that this comment was outside the scope of this comment period; however, the exception in this section would apply for individual patients should a difference be identified by the prescriber for a specific patient. Additionally, while the intent is similar to 503a, the Board determined that duplicating the language was not appropriate for these regulations.

1735.1(m)	Rheta Sandoval & James McNulty	Dr. Sandoval and Dr. McNulty expressed concern that the added language is subject to interpretation. They requested clarifying language on how to “test” the airflow requirements and if the intent is to assess the air velocity across the line of demarcation (when the displacement airflow method is employed).	The Board rejected this comment. The added language is included to guide the licensee in assessing their facilities. If displacement airflow used, the specifics outlined in the regulation must be followed. What to test is up to the Pharmacist-in-Charge. Additionally, the Board Inspectors have received or will receive extensive training on the expectations from the FDA.
1735.1(m)	Bruce Lepley	Mr. Lepley requested that the language be clarified so that the velocity will only be measured in the direction from the clean area to the ante area. Additionally, he requested clarification on how this should be documented/demonstrated.	The Board rejected this comment. The Board determined that the language is clear as it states "into the ante-area." The licensee will need to provide documentation and demonstrate that requirements are met when displacement airflow is utilized. The Board believes that it is up to the PIC to determine how the documentation is to be recorded and kept, but that the information can be maintained with the Policies and Procedures or the Quality Assurance documents.
1735.1(t)	Bill Jones	Mr. Jones expressed concern that "unintended" breaks in compounding (restroom, meal break, employee question) would result in different lot numbers because of the regulations definition of "Lot" and could result in an unnecessary error. He recommended that "uninterrupted" be removed from the language.	The Board rejected this comment. The Board determined that the comment was outside the scope of this comment period. The Board determined that proper planning by compounding staff will prevent these issues from occurring.
1735.1(u)	Douglas Barcon	Dr. Barcon suggested that the term “efficacy” did not appear to be appropriate and suggested that it be changed to “quality” or “competency.”	The Board rejected this comment. The Board determined that Efficacy is commonly understood by pharmacists to be the ability to produce the intended result. The purpose is to measure the ability of compounding personnel.
1735.1(u)	Brian Warren	Mr. Warren requested clarification of the meaning of “evaluated for sterility.” He suggested that the sentence be changed to In-house sterility evaluation.	The Board rejected this comment. The Board determined that the proposed change was not necessary and did not add to the clarity of the regulation. The Board believes that the PIC needs to define how the product will be evaluated. The Board cannot tell the PIC how to practice, the PIC needs to determine that within regulatory requirements.
1735.1(y)	Marie Cottman	Dr. Cottman requested that the potency exemption be removed and exempt specific products instead. She expressed concern that acute care facilities are exempted, but the local jail is not.	The Board rejected this comment. The Board determined that this comment was outside the scope of this comment period. While the Board understands Dr. Cottman’s point, the Board could not determine a safe way to allow all pharmacies this exemption. Additionally, the list of products could become extensive.

