

SECOND SUPPLEMENTAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted additional changes to these proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the first 15-day availability public comment period, which began on March 29, 2019 and ended on April 15, 2019. Additionally, the document identified below is added to the rulemaking file as a document relied upon.

Documents Relied Upon: For purposes of Government Code section 11347.1, this document, “Second Supplemental Statement of Reasons,” is added to the rulemaking file, deemed a document relied upon, and designated as **Reference 2**.

Regulation Text: Additional changes are proposed as follows:

Restructuring change:

Comments received during the first 15-day availability public comment period expressed concerns regarding the proposed diagnostic medical physicist’s (DMP) and health physicist’s (HP) definitions and requirements and may create confusion due to inconsistency with current industry standards, other regulations, and accrediting body and professional definitions. Therefore, terminology and structural changes are made, and the initially proposed provisions regarding DMPs and HPs are deleted.

For consistency with the regulatory task, those persons performing radiation protection surveys pursuant to section 30312(b)(5) are now referred to as therapeutic survey physicists (TSP), and those performing calibrations pursuant to section 30312(b)(4) are now referred to as therapeutic calibration physicists (TCP). For clarity and readability, the requirements, eligibility, and renewal provisions for TSPs and TCPs are now restructured and divided into separate provisions as follows:

Initially proposed section	Terminology or restructuring change	Revised or new proposed section
30313.05 – HP requirements	HP replaced with TSP.	30313.05 – TSP requirements.
		30313.07 – TSP authorization eligibility & issuance.
		30313.09 – TSP authorization renewal.

Initially proposed section	Terminology or restructuring change	Revised or new proposed section
30313.10 – TMP requirements	TMP replaced with TCP.	30313.10 – TCP requirements.
30313.15 – HP & TMP authorization eligibility & issuance.	<p>HP replaced with TSP, & TSP components now placed into § 30313.07.</p> <p>TMP replaced with TCP, & TCP components remain in § 30313.15.</p>	30313.15 – TCP authorization eligibility & issuance.
30313.20 – HP & TMP authorization renewal.	<p>HP replaced with TSP, & TSP components now placed into § 30313.09.</p> <p>TMP replaced with to TCP, & TCP components remain in § 30313.20.</p>	30313.20 – TCP authorization renewal.

Section 30306:

- No additional changes to subsection (a) are proposed.
- Subsection (b): The following changes are made for the stated reasons:
 - Paragraph (6) is deleted due to comments and for consistency with the deletion of proposed section 30313.04. See discussion for section 30313.04.
 - Paragraph (7) and (8) are redesignated as paragraphs (6) and (7) to maintain a coherent structure, due to the deletion of paragraph (6).
 - Paragraph (9) is deleted because paragraph (6) and proposed section 30313.04 are proposed to be deleted. See discussion for section 30313.04.
 - Paragraph (10) is redesignated to paragraph (8) due to the deletion of paragraph (9).
 - Paragraphs (11) and (12) are deleted for consistency with new terminology and associated acronyms as proposed in paragraphs (22) and (23). Health physicist is generally understood as pertaining to a broad occupational field that includes both radioactive materials and radiation producing machines. As proposed, “health physicist” is replaced with “therapeutic survey physicist,” with subsequent deletion and proposal of associated acronyms for clarity and consistency with the associated regulatory task.
 - Paragraphs (13) through (24) are redesignated as paragraphs (9) through (21) to maintain a coherent structure.

- Paragraph (19) is added to reduce the volume of provisions referring to these persons.
- Paragraph (20), as redesignated, is revised for consistency with proposed sections 30313.10 and 30313.15 making terminology more clearly associated with the regulatory task, and to remove an unnecessary citation to section 30315.60 in paragraph (20), as redesignated.
- Paragraphs (22) and (23) are added for consistency with the proposed restructuring, discussed previously, of the requirements, eligibility, and renewal provisions for a therapeutic survey physicist.
- Paragraph (25) is repealed for consistency with proposed changes in paragraphs (19) and (20).
- Paragraph (26) is redesignated as paragraph (24) to maintain a coherent structure.

Section 30307:

- Commenters recommended changes to subsection (a)'s provisions regarding fluoroscopic X-ray equipment. However, because those comments are not within the scope of this proposal, the comments are not addressed but will be used for purposes of future rulemaking addressing equipment standards.
- No additional changes to subsection (a) are proposed.
- Subsection (b): The following changes are made for the stated reasons.
 - Paragraphs (3) and (4): Due to deletion of section 30313.04 and definition changes as proposed in section 30306(b)(9), (11), (20), and (22), proposed provisions pertaining to DMP, HP, and TMP are revised for consistency.
- Subsection (c) is deleted for the same reasons discussed regarding section 30313.04.

