

## 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 public comment period, which began on November 9, 2018 and ended on December 28, 2018. 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, "Supplemental Statement of Reasons," is added to the rulemaking file, deemed a document relied upon, and designated as **Reference 4**.

**Regulation Text:** Additional changes are proposed as follows:

The regulation text document, page 2, now displays the Group and Article (i.e., organizational hierarchy) where the provisions, within Subchapter 4, are located. This results in no regulatory effect.

### **Section 30306:**

- No additional changes to subsection (a) are proposed.
- Subsection (b): The following changes are made for the stated reasons.
  - Paragraph (1)(A) is revised to clarify that the indicated organization is incorporated, resulting in no regulatory effect.
  - Due to comments, paragraphs (6), (11), and (23) are revised for consistency with each of the defined terms, and to delete unnecessary verbiage regarding tasks performed, increasing clarity. Also, paragraph (6) is revised for clarity by relocating subparagraphs (A) and (B) to newly added section 30313.04. See section 30313.04 for discussion.
  - Due to comments, paragraph (22) is revised for consistency with the discussion of the provision found on page eight of the Initial Statement of Reasons (ISR). The phrase "the acts and omissions of persons being supervised" is deleted, as unnecessary, since the concept lies within being responsible for quality, radiation safety, and the technical aspects of activities being supervised. Due to deletion of that phrase, the provision is revised for grammatical purposes.
- No additional changes to paragraphs (2) through (5), (7) through (10), (12) through (21), and (24) through (26) of subsection (b) are proposed.

### **Section 30307:**

- No additional changes to subsection (a), and paragraphs (1) and (2) of subsection (b) are proposed.
- Subsection (b): The following changes are made for the stated reasons.

- Paragraphs (3) and (4): Due to comments, the provision is revised to ensure the user verifies the DMP's qualifications, and to establish the start of the continuing education (CE) cycle for the DMP, required by the specified provision. Under this proposal, the Department is the approver of and establishes the CE cycle for an HP and a TMP, and the user, not the Department, is the DMP approver. Thus, the provision is needed to establish the CE cycle period as it pertains to the DMP.
  - As recommended, a minimum performance standard for supervised persons, other than a DMP, HP, or TMP, is added to ensure that person can, as determined by the DMP, HP or TMP, properly setup and perform the measurement using appropriate equipment.
- Subsection (c):
  - The provision is revised through restructuring to more clearly present what records must be maintained, resulting in no regulatory effect.
  - Due to comments, proposed paragraph (3) is added so that the Department can determine compliance with the cited provisions and ensure facilities maintain safe, functioning X-ray equipment, as discussed on page 10 of the ISR regarding subsection (c).

**Section 30313.04:**

- New section 30313.04 is added to more clearly present the criteria initially proposed in paragraphs (6)(A) and (6)(B) of section 30306(b). That criteria remains unchanged except that:
  - Due to comments, the total number of hours (training plus work experience) (subsection (a)(2)) is reduced from 4,000 to 2,000. Thus, the individual would only need to have completed 2,000 of training and work experience.
  - Due to comments, proposed subsection (a)(2) clarifies that work as part of a medical physics residency program meeting the specific criteria may be counted towards the work experience requirement. This also maintains consistency with the changes to sections 30313.05(a)(2)(B) and 30313.10(a)(2)(B).
- Due to comments, proposed subsection (a)(3) is added to ensure a DMP maintains continuing competency, and is needed for the same reasons as discussed on pages 22 and 23 of the ISR for section 30313.35, regarding continuing education (CE). Because the user (i.e., facility), not the Department, is the approver of the DMP, the provision clarifies when the CE cycle begins so that the individual knows when CE must be obtained. See also the discussion of sections 30307(b)(3) and (b)(4) above.
- Due to comments, proposed subsection (b) is added to clarify that the criteria in the cited provisions can also be used since it exceeds the criteria in subsections (a)(1) and (a)(2). Based on the comments prompting addition of subsection (a)(3) and for consistency with and for the same reasons as that change, the provision clarifies that these individuals would remain subject to the CE provision since an individual,

under this section, is not subject to the CE requirement in section 30313.35. This also results in a uniform, simple application by removing the need to remember who may or may not be subject to CE.

