

FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications.

Restructuring change:

Comments received during the first 15-day public availability comment period expressed concerns that the proposed diagnostic medical physicist’s (DMP) and health physicist’s (HP) definitions and requirements may create confusion, due to inconsistency with current industry standards, other regulations, and accrediting body and professional definitions. Therefore, terminology and structural changes were 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.
30313.10 – TMP requirements	TMP replaced with TCP.	30313.10 – TCP requirements.
30313.15 – HP & TMP authorization eligibility & issuance.	HP replaced with TSP, & TSP components now placed into § 30313.07. TMP replaced with TCP, & TCP components remain in § 30313.15.	30313.15 – TCP authorization eligibility & issuance.

Initially proposed section	Terminology or restructuring change	Revised or new proposed section
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.

Page 1 of the regulation text:

- The titles of Group 3 and Article 4 of Group 3 are added to indicate the location, within Subchapter 4, Chapter 5, Division 1 of Title 17, in which the sections of this proposal are found. This results in no regulatory effect.

Section 30306:

- No additional changes to subsection (a) were made.
- 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.
 - Paragraph (1)(B) is revised to correctly identify the organization, resulting in no regulatory effect.
 - Paragraph (6) is deleted due to comments and for consistency with the deletion of proposed section 30313.04, proposed at the first 15-day public availability comment period.
 - Paragraphs (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 due to the deletion of paragraph (6).
 - 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 of the requirements, eligibility, and renewal provisions for a therapeutic survey physicist, discussed previously.
- Paragraph (25) is deleted 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), and paragraphs (1) and (2) of subsection (b) were made.
- Subsection (b):
 - Paragraphs (3) and (4): Due to deletion of section 30313.04, proposed at the first 15-day public availability comment period, and definition changes in section 30306(b)(9), (11), (20), and (22) relating to DMPs, HPs, and TMPs, proposed provisions using those terms were revised, with provisions specific to DMPs entirely removed for consistency and to address comments.
- Subsection (c) is deleted due to comments indicating the DMP proposal was inconsistent with current industry standard, other regulations, accrediting body and professional definitions. Thus, the proposed provisions addressing DMPs were entirely removed for further evaluation.

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) were made.
- Subsection (b):
 - Paragraphs (4), (5), and (7)(C): Revisions are for consistency with terminology changes as proposed in section 30306(b)(19), (20), (22), and (23).
 - Paragraph (4): In the initially proposed text, the word "X-ray," found in the first and second sentences, was presented as existing text. However, that word should have been presented as added text (i.e., "X-ray") for consistency with existing text. For purposes of the third 15-day public availability period, the word was shown as added following the indicated change methodology for that comment period.

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 changes previously discussed.
- No additional changes to subsection (a), paragraphs (1)(A), (1)(C), (1)(D), (2), and (2)(A) of subsection (a) were made.
- 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): Due to comments, the term “diagnostic medical physicist” in section 30306, and proposed provisions addressing that concept, is deleted due to comments indicating the DMP proposal was inconsistent with current industry standard, other regulations, accrediting body and professional definitions. Thus, the proposed provisions addressing DMPs were entirely removed for further evaluation. Due to additional comments, subparagraphs (A) and (B) are deleted and replaced with new proposed subparagraph (A) to clearly present the changes in one formatting methodology. New subparagraph (A) is needed to clarify what constitutes training and work experience, and how to account for work or education obtained while in a medical physics residency program. To ensure training meets an industry-acceptable standard instead of an individually-determined standard, the proposed revision would require the training be approved, or obtained through a program accredited, by the indicated organization, the same organization accepted for purposes of continuing education in proposed section 30306(b)(1)(A). Completion of a residency program (subparagraph (A)1) demonstrates the individual has received significant education, training, and work experience necessary for applying health physics or radiological health physics in a clinical setting. Program completion prepares individuals for starting a clinical certification process, such as that offered by the organizations identified in section 30313.05(a)(1), but does not automatically result in board certification. Crediting all of the training hours and half of the work experience hours is appropriate due to the rigorous curriculum, and oversight, of these accredited programs. Subsection (a)(2) provides an alternative to certification under subsection (a)(1), intended to be similarly rigorous to board certification, but not exactly equivalent to certification. Thus, because completion of a residency program does not automatically result in board certification, only 1,000 hours of the required work experience is credited to the required work experience hours. The remaining 1,000 hours of work experience under supervision of a qualified person is needed to provide the Department a measure of confidence, based on a qualified person’s oversight, that the individual can competently and safely perform the required activities. Partial completion (subparagraph (A)2) demonstrates the individual has received only some amount of education, training, and work experience. Thus, because it is unknown how much of a