Section 30312:

- Commenters recommended changes to subsection (a)'s provisions regarding therapeutic X-ray equipment. However, because those comments are not within the scope of this proposal, the comments are not addressed but will be used for purposes of future rulemaking addressing equipment standards.
- No additional changes to subsection (a) are proposed.
- Subsection (b): The following changes are made for the stated reasons:
 - Paragraphs (4), (5), and (7)(C): Revisions are for consistency with terminology changes as proposed in section 30306(b)(19), (20), (22), and (23).

Section 30313.04:

- Comments received during the 15-day comment period expressed concerns regarding the proposed diagnostic medical physicist's (DMP) definition and requirements. Comments indicated that as proposed, the training and certification do not match the regulatory task creating confusion as it is inconsistent with current

industry standard, other regulations, accrediting body and professional definitions. Thus, the proposal addressing diagnostic medical physicists is entirely removed for further evaluation.

Section 30313.05:

- Section title and subsection (a): Revised for consistency with terminology changes as proposed in section 30306(b)(22) and (23), and the restructuring of the requirements, eligibility, and renewal of authorization provisions.
- Subsection (a):
 - Paragraphs (1) and (2)(B): Because section 30313.05 is now specific to TSPs, it is necessary to reference the certification titles of the organizations that are acceptable for TSP authorization. Terminology in paragraph (2)(B) is revised for consistency with section 30306(b)(20) and (22).
 - Paragraph (2):
 - Subparagraphs (A) & (B): Due to comments, the term “diagnostic medical physicist” in section 30306, and proposed provisions addressing that concept, is deleted as discussed regarding section 30313.04.

Section 30313.07: As restructured, this newly proposed section would specify the eligibility requirements for an individual to become authorized as a TSP. As discussed in subsection 30306(b)(11) and (12), health physicist is proposed to be replaced with TSP to more clearly associate the term with the regulatory task. The provisions pertaining to a TSP are restructured as discussed previously.

- Subsection (a) is needed to provide information on how to become eligible for TSP authorization. This section also specifies what is considered an acceptable application and establishes the eligibility criteria.
 - Paragraph (1) is necessary to identify and correspond with the applicant.
 - Paragraph (2) is necessary to uniquely identify the applicant and to comply with Family Code section 17520, which addresses child support enforcement. The social security number or individual tax identification number is also needed when taking disciplinary action, such as suspension, revocation, amendment, or restriction of authorization.
 - Paragraph (3) is necessary to identify the documents and information an applicant must submit to determine if the applicant meets the eligibility requirements.
 - The proposed exception to the proposed submittal of sample reports, applies to those certified by ABR in Therapeutic Medical Physics. This is acceptable because such individuals have completed a rigorous review process to ensure competence of the individual, and it is not necessary to duplicate such a process by submittal of survey reports.
 - Submittal of survey reports, as proposed, is needed to evaluate the applicant’s knowledge, skills, and ability to determine if the building

housing X-ray equipment is protective. At least three reports are needed to adequately evaluate report consistency, reliability, accuracy, and ability to communicate to the responsible facility. A specific survey report addressing high energy X-ray equipment is needed because such equipment presents greater physics challenges, as an increase in energy increases the penetrability of X-rays through building materials.

- If the applicant meets the eligibility requirements based on their education, training, and work experience (section 30313.05(a)(2)), then a letter signed by the applicant's supervisor is required. The letter is needed to establish a minimum confidence level that the applicant is competent and can ensure safety of the public and workers.
 - Subparagraph (A) is needed to identify the applicant's supervisor so that the Department may contact the supervisor as appropriate.
 - Subparagraph (B) is needed to confirm that the trained individual is the actual applicant.
 - Subparagraph (C) is needed to ensure training and experience was obtained no longer than five years from the application date.
 - Subparagraph (D) is needed to provide a second method of verifying the applicant's documentation.
 - Subparagraph (E) is needed to provide an additional level of assurance from the supervisor that the applicant obtained the required experience.
- Paragraph (4) is necessary to clarify that a fee must be submitted. The application fee is needed to cover the cost of processing applications, developing and training staff, conducting quality assurance, issuing authorization documents, maintain records, etc. (See the discussion in the ISR, commencing on page 24, regarding section 30313.45).
- Subsection (b) is necessary to specify how long the authorization is valid. The three-year renewal term is proposed to maintain consistency with the renewal term specified in section 30315.60 pertaining to the authorization of mammography medical physicists. This maintains consistency with the American Board of Radiology (ABR) and other states such as Maryland, Michigan, Nevada, New York and South Carolina. This provides uniformity between California and other states, as specified by the Legislature in H&S Code section 114965.