1735.1(y) Incorrectly Identified as (z)	Bruce Lepley	Mr. Lepley expressed concern over the definition of "potency" as it is used differently in USP 797. He requested that the definition be removed.	The Board rejected this comment. The Board determined that this comment was outside the scope of this comment period. Additionally, this comment was submitted during the first 15-day comment period and was rejected. The term "Potency" is used within regulation and needs to be defined for clarity.
1735.1(ab) Incorrectly Identified as (ac)	Bruce Lepley	Mr. Lepley expressed concern that automated robots needed to be placed in an ISO Class 5 or better air environment. He indicated that these robots are made to be simply put or placed in the appropriate air environment (ISO Class air).	The Board rejected this comment. The Board determined that this comment was outside the scope of this comment period. Additionally, this comment was submitted during the first 15-day comment period and was rejected. The Board determined that the language was appropriate as automated robots require a class 5 or better environment in USP 797. The Board disagrees that the robots can be placed in any environment.
1735.1(af)	Rheta Sandoval & James McNulty	Dr. Sandoval and Dr. McNulty identified a typographical error to change the word "meet" to "met"	The Board rejected this comment; however the term was changed to "meets" based on another comment received.
1735.1(af)	Douglas Barcon	Dr. Barcon suggested deleting the s in "its" and change "meet" to "meets"	The Board accepted this comment and the grammatical corrections were made.
1735.1(af) Incorrectly Identified as (ag)	Bruce Lepley	Mr. Lepley requested an exemption to allow for a sink within 3 feet of a ISO Class 5 PEC if its a CACI.	The Board rejected this comment. The Commenter provided the same comment twice previously and it was rejected each time as well. The Board has found no reliable data to support the belief that it is safe for a sink to be placed near a CACI and no reliable data was provided. The Board maintained it's position that there is a risk of contamination if there is a sink/drain within 3 feet of the compounding area.
1735.2(c)	Bill Jones	Mr. Jones expressed concern that this section appears to violate the Federal Food Drug and Cosmetic act section 503A.	The Board rejected this comment. The Board determined that the comment is outside the scope of this comment period. It is the Board's understanding that the FDA is currently working on draft guidance to permit "office use compounding" at the request of the US Congress. The Board will continue to allow this practice while the FDA reassess this topic. Should the FDA decide against allowing office use compounding, the Board will revisit this policy at that time.
1735.2(c)(1), (3)	Kaiser	Kaiser requested that the Board not eliminate the ability of pharmacies to compound for prescriber's office dispensing.	The Board rejected this comment. The Board determined that the comment is outside the scope of this comment period. Additionally, the Board determined that Office Dispensing is not permitted by the FDA. While the FDA is reassessing the issue of "office use" (which is permitted under these regulations), non-patient specific office dispensing is not allowed. These products would need to be obtained from a licensed 503b facility.

1735.2(i)	Bruce Lepley	Mr. Lepley expressed concern that CSP's (e.g. reconstituted vials) will have BUDs that exceed the limitations in this section when made following a manufacturer's directions. Additionally, he indicated that stability studies will not be provided by the manufacturer.	The Board rejected this comment. The Board determined that the commenter is referring to "sterile" preparations. Reconstitution is not considered compounding and would not apply. This section specifically addresses "nonsterile" preparations and the commenters comment would not apply. The specific BUD for sterile preparations is found in 1751.8. Additionally, the language was obtained from USP 797.
1735.2(i)(1)(E)	Douglas Barcon	Dr. Barcon requested clarification as USP 795 provides storage temperatures.	The Board rejected this comment. The Board determined that this comment was outside the scope of this comment period. The Board determined that while the Board is utilizing USP 797 for several areas, these regulations are not an exact replica.
1735.2(i)(1)(A-F)	Marie Cottman	Dr. Cottman expressed concern that this section does not allow for the extension the beyond use date with appropriate testing.	The Board rejected this comment. The specific testing guidelines are provided in 1735.2(i)(3). The exemptions here apply to all compounding and are not specific to sterile compounding.
1735.2(i)	Brian Warren	Mr. Warren requested clarification if the tests in section 1732.2(i)(3) are required for both sterile and non-sterile compounds for the extension of beyond use dating? Additionally, he inquired about defining method suitability and change point in time studies.	The Board rejected this comment. The exemptions here apply to all compounding and are not specific to sterile compounding. Additionally, section 1735.2 applies to all compounding (sterile and non-sterile). Specifically, 1735.2(i)(1) is non-sterile compounding and 1735.2(i)(2) is sterile compounding. Section 1751 applies to only sterile compounding. A method suitability is a practice standard and cannot be defined in regulation. Finally, the change point in time potency is not the same thing as a stability study.
1735.2(i)(1)	Pamela Almeida	Dr. Almeida expressed concern that the proposed language "any of the following" implies that it is inclusive even when stability data demonstrates a longer expiration date then those listed in D, E, F cannot be exceeded. She believes that is contradicts USP <795>.	The Board rejected this comment. While the Board is utilizing USP 795 for several areas, these regulations are not an exact replica. The Board determined that the intent is the same. Section 1735.2(i)(3) provides for an extended BUD based on stability studies.
1735.3(a)(2)	Rheta Sandoval & James McNulty	Dr. Sandoval and Dr. McNulty requested that recordkeeping be permitted in an electronic format.	The Board rejected this comment. The record needs to be a single document that is available for inspection. While it can be a electronic document, it still needs to be printed and stored in the pharmacy. Additionally, it needs to be one collated document and not consist of several documents staff needs to look though to get the information they need.
1735.4(a)(3)	Bill Jones	Mr. Jones requested an exemption for 503B facilities to reduce the necessary information on the label.	The Board rejected this comment. The Board determined that facilities still need to label products from 503B entities for patient safety.

