Code Section Section (Subdivision)	Commenter	Comment	Response
1738.4(c)	Tommy Mai Huntington Health, CSHP	Rationale: The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. Recommendation: Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier" Recommendation: (c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type ~~and PEC unique identifier~~ used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.	Staff staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months as training occurs. The PEC unique identifier is necessary to identify where the competency was performed. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment.
1738.4(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The current USP 825 chapter does not require the PEC unique identifier to be documented for personnel training. Requiring a PEC unique identifier only adds to the additional documentation burden. Recommendation: Recommend the Board of Pharmacy to consider removing the requirement of "PEC unique identifier." Recommendation: (c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type ~~and PEC unique identifier~~ used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding.	Staff staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that the requirement to document would occur once every three to six months as training occurs. The PEC unique identifier is necessary to identify where the competency was performed. Further, the documentation ensures that a compounding personnel need only complete a single training and can leverage that training in other compounding environments with the same equipment.
1738.5(b)	Paul Mahan Siemens Medical	The draft regulation should harmonize with <825> in that temperature and humidity monitoring should take place in the area containing a hot-cell.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation. Board staff note that the proposed regulation text is consistent with existing law CCR 1751.4(k). Staff note that the proper choice of placement of an SRPA in the preparation of sterile products. Staff also note provisions in California Code of Regulations Title 24 and other legal provisions also establish temperature requirements for which licensees must comply. Staff note that Title 24 provisions are more restrictive related to temperatures.
1738.5(d)	Wendy Waldman Torrance Memorial Medical Center	Rationale: Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. Recommendation (d) <u>Radiopharmaceutical</u> compounding shall not take place in the SRPA.	Board staff have reviewed the comment and do not recommend a change in the proposed text. The Board staff note that the article applies to radiopharmaceuticals.

1738.5(d)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: Per USP 825, for compounding sterile radiopharmaceuticals, the ISO 5 PEC must be placed in a classified area. However, non-radiopharmaceutical sterile compounds were not applicable for this restriction in USP 825. Prohibiting all compounding at SRPA would have a significant impact in the workload on health-systems that does not have a dedicated classified room for radiopharmaceuticals as they would not be able to prepare any supportive meds that has an SRPA. Recommendation (d) Radiopharmaceutical compounding shall not take place in the SRPA.	Board staff have reviewed the comment and do not recommend a change in the proposed text. The Board staff note that the article applies to radiopharmaceuticals.
1738.5(j)	Melanie Horn Sutter Health	Request clarification on the purpose of dynamic airflow smoke pattern test for the classified spaces outside of the ISO-5 PEC every 6 months. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection. This does not align with CETA standards for frequency of SEC smoke pattern testing.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.
1738.5(j)	Wendy Waldman Torrance Memorial Medical Center	Rationale: USP 825 requires a visual smoke study for classified spaces if there are low air returns. A dynamic airflow smoke pattern test is conducted initially and every 6 months to ensure proper PEC placement and staff maintaining unidirectional airflow (first air). Recommendation Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. In addition, recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.
1738.5(j)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: USP 825 requires a visual smoke study for classified spaces if there are no low air returns. The proposed regulation is inconsistent with USP. Pharmacies shall conduct PEC dynamic airflow smoke pattern tests every 6 months, however to include classified space with low air returns results in unnecessary testing and cost burden for institutions. Recommendation Request clarification on the purpose of dynamic airflow smoke pattern test for all classified spaces. Recommend the BOP be consistent with USP 825 recommendations and remove this proposed subsection.	Board staff have reviewed the comment. Board staff recommend removal of the paragraph as the requirement for smoke studies are established in the Chapter.
1738.6(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). Infection Control and current evidence does not support that trending genus level below actionable levels will yield data that will reduce patient risks; however, this will result in increase in costs and workload. Recommendation: (b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."