Section 30313.09: This newly proposed section carries out the restructuring of proposed section 30313.20 into two specific sections as discussed above. The need for each provision is as discussed on pages 20 and 21 of the ISR regarding section 30313.20.

Section 30313.10:

- Section title and subsection (a): Revised for consistency with terminology changes as proposed in section 30306(b)(19) and (20), and to clearly reference eligibility requirements for authorization as a TCP. The provisions pertaining to a TCP are restructured as discussed previously.
- No additional changes to paragraphs (1)(A) and (1)(C) are proposed.
- Subsection (a):
 - Paragraph (1)(B) is revised, due to comments, to delete reference to medical health physics, as not being an adequate certification category.
 - Paragraph (2):
 - Subparagraphs (A) & (B): Due to comments regarding DMPs, the term in section 30306, and proposed provisions addressing that concept, is deleted. See section 30313.04 for additional discussion.

Section 30313.15:

- Section title and subsection (a): Revised for consistency with terminology changes proposed in section 30306(b)(19) and (20).
- No additional changes to subsections (a)(1) and (a)(2), and subsection (b) are proposed.
- Subsection (a):
 - Paragraph (3): Due to restructuring and changes to the section title and subsection (a), this provision is no longer needed, so it is deleted.
 - Paragraph (4):
 - Redesignated to paragraph (3) to maintain a coherent structure, and revised for consistency with section 30313.10 and to ensure correct grammatical usage.
 - References to section 30313.05 and its subsections are revised for consistency with the restructuring changes discussed previously.
 - The proposed exception to the proposed submittal of sample reports, applies to those certified by ABR in Therapeutic Medical Physics. This is acceptable because such individuals have completed a rigorous review process to ensure competence of the individual, and it is not necessary to duplicate such a process by submittal of survey reports.
 - Submittal of specific reports are proposed for the reasons specified regarding section 30313.07(a)(3), except that these reports are specific to the actual therapeutic X-ray system that delivers the radiation instead of the room's shielding in which the system is housed.
 - Paragraph (5) is redesignated as paragraph (4) to maintain a coherent structure.

Section 30313.20

- Section title and subsection (a): Revised for consistency with terminology and restructuring changes discussed previously.
- Subsection (a):

- Paragraph (1) is revised, due to comments, to clarify the “grandfathering” process. The provision is also revised to clarify what information must be submitted. The added phrase, “in lieu of the authorization number” is necessary because, due to Chapter 838, Statutes of 2018 that amended Family Code section 17520, the ITIN may be accepted in place of the SSN.
- Paragraph (2) is revised to more clearly state to whom the exception applies, and to specify an alternate renewal pathway, subparagraph (A), for board-certified individuals to renew. Paragraph (2)(A)-(D), redesignated as subparagraph (B)1-4, now includes provisions in initially proposed section 30313.35 (proposed to be deleted under this second availability period) to place CE requirements in one location. These provisions are needed to specify the documentation needed to confirm completion of required CECs, is based on existing section 30403.05, which pertains to renewal applications under the RT Act, and needed to determine if the completed CECs meet section 30306(b)(1).

Section 30313.25: The provision is revised for consistency with the proposed terminology and restructuring changes as discussed previously, and the 1st 15-day proposed changes due to Chapter 838, Statutes of 2018 that amended Family Code section 17520.

Section 30313.30: Section title and subsection (a) are revised for consistency with the proposed terminology and restructuring changes discussed previously.

Section 30313.35: Repealed as unnecessary because the continuing education information is proposed to be included within sections 30313.09 and 30313.20.

Section 30313.40: Section title and subsections (a) and (b) are revised for consistency with terminology and restructuring changes previously discussed, and to clearly identify what individuals were previously authorized or approved to conduct; namely, therapeutic X-ray system calibrations and radiation protection surveys rather than reference to the previous version of section 30312, which will not be readily available. As revised, it clarifies to whom the provision applies.

Section 30313.45: Subsections (a) and (b) revised for consistency with the proposed restructuring discussed previously.

Section 30313.50: Subsection (a) is revised for consistency with the proposed terminology and restructuring changes discussed previously, and to correct grammar in paragraph (8).