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1	1738 et seq	T. McConnell	The proposed designated person language should align with the <825> definition in that one or more individuals should be able to be this designated person simply because the responsibilities are such that a single person would not be able to take a vacation otherwise. Furthermore, the language should mirror the <795> and <797> text. This language would be the following: Designated person (s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and the personnel as related to the preparation of radiopharmaceuticals. Nothing in this definition allows for a designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require the professional judgement of a pharmacist. Nothing in this definition prohibits the PIC from also serving as the designated person.	Board staff have reviewed the comment and note that the as part of the proposed changes to the second modified text, the Board included text to clarify that nothing in the definition prohibits the PIC from also serving as the designated person. Board staff believe such a change may also be appropriate in this article. Board staff are offering the following change: 1738 (c) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals. **Nothing in this definition prohibits the PIC from also serving as the designated person.**
2	1738.1	CA Rheumatology Alliance And CA Society of Plastic Surgery	We have reviewed the staff responses to our comments and continue to be concerned with the applicability of the proposed regulations on physicians and their ability to "compound" medications in their offices. Although physicians may not be under the enforcement jurisdiction of the Board of Pharmacy, we believe the proposed regulations would change the standard of care for when physicians compound medications and will not allow rheumatologists/physicians to buffer injection/ infusion medications in-office. We are interpreting the proposed regulations to require a pharmacist be present or performing the buffering of the injection/ infusion medications. Rheumatology practices/physicians would not be able to afford to employ a pharmacist for this one	Board staff have reviewed the comment and do not recommend a change to the proposed text based on the comment. Board staff note that the Board has previously considered this comment, most recently during the January 8, 2025, Board Meeting and determined that the requested change is not appropriate. As was previously shared, staff note the Board only has jurisdiction over individuals and businesses within its practice act. Board staff read the comment as suggesting that the Board's proposed regulations would apply to a physician. Business and Professions Code section 4170(c) makes clear that the Medical Board of California is specifically charged with the enforcement of Pharmacy Law (Chapter 9, Division 2

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			purpose. This would lead to rheumatology practices no longer offering this service for our patients. Patients would then be forced to obtain their injection/infusions at a hospital or infusion center which would not only be less convenient for our patients, but it would be more expensive for the patient and the overall healthcare system. We believe it is important to note we are not aware of any issues with rheumatologists/physicians "compounding" injection/ infusion medications. We would like to propose the Board of Pharmacy adopt the language suggested by the California Medical Association as shown below: § 1738.1: In addition to the standards in the USP Chapter 825, the processing of Radiopharmaceuticals shall meet the requirements of this section. **This article shall not apply to compounding by or under the direct supervision of a licensed physician and surgeon.**	of the Business and Profession Code) with respect to its licensees. It may be appropriate for the commenter to confer with their licensing board to discuss their concerns. Board staff note that the Medical Board of California has previously provided a written response to individuals inquiring about the applicability of the Board of Pharmacy's regulations to individuals and practices that operate under the jurisdiction of the Medical Board of California. Below is the information provided from the Medical Board - - Dear Ms. Sodergren: I understand that some concerns have been raised by stakeholders about the applicability of the Board of Pharmacy's pending compounding regulations to licensees of the Medical Board of California (MBC). Existing statute (see Business and Professions Code (BPC) section 2220.5) makes it clear that only the MBC can discipline its physician licensees. Whenever a physician is engaging in compounding (or any other action that their medical license authorizes them to perform) they must always do so consistent with the standard of care. For the purposes of MBC's enforcement program, the standard of care is established by expert testimony in the context of the facts and circumstances of a specific case. It is certainly possible that whatever regulations that are implemented by the Board of Pharmacy may influence the standard of care for physicians who are compounding, especially since some of the proposed regulations reflect what is already required for physician compounding under federal law, including, but not limited to, Section 503A of the Federal Food, Drug, and Cosmetic Act (BPC section 2225(b) allows MBC to investigate violations of federal law related to the practice of medicine).

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				Feel free to share this message with others as you see fit who might also be concerned about the applicability of their pending regulations to the physician community. Please contact me if you have any further questions. Sincerely, Reji Varghese Reji Varghese is the Executive Director for the Medical Board of California. The Medical Board is charged with evaluating compounding practices and the standard of care relevant to its licensees.
3	1738.5	T. McConnell	With regards to 1738.5 Facilities and Engineering Controls (d), the intention of the hot cell can be the total of the SRPA because it provides a full physical barrier on the outside. This would eliminate the need for (1) under this section that reads: Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.	Board staff have reviewed the comment and do not recommend a change to the proposed regulation text. Staff note that not every facility engaged in radiopharmaceuticals uses a hot cell.
4	1738.10(c)	CSHP	The proposed language is inconsistent with USP 825 recommendations, and will require health-systems to incorporate patient need which may not be pertinent information. **Recommendation(BOLD):** We once more reiterate the comments by both us and others at various stages through this rulemaking process that USP has sufficient standards to promote and protect patients. This proposed regulation fails to demonstrate the necessity for patient safety beyond that required by USPR. We recommend that this subsection be deleted. ~~(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~~**	Board staff have reviewed the comment and do not recommend any changes to the proposed text. Staff note that at the January 8, 2025, Board meeting, this subdivision was discussed. At that time the Board approved changes for the second modified text to provide additional clarification of the requirement, which specifically requires that an SOP be developed. Staff note that minor deviations are not always patient specific. There is nothing in the second modified regulation text requiring health-systems to incorporate patient need, unless the facility's SOPs establish such a requirement. The Chapter defines "preparation with minor deviations" as, "The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers

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			~~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 radionuclides purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.~~	recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (e.g., dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (e.g., a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods." Upon review of the second modified text, however, the need for nonsubstantive changes to the language were identified, which is reflected in the recommended third modified text.
5	1738.11(b)	PCCA	Recommend: Remove the language: "When the COA is received from a supplier, it must provide the name and address of the manufacturer." Rationale: See comment in response to Sections 1735.7(c)(1) and 1736.9(d).	Board staff have reviewed the comment and do not recommend changes to the proposed text. The Board previously considered these comments on several occasions including as part of its discussion during the November 5-6, 2024, Board Meeting. As was noted at that time, Board staff have reviewed the comment and do not recommend any changes to the proposed text based on the comments. Staff note that while existing law provides flexibility to record the manufacturer under limited circumstances, continuation of the current provision is not appropriate as it hampers the ability of a facility to respond appropriately in the event of a product recall. Staff further noted that the Board's proposed regulation text is more explicit than the Chapter for the reasons cited elsewhere in this response. Staff note that the Chapter requires either the recording of the manufacturers or vendors; however, in separate guidance issued by the FDA, the facility needs to have transparency into the supply chain and

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				awareness of the manufacturer (where the manufacturer and vendor are different.) The FDA has released guidance in this area, including the importance of compounders knowing their suppliers - - https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-know-your-bulks-and-excipientssuppliers. Lastly, requiring providing the identity of the manufacturer of a component to a compounder who is compounding with that component without requiring more information be provided does not appear to be requiring the disclosure of a trade secret under Civil Code section 3426.1(d). Moreover, vendors can take steps when contracting with compounders to protect the information related to their business arrangements with manufacturers. Staff refer the commenter to the underlying data portion of the Modified Initial Statement of Reasons, which includes the above referenced FDA guidance document.
6	1738.14(c)	CSHP	The board did not demonstrate that it understood and considered the comment in that it only responded to the part where 3 business days was recommended. There was no acknowledgement of understanding of our concern that the language seems to suggest that the review must be completed within a 72 hours timeframe. We pointed out that a review can start within 72 hours but it can take longer to complete once further investigation is needed. We would like to recommend again that the word "shall start" be added to the language. The way that the proposed regulation is written, seems to suggest that the review must be completed within 72 hours since it states that "such review shall be documented and dated as defined in the SOPs." The proposed language	Board staff have reviewed the comment and believe the intent of the regulation text is clear, in that the proposed regulation text does not expressly require that the investigation into the complaint must be completed within 72 hours; rather the regulation text states that the complaint shall be reviewed within 72 hours of receipt. To best address the issue raised by the commenter, however, Board staff offer the following change be made: 1738.14 (c) In addition to subsection (b), **the pharmacist-in-charge shall initiate a review of any ~~all~~** complaints made to the facility related to a potential quality problem with a radiopharmaceutical and **any ~~all~~** reported

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			requirement for a documentation and dating of the review together with the preceding sentence's requirement for review within 72 hours from the receipt of the compliant could be seen as requiring the review to be completed within the 72 hours timeframe. A requirement of 72 hours may not provide sufficient time for pharmacies to thoroughly investigate and determine root causes. It is reasonable to expect that a review after a complaint be started within three business days. Investigation could take longer than this due to many factors involved in such an investigation that needs to be looked at. Many of these may not be available or apparent within this timeframe. **Recommendation (BOLD):** We recommend that the intent of this proposed regulation be clarified with the following proposed language: (c) In addition to subsection (b), all complaints made to the facility related to a potential quality problem with a CSP and all adverse drug experiences events shall be reviewed by the pharmacist-in-charge **and shall start** within 72 hours of receipt of the complaint or occurrence of the adverse drug experience. Such review shall be documented and dated as defined in the SOPs.	adverse drug experiences **~~as defined in 21 CFR 310.305(b)~~** ~~events~~ **~~shall be reviewed by the pharmacist-in-charge~~** within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs. In the event the PIC is not available within 72 hours, the PIC will define in the SOPs the pharmacist who will be required to review.