1738.6(b)	Melanie Horn Sutter Health	USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). The proposed BOP language is not consistent with USP 825 and requires identification every CFU count at least to the genus level regardless of if they exceeded the CFU action levels which is a considerable burden that is not the requested standard for USP 797 1736. Recommend harmonizing requirement to 1736 if revised and not USP 825 standard. CETA. CETA Application Guide CAG-003:2022 Certification of Sterile Compounding Facilities for USP Compliance. Accessed May 20th, 2024. In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1738.6(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: USP 825 recommends identifying sampling results on a genus level for actionable CFUs (CFUs exceeding action levels). BOP language is not consistent with USP 825 recommendations, and in contrast will require health-systems to identify every CFU count at least to the genus level regardless of if they exceeded the CFU action levels. Recommendation: (b) In addition to the SOPs at a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, ~~regardless of~~ when the colony forming units (CFU) count exceeds action level to trend for growth of microorganisms. Trends of microorganism growth must be identified and evaluated.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text not based on this comment. As indicated in the ASHP release "Pharmacy Environmental Monitoring (EM) Implementation Toolkit- "A hallmark of a strong EM program is the measurement of progress in order to continuously program compounding conditions, and effectively correct excursions." This document further provides metrics to consider during tracking efforts and descriptions of the benefits of the trending. Staff note that the ASHP document recommends monitoring monthly; however, the Board's proposed regulation text only requires trending every six months. Further as noted in USP Chapter 1161, "Particulate counts as well as microbial counts within controlled environments vary with the sampling locations and the activities being conducted during sampling. Monitoring the environment for nonviable particulates and microorganisms is an important control function because they both are important in achieving product compendial requirements for Foreign and Particulate Matter and Sterility in Injections and Implanted Drug Products." Also included in Chapter 1161, "Environmental microbial monitoring and analysis of data by qualified personnel can assist in ensuring that a suitable state of control is maintained." And the Chapter further provides, "Since the advent of comprehensive environmental monitoring programs, their applications in capturing adverse trends or drifts has been emphasized."
1738.10(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. Recommendation: (c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need~~ or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. The proposed regulation text establishes the areas that must be covered in a facility's SOPs and staff note that deviations are necessary at times to meet a patient's need. The facility's SOPs will define the circumstances under which a deviation may be necessitated.

1738.10(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: The proposed language is inconsistent with USP 825 recommendations, will require health-systems to incorporate patient need which may not be pertinent information. Recommendation: (c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in USP Chapter 825) an SOP shall at least define the circumstances that necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, ~~include patient need or~~ facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. The proposed regulation text establishes the areas that must be covered in a facilities SOPs and staff note that deviations are necessary at times to meet a patient's need. The facility's SOPs will define the circumstances under which a deviation may be necessitated.
1738.14(b)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	Board staff have reviewed the comment and recomment a change to the proposed regulation text, however not solely based on this comment.
1738.14(b)	Paul Mahan Siemens Medical	Proposed text: The board shall be notified in writing within 72 hours of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law. Comment: This should exclude delivery mishaps, unless they are related specifically to pharmacy practice errors (e.g., mislabeling or mispackaging errors by the pharmacy personnel causing the delivery mishap)	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.
1738.14(b)	Melanie Horn Sutter Health	Radiopharmaceuticals can be obtained from manufacturers in ready to inject forms (while limited) the scope of this statement does not clarify the Board scope regarding complaints of a manufactured product. The notification obligation addressed by the processing nuclear pharmacy and extended to 3 business days.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment. The proposed change offered by staff incorporate the definition used in federal law to ensure clarity in the proposed regulation text.
1738.14(b)	Wendy Waldman Torrance Memorial Medical Center	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (b) The board shall be notified in writing within ~~72 hours~~ 3 business days of a complaint involving a radiopharmaceutical. Recalls and adverse events must be reported to the Board and other agencies in compliance with relevant provisions of law.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.
1738.14(c)	Rita Shane Cedars-Sinai, Tommy Mai Huntington Health, CSHP	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.

1738.14(c)	Wendy Waldman Torrance Memorial Medical Center	Rationale: A requirement of 72 hours may not provide sufficient time for health-systems to investigate and notify the necessary regulatory bodies in cases where it occurs over the holiday weekend. Recommendation: (c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all reported adverse events shall be reviewed by the pharmacist-in-charge within 3 business days ~~72 hours~~ of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.	Board staff have reviewed the comment and recommend a change to the proposed regulation text, however not solely based on this comment.