program was completed, documentation, submitted pursuant to section 30313.07, is used for determining how much coursework was completed. The coursework hours are applied first to the required training hours because curricula are generally designed to establish a base understanding of the science, and then putting the science into practice. Further, limiting the amount of any excess coursework hours applicable to work experience is needed since partial completion indicates the individual, depending on an individual's circumstance, likely obtained limited experience in the clinical setting. The maximum amount of coursework hours attributable to the required work experience hours is set at one-half of the amount attributable for completion of a residency program due to the limited and variable nature of partially completing a residency program.

- Paragraph (2), for grammatical purposes, is revised by adding a comma after the word "science."

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, 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.
- Due to comments, the provision was clarified to specify the types of documents that would satisfy the requirement. For documentation of training, the indicated information is needed to ensure training is related to the specified physics discipline, that it was completed within the specified time frame, and is approved by the specified organization.
- Due to comments, the provision addressing submittal of a written letter is clarified for purposes of documenting work experience that occurs under multiple supervisors. When work experience occurs under multiple supervisors, the statement regarding competency is necessarily different from when supervision is provided by a single supervisor, since the Department makes the determination the individual, based on the documentation, is competent to function independently as an authorized individual.
- Subparagraph (E) is revised for consistency with the structural change of section 30313.05(a)(2), as discussed above, and to address comments regarding documenting work experience that occurs under multiple supervisors.
- Paragraph (4) is necessary to clarify that a fee must be submitted. The application fee is needed to cover costs as discussed 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. Due to comments, subsection (a) was revised to clarify what constitutes an acceptable application.

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. Due to comments, subparagraphs (A) and (B) are deleted and replaced with new proposed subparagraph (A) for the same reasons discussed above regarding section 30313.05, specific to the TCP and section 30313.15.

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.
- Due to comments, subsection (a) was revised to clarify what constitutes an acceptable application.
 - Paragraph (3): Due to restructuring and changes to the section title and subsection (a), this provision is no longer needed, so it is deleted. Due to comments, the provision was revised for the same reasons discussed above regarding section 30313.07(a)(3), specific to the TCP and section 30313.10.
 - 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 is 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): The added phrase is needed to clarify what constitutes an acceptable application. Additionally:
 - 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. Paragraph (2)(A)-(D), redesignated as subparagraph (B)1-4, now includes provisions that had been in initially proposed section 30313.35 (proposed to be deleted) to place CE requirements in one location. These provisions are needed to specify the documentation needed to confirm completion of required CECs, are based on existing section 30403.5, which pertains to renewal applications under the RT Act, and are also needed to determine if the completed CECs meet section 30306(b)(1). Regarding reference to section 30403.5, see below discussion of the Second 15-day SSR.

Section 30313.25: The provision is revised for consistency with the proposed terminology and restructuring changes, and with 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.
- Subsection (a):
 - In the text for the 2nd 15-day public comment (PC) period, section 30313.20 is shown as being added. However, that section number is shown as added in the initial proposed text. Thus, the 2nd 15-day PC text should have shown that section in single underline.
 - The word “and” is added between paragraphs (1) and (2) for consistency with provisions on which this section is based as discussed in the ISR, page 22. This results in no regulatory effect.

- New paragraph (2) is added to clarify what constitutes an acceptable application. It is based on existing provisions addressing processing of applications found in section 30405(a)(2).
- Initially proposed paragraph (2) is redesignated as paragraph (3) to maintain a coherent structure.
- Subsection (b):
 - The colon found at the end of paragraph (1) is changed to a semi-colon for punctuation consistency with other provisions, resulting in no regulatory effect.
 - The comma found after the word “fee” is removed for punctuation consistency with other provisions, resulting in no regulatory effect.