1735.4(a)(3)	Kaiser	Kaiser requested an exemption from the requirement that the rate of infusion shall be included on the label. He indicated the rate of infusion may change based on the patient condition.	The Board rejected this comment. The Board determined that the rate of infusion needed to be on label for patient safety in health care facilities. The facility can use a range of infusion rates if necessary. The same argument could be made for any medication dispensed by a pharmacy as any treatment plan can be altered at any time.
1735.6(e)	Sandy Atwater	Ms. Atwater expressed concern that the PEC utilized by her employer does not need to be vented according to the manufacturer, and is classified as a closed system isolator. She would like clarification as to how closed system isolators are addressed in the regulations?	The Board rejected this comment. The Board determined that all hazardous PEC compounding must be externally vented or vented via a "redundant-HEPA filtered series" as required in USP 800. The Board recommends the commenter refer to section 1735.1(f). The Board acknowledges the example provided, but determined that the example is not unidirectional turbulent airflow. Re-circulating air when compounding poses both a patient safety risk and a health safety risk to the compounder.
1735.6(e)	Bill Jones	Mr. Jones expressed concern that the requirement for a seamless room will be difficult and requested that the term be removed from the language.	The Board rejected this comment. The Board determined that the comment is outside the scope of this comment period; however, the Board determined that "seamless" is a requirement of USP 800.
1735.7(a)	Douglas Barcon	Dr. Barcon expressed concern that environmental services, housekeeping, and maintenance should not need to be trained in all aspects of policies and procedures, because it is beyond the scope of their job descriptions.	The Board rejected this comment. The Board determined that this comment is outside the scope of this comment period; however, the Board determined that these staff must be appropriately trained if they are working within the compounding areas for their safety, the safety of other staff, and the safety of patients.
1735.8(c)	Kaiser	Dr. O'Brien indicated that the language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. As proposed the regulation would add major costs to hospital and other pharmacy-compounding.	The Board rejected this comment. The same comment was submitted during the 45-day and the 15-day comment periods and rejected. This section specifies the requirements of a quality assurance plan. It does not state that "any and all" products be tested. The language in this section includes the frequency of testing and the testing schedule in the plan. The PIC would decide the frequency of testing, the products to be tested, and the type of testing.
1735.8(c)	Bruce Lepley	Mr. Lepley express concern that the language implies that all products compounded by a pharmacy must be tested for integrity, potency, quality and labeled strength at least annually.	The Board rejected this comment. This section specifies the requirements of a quality assurance plan. It does not state that "any and all" products be tested. The language in this section includes the frequency of testing and the testing schedule in the plan. The language specifically states "analysis of specified compounded drug preparations." The PIC would decide the frequency of testing, the products to be tested, and the type of testing and include that information in the quality assurance plan.