**Section 30313.05:**

- No additional changes to subsection (a), paragraphs (1)(A), (1)(C), (1)(D), (2), and (2)(A) of subsection (a) are proposed.
- Subsection (a)(1)(B): Due to comments, the provision is revised to ensure those certified by the indicated organization have completed education and work experience specific to radiologic physics, including diagnostic medical physics. Individuals only certified by the organization have education, training and experience emphasizing radioactive material usage rather than medical diagnostic X-ray machine usage. See also the discussion of subsection (a)(2)(B) regarding allowing residency work to apply to the proposal.
- Subsection (a)(2): Due to comments and for consistency with the revision of subsection (a)(1)(B), the provision is revised to ensure those following the education/experience pathway for authorization have training and experience (T&E) specific to diagnostic X-ray systems. This is needed because, as initially proposed, these persons' T&E could be specific only to health physics without have any experience with diagnostic X-ray systems.
  - The provision is also revised, due to comments, to allow work, as part of a medical physicist residency program, to be counted in the required number of work experience hours. Such work is appropriate since it includes evaluating and testing of diagnostic X-ray systems.

**Section 30313.10:**

- No additional changes to subsection (a), and paragraphs (1)(A), (1)(C) and (2)(A) of subsection (a) are proposed.
- Subsection (a)(1)(B) is amended for clarity and consistency with the indicated organizations' program areas. Though it no longer provides certification in radiation oncology physics, and now issues certification only in medical health physics, some individuals currently hold this certification. Thus, individuals who hold either certification would meet the provision.
- Subsections (a)(2)(A) and (a)(2)(B): Due to comments, the provision is revised to:
  - Ensure individuals have the specified training and experience. This is needed because of the numerous differences between radiologic X-ray equipment used for therapeutic and diagnostic purposes. This experience is also needed because this proposal would allow the TMP to function for purposes of section 30307(b)(3) or (b)(4), and failure to have this experience could result in overexposures due to incorrect testing of the equipment.
  - The number of hours, 500 for training and 500 for experience, is proposed for consistency with section 30313.05(a)(1)(B)2 and (a)(2)(B) but the 1,000 hours proposed in that section is split between the T&E requirement in this

proposal. Splitting the hours evenly between the two requirements is needed to retain intended similarities between the certification pathway (paragraph (1)) and the T&E pathway (paragraph (2)) that focus on therapeutic uses of X-ray equipment. The total 1,000 hours is based on industry comments and is split evenly (i.e., 50%/50%) to maintain a simple distribution instead of some odd numbered distribution (e.g., 17%/83%, etc.) making documentation susceptible to transcribing errors. An alternative considered was to require 50% of the work experience hours be focused on diagnostic X-ray systems. This alternative was rejected because it would result in the T&E pathway being less similar to the certification pathway, and less focused on therapeutic physics.

- Allow work as part of a medical physicist residency program to be counted in the required number of hours. Such work is appropriate since it includes evaluating and testing of diagnostic X-ray systems.

**Section 30313.15:**

- No additional changes to subsection (a), paragraphs (1), and (3) through (5) of subsection (a), or subsection (b) are proposed.
- Subsection (a)(2) is revised to include the individual taxpayer identification number (ITIN). This change is due to Chapter 838, Statutes of 2018 that amended Family Code section 17520.

**Section 30313.20:**

- No additional changes to subsection (a), paragraphs (2)(A), (2)(C), (2)(D), and (3) of subsection (a) are proposed.
- Subsection (a)(1) is revised to:
  - Due to comments, more clearly present the “grandfathering” process (section 30313.40) for previously approved health or therapeutic medical physicists. As discussed on pages 22 and 23 of the ISR regarding section 30313.40, the provision is a transition process that accepts the individual’s previously Department-issued authorization as meeting, as applicable, proposed sections 30313.05 or 30313.10 so that all subject individuals would be included in the proposed authorization and re-authorization processes.
  - Include the ITIN due to Chapter 838, Statutes of 2018 that amended Family Code section 17520. Grammar is corrected and acronyms added for brevity and clarity, resulting in no regulatory effect.
- Subsection (a)(2), due to comments, is revised to:
  - More clearly present the “grandfathering” process (section 30313.40) for previously approved health or therapeutic medical physicists. See also the discussion regarding subsection (a)(1).
  - In subparagraph (B), add “or provider” since online continuing education sessions may not identify an instructor.

**Section 30313.25:**

- The provision is revised to include the ITIN and ensure correct grammatical usage. This change is due to Chapter 838, Statutes of 2018 that amended Family Code section 17520.