Section 30313.35: Repealed as unnecessary because the continuing education information is relocated 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. This eliminates the 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 is paragraph (8).
 - Due to comments, to clearly inform individuals of those factors used for determining when an action will be taken.
- Due to comments, new subsection (b) is needed to identify and inform individuals of the factors the Department must consider as to whether an action will be taken. Consideration of these factors, and any other factors bearing on a given case, allows consistent application for all actions taken. The factors are derived from circumstances typically considered in initiating prior Department enforcement cases, and are used in formulating, for a given case, an accusation for initiating an action, and the statement of issues for substantiating an action. If an action is taken, HSC § 115145 invokes due process procedures.
 - Paragraph (1) is needed to establish a fundamental understanding of the individual case, such as determining what occurred, when and why it occurred, whether it occurs often, whether others were involved, motivations driving the action or non-action, or if a criminal act occurred.
 - Paragraphs (2), (3), and (7) are needed to determine and identify the event’s outcome, and if some circumstance would make the outcome worse, impacting

- the decision on what action, pursuant to subsection (a), should be taken by the Department in a given case.
- Paragraphs (4), (5), and (10) are needed for evaluating an individual's compliance history, inasmuch as that history bears materially on that individual's ability to fulfill his or her obligations, including, but not limited to, technical competency relating to ionizing radiation.
 - Paragraphs (6), (8), (9), (11), and (12) are needed to determine if reasons exist for reducing imposed penalties, or for taking a less severe disciplinary action.
 - The section note is revised to include section 115145 as a reference. That provision identifies applicable due process laws and proceedings.

Second 15-day Supplemental Statement of Reasons (SSR) (Reference 2):

- Section 30313.20(a)(2):
 - Reference to section 30403.05 found on page 7 of the Second SSR, should be a reference to section 30403.5, resulting in no regulatory effect.

Reference Numbering:

- The 1st 15-day SSR is changed from "Reference 4" to "Reference 1" for consistency with the 1st 15-day public notice (PN). This "reference" numbering error was found prior to publication of the 2nd 15-day PN, allowing designation of the 2nd 15-day SSR as "reference 2" instead of "reference 5." This correction results in no regulatory effect.

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE:

- INITIAL NOTICE PERIOD OF NOVEMBER 09, 2018 THROUGH DECEMBER 28, 2018;
- PUBLIC HEARING HELD ON DECEMBER 28, 2018;
- FIRST 15-DAY PUBLIC AVAILABILITY PERIOD;
- SECOND 15-DAY PUBLIC AVAILABILITY PERIOD; and
- THIRD 15-DAY PUBLIC AVAILABILITY PERIOD.

This regulation (DPH-10-007) was made available to the public from November 09, 2018 through December 24, 2018, ending at 5:00 p.m. A public hearing request was received, and a public hearing was held on December 28, 2018. Therefore, the original public comment period ending date was extended to December 28, 2018. Additional 15-day public availability periods were conducted beginning on: March 29, 2019 ending on April 15, 2019; August 27, 2019 ending on September 11, 2019; and, February 6, 2020 ending on February 21, 2020. Comments were received during the first 15-day availability period, and no comments were received during either the second or third 15-day availability periods.

List of Commenters during Initial 45-day Proceeding held from November 9, 2018 through December 28, 2018, extended due to public hearing. (Written testimony)

1. Fady Kassem, Medical & Health Physicist, Medical Radiation Physics, Inc.

- 1a Fady Kassem, Medical & Health Physicist, Medical Radiation Physics, Inc.
2. Tom Oshiro, Associate Clinical Professor – Radiological Sciences, University of California Los Angeles, David Geffen School of Medicine
3. Yifang Zhou, Chief Diagnostic Medical Physicist, Cedars – Sinai Medical Center
4. Michael Campbell, President, American Association of Physicists in Medicine – Southern California Chapter
- 4a Michael E Campbell, CHP, DABR, President, AAPM-SCC
5. Chris Campen, Medical Physicist, Naval Medical Center – San Diego
6. Yao-Jin Qian, Chief Medical Physicist, Kaiser Permanente
7. Jonathan Caldwell, JTC Medical Physics
- 7a. Jonathan Caldwell, JTC Medical Physics
8. Geoffrey West, President & Chief Medical Physicist, West Physics
9. Cindy Tomlinson, Senior Patient Safety and Regulatory Affairs Manager, American Society for Radiation Oncology
10. Darlene M. Belmonte, CEO, Medical Physics Consulting Services, Inc.
11. Richard J. Martin, Government Relations Program Manager, American Association of Physicists in Medicine
- 11a. Richard J. Martin, Governmental Relations Program Manager, American Association of Physicists in Medicine
14. Robert Achermann, Executive Director, California Radiological Society
15. Areg Bejanian
16. Virgil Cooper, Nuclear/Diagnostic Medical Physicist
17. Marc Cramer, M.S., DABR, Regional Director & Senior Medical Physicist, West Physics
18. Huanjun Ding, Ph.D., DABR, Certified Medical Physicist, Therapy Physics, Inc.
19. Tyler S. Fisher, M.S., DABR, Certified Medical Physicist, Therapy Physics, Inc.
20. Melissa C. Martin, FACR, FAAM, Therapy Physics Inc.