1751.1(a)(5)	Several comments about smoke studies were received	Several commenters expressed concern about the requirements for smoke studies. They indicated that smoke studies should be limited to the ISO class 5 PEC in this regulation. Additionally, they expressed concern about the purpose of the video, how to store the video, and how often the studies needed to be completed. They also indicated that smoke studies are done by a third party and it may not be possible to obtain the video. Additionally, they indicated that the location where the smoke studies should be done was not clear and it may increase the cost of the certification.	The Board rejected these comments. Smoke studies are required in USP 797. The videos provide confirmation of appropriate airflow and placement of equipment in the cleanroom and adjacent areas. The Board determined that they are beneficial to ensure proper airflow for employee and patient safety and it is necessary for inspectors to be able to confirm that a smoke study was completed.
1751.1(a)(8) Incorrectly identified as (a)(7)	Bruce Lepley	Mr. Lepley expressed concern that the regulation doesn't allow use of a continuous recording device.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. The same comment was submitted during the 45-day and the 15-day comment periods and rejected. However, the regulation language is not disallowing electronic monitoring as long as it is documented daily. It is up to the PIC to determine "how" the documentation is done. A continuous recording device should have the capability to produce documents that show daily documentation.
1751.1(b)	Marie Cottman	Dr. Cottman expressed concern that this section is confusing and requested that the language be modified to read 1735.2(c).	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board determined that the reference to 1735.2 is correct as sections (a), (b), and (c) apply.
1751.3(e)	Bruce Lepley	Mr. Lepley expressed concern that all personnel must review all changes to all compounding policies and procedures, even if they do not directly impact their job duties in a material fashion. Additionally, he states a signature and date should only be required if there is a significant practice change being implemented as a result of any changes in policies and procedures.	The Board rejected this comment. The same comment was submitted during the first 15-day comment period and was rejected. The Board determined that all staff need to have an understanding of the policies and procedures for safety of all employees. Additionally, the signature and date requirement is to ensure that all staff read and understand the policies and procedures.
1751.4(d)	Bruce Lepley	Mr. Lepley states that USP 797 does not make any stipulation or requirement of mandatory use of a sterilizing agent and only makes the stipulation of sanitizing and disinfecting. He recommends the removal of the requirement to use a sporicidal agent monthly. If the requirement is not removed, specifies that it is for the cleaning of floors.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. The same comment was submitted during the first 15-day comment period and was rejected. The oversight of this issue is in USP 797. Additionally, refer to USP 1072 (Disinfectant and Antiseptics).
1751.4(d)(1)	Marie Cottman	Dr. Cottman recommended that the language be modified to only require cleaning when the cleanroom is used as not all facilities access their cleanroom everyday.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. The same comment was submitted during the 45-day comment period and was rejected. The Board determined that cleaning is necessary even if the cleanroom is not used as it is possible for someone to still enter the cleanroom and contamination may occur.

1751.4(e)	Bruce Lepley	Mr. Lepley expressed concern over the use of the words “using a suitable sterile agent” to “using a suitable disinfecting agent” to mitigate the risk of confusion that the use of a sterilizing agent is required to disinfect the PEC. There could be confusion if these two words are used in the same sentence. Mr. Lepley also requested that the 30 minute and before/after each lot disinfection requirements be removed as it would impair the ability to effectively use the PEC.	The Board rejected this comment. The same comment was submitted during the first 15-day comment period and was rejected. The verbiage within the regulation is clear and from USP 797/USP 1072. Disinfection is necessary for patient safety to prevent accidental contamination.
1751.4(g)	Sandy Atwater	Ms. Atwater expressed concern that the PEC utilized by her employer does not need to be vented according to the manufacturer, and is classified as a closed system isolator. She would like clarification as to how closed system isolators are addressed in the regulations?	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. Additionally, the Board determined that all hazardous PEC compounding must be externally vented or vented via a "redundant-HEPA filtered series" as required in USP 800. The Board recommends the commenter refer to section 1735.1(f). The Board acknowledges the example provided, but determined that the example is not unidirectional turbulent airflow. Re-circulating air when compounding poses both a patient safety risk and a health safety risk to the compounder.
1751.4(g)	Bruce Lepley	Mr. Lepley expressed concern about the definition of hazardous. He recommended that the definition be modified to “hazardous” to mean “all anti-neoplastic agents used to treat neoplasms identified by the National Institute for Occupational Safety (NIOSH).....”	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. Additionally, the Board does not agree that hazardous only applies to those used to treat neoplasms. The intent of regulation is for any compounded preparation prepared in PEC used to compound "hazardous" compounds will be labeled as "hazardous" regardless if the medication is not defined as "hazardous." This is because cross-contamination can occur.
1751.4(g)	Bruce Lepley	Mr. Lepley expressed concern that a PEC does not need to be externally vented when compounding with hazardous material. He stated that many hazardous agents will vaporize at room temperature.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board disagreed with the comment as externally venting is required in USP 800. Additionally, this is a safety issue for both patients and staff.
1751.4(i)	Douglas Barcon	Dr. Barcon requested expressed concern that non-turbulent air flow throughout the workspace may not be possible and requested clarification. Additionally, he requested that LAFW PECs be added to the regulation because they must also provide unidirectional air flow patterns without turbulence.	The Board reject this comment. The Board understands that LAFW PECS provide unidirectional air flow patterns. Additionally, turbulent airflow as a result from recycled air within the critical sites is an issue with some CAI/CACI. The Board cannot draft the regulations to address every possible issue that may arise.

1751.5(a)(6)	Bruce Lepley	Mr. Lepley expressed concern about prohibiting the use of nail polish in an ISO Class 5 or 7 area as USP 797 only restricts artificial nails or extenders.	The Board rejected this comment. The Board determined that the comment was outside the scope of the 15-Day Comment Period. However, the Board determined that nail polish can chip and contaminate a preparation. The Board found no reliable scientific studies to show otherwise and the commenter provided no studies.
1751.6(e)(1)(E)	Bruce Lepley	Mr. Lepley recommended that the statement "which contain the same amount or greater of volume transferred during the selected manipulations" be removed because it implies that the media-fill test performed by personnel must involve a volume transfer.	The Board rejected this comment. This section was previously removed from the regulation text prior to this 15-day comment period.
1751.6(e)(2)	Rheta Sandoval & James McNulty	Dr. Sandoval and Dr. McNulty identified a typographical error and recommended the word "performs" be changed to "performed"	The Board agreed with this comment and the grammar corrections were made.
1751.6(e)(2)	Douglas Barcon	Dr. Barcon also identified a typographical error and recommended the word "performs" be changed to "performed"	The Board agreed with this comment and the grammar corrections were made.
1751.6(j)(2)	Kaiser	Kaiser requested clarification on the intent of this section. They indicated the language is unclear what training is required.	The Board rejected this comment. The Board determined that the language states "they must successfully complete practical skill training in aseptic technique and aseptic area practices." The Board believes that the PIC must use their professional judgment to decide the skills necessary within the regulatory requirements.
1751.7(b)(1)	Judith Brosz	Dr. Brosz expressed concern that that term "Involved" is vague and subject to misinterpretation.	The Board rejected this comment. The Board determined that when the section is taken in it's entirety, the text is clear. "Involved" is the appropriate word when designating the particular individuals within the pharmacy.
1751.7(b)(1)	Bill Jones	Mr. Jones expressed concern that the requirement for the volume of the media fill to be equal to or greater than the volume transferred during compounding should not be required. He recommended that the language be changed to emphasize the performance of the compounding steps and aseptic manipulations.	The Board rejected this comment. The Board determined that in order to adequately assess compounding steps and aseptic manipulations the same volume as that being compounded is necessary. Simulation of media fill is not a true simulation if the same volumes are not used. The volume is very important to guard against worker fatigue.

1751.7(b)(3)	Bruce Lepley	Mr. Lepley requested an exemption to allow for a sink within 3 feet of a ISO Class 5 PEC if its a CACI.	The Board rejected this comment. The Board determined that sinks are not permitted due to contamination risk. Additionally, this section addresses the pharmacy's quality assurance plan and process validation. This would not be the appropriate area to add a sink exception. Previous comments submitted by commenter requesting a sink exception in other sections have also been rejected.
1751.7(b)(3)	Bill Jones	Mr. Jones expressed concern that the revalidation requirements are too broad and sometimes inappropriate. He doesn't believe revalidation should be mandated in the regulation and believes that an unacceptable quality assurance result could be unrelated to an individual's aseptic technique or the ability of the environment to maintain appropriate levels of control. He suggested that the requirement be removed that be defined in the licensees standard operating procedure.	The Board rejected this comment. The Board determined that any variance of those indicated in 1751.7(b)(3) should pose a concern to the licensee and could potentially compromises the integrity of the compound environment. The Licensee would need to revalidate their processes to determine that cause of the variance.
1751.7(e)(1)	John Voliva	Mr. Voliva indicates that USP <797> allows for an alternate method of sterility testing and requested that an exemption be added to allow alternate methods as well.	The Board rejected this comment. The Board determined that the FDA has not approved alternative methods. Until the FDA has provided clear guidance on alternative methods, the Board cannot rely on the results. Currently, there is not enough verifiable data to support method accuracy and patient safety is at risk.
1751.7(e)(1)	Douglas Barcon	Dr. Barcon identified a typographical error and recommended that "preparation" be changed to "preparations."	The Board agreed with this comment and grammatical corrections were made to the text.
1751.7(e)(1)	Marie Cottman	Dr. Cottman express concern that sterility testing needed to be USP chapter 71 compliant. She indicated that other sterility tests are available (and faster) such as the Rapid Scan RDI. She expressed concern that USP 71 is out of date with current technologies and will reduce patient access. She recommended that the Board allow an exemption for pharmacies to develop process for sterility testing and remove the USP 71 reference.	The Board rejected this comment. The Board determined that USP 71 is current accepted standard by the FDA for compounding. The FDA has not approved alternative methods. Until the FDA has provided clear guidance on alternative methods, the Board cannot rely on the results. Currently, there is not enough verifiable data to support method accuracy and patient safety is at risk.
1751.7(e)(2)(B)	John Voliva	Mr. Voliva expressed concerned that some compounded sterile preparations for inhalation may require a longer course of therapy than five days. He requested that the Board increase the quantity for 15 days.	The Board rejected this comment. The Board noted that the 5 day inhalation exception was added to allow time for the patient/prescriber to obtain the prescription from a 503b facility. The exemption was not added to allow a pharmacy to administer the product to the same patient every 5 days. Patient safety is at risk if the product is not tested for sterility.

1751.7(f)	Judith Brosz	Dr. Brosz requested that the Board clarify that employee conducting remote checking of sterility should not have the identical training requirements as those performing the actual compounding.	The Board rejected this comment. A person cannot look at a product and see sterility. If the person is part of the compounding process and checking sterility, the person must be trained and demonstrate the ability to check sterilization and process involved. The PIC determines how such training and demonstration is done in the context of a particular pharmacy.
1751.8(b)(1)	Marie Cottman	Dr. Cottman expressed concern that USP<797> uses the phrase "one or more of the following" and these regulations indicated all of the following apply. She recommended that the word "all" be changed to "one or more"	The Board rejected this comment. The Board determined that the comment is outside the scope of this comment period.
1751.8(a)(1), (b)(1), & (c)(1)	Douglas Barcon	Dr. Barcon indicated that a CACI can be used in place of a CAI for non-hazardous compounding depending on air pressure and shouldn't be removed from these sections.	The Board rejected this comment. While the Board understands that a CACI can be used to compound non-hazardous, the Board determined that it would be utilized as a CAI in those instances. The Board believed that the term did not need to be add back in.
1751.8(e)	Bruce Lepley	Mr. Lepley requested that the labeling for "immediate use only" be replaced with the hour BUD to avoid confusion with other regulatory agencies. He also requested that the section be reword to use "a delay could harm the patient" to avoid confusion. Additionally, Mr. Lepley asked if the regulation applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.	The Board rejected this comment. The Board determined that the comment is outside the scope of this comment period. This same comment was submitted during the 45 day comment period and was rejected at that time as well. The Board rejected this comment as the Board determined that the additional language is not needed. Depending on the hospital, "Immediate use" does not necessarily mean what the commenter is requesting to change it to. These regulations apply to all sterile compounding as defined by CCR 1751. It applies to Pharmacy compounding, but does not apply to those not licensed by the Board.
1751.9(b)(2)	Bruce Lepley	Mr. Lepley recommended that single-dose containers to be used for 6 hours (or per manufacturer recommendation) as long as the container was needed-punctured in ISO class 5 or better air and the container is then sealed with a sterile seal before removing it from the PEC.	The Board rejected this comment. The Board determined that the use of a sterile seal does not ensure that the product remains free from microbial risk, especially when brought outside of an ISO Class 5 or better area. This is not a safe practice.
Overall Comments	Brian Warren	Mr. Warren expressed concern that USP 795 does not mention method suitability tests, or container closure tests for extending the BUD of Non-Sterile compounds.	The Board rejected this comment. The Board notes that extending of the BUD encompass both sterile and non-sterile compounds in the current regulations.

Overall
Comments

Brian Warren

Mr. Warren recommended that section 1250.4 be revised to address sterilization via radiation autoclaving.

The Board rejected this comment as outside the scope. CCR section 1250.4 is currently not subject to revision. The Board acknowledges the issue, but cannot modify the Title 24; additionally, the Board acknowledges that B&P 4127.7 is also an issue.