List of Commenters during Public Hearing held on December 28, 2018. (Verbal and Written testimony)

12. Sonja Dietrich, Medical Physicist, UC Davis Medical Center (*public hearing*)
13. Randall Holt, CEO, Pacific Crest Medical Physics (*public hearing*)

List of Commenters during First 15-day Comment Period held from March 29, 2019 through April 15, 2019. (Written Testimony)

- 1b. Fady Kassem, Medical & Health Physicist, Medical Radiation Physics, Inc.
- 1c. Fady Kassem, Medical & Health Physicist, Medical Radiation Physics, Inc.
- 2a. Tom Oshiro, Ph.D., DABR, Associate Clinical Professor – Radiological Sciences
- 7b. Jonathan Caldwell, JTC Medical Physics
- 10a. Darlene M. Belmonte, M.S., DABR, President, Medical Physics Consulting Services, Inc.
- 14a. Robert Acherman, Executive Director, California Radiological Society
- 15a. Areg Benjanian

- 19a. Tyler S. Fisher, M.S., DABR, Certified Medical Physicist, Therapy Physics, Inc.
- 20a. Melissa C. Martin, FACR, FAAM, Therapy Physics Inc.
- 21. JoAnn Ramirez, Lead Technologist, Casa Colina Hospital and Centers for Rehabilitation
- 22. Gregory Blishak, Dignity Community Care, French Hospital Medical Center, Director, Radiology, San Luis Diagnostic Center, Womens Health and Imaging Center
- 23. Kory Kodimer, Ph. D., Manager, Health & Medical Physics Services
- 24. Angela R. Keyser, Executive Director, American Association of Physicists in Medicine (AAPM)
- 25. Cynthia H. McCollough, PhD, FAAPM, FACR, FAIMBE, Brook-Hollern Professor, Professor of Medical Physics and Biomedical Engineering, Director, CT Clinical Innovation Center and X-ray Imaging Core

List of Commenters during Second 15-day Public Comment Period held from August 27, 2019 through September 11, 2019. (Written Testimony)

No additional comments were received.

List of Commenters during Third 15-day Comment Period held from February 6, 2020 through February 21, 2020. (Written Testimony)

No additional comments were received.

Summary of comments and responses.

Note: The digit or digit and letter before the decimal point designation identifies the Commenter as listed above. The digit(s) after the decimal point indicate the identified comment from that commenter.

1.1 Requested minutes, text proposed, board members and all documentation related to this matter.

Response: The individual was provided the public notice which contains the information requested. As to references to minutes and board members, the Department is not aware of any type of statutory committee applicable to this proposal, or the regulations implementing the Radiation Control Law. Under the Radiologic Technology Act (Health and Safety Code (HSC) § 27(f)), there is a statutory advisory committee (HSC § 114855) but it has no advisory role within the Radiation Control Law.

1a.1 What is the reasoning behind this push to license medical physicists in California? The old system has been working for decades.

Response: The ISR provides the policy statement overview and problem statement indicating that, though regulations require individuals who perform therapeutic X-ray

system output calibrations and radiation protection surveys of therapeutic X-ray installations to be Department-approved, regulations fail to specify the qualifications and processes for authorizing those individuals. It is unclear if the referenced “old system” is the current regulations. Regardless, the ISR clearly presents the problems with the current regulations and discusses the reasons for the proposal to formalize the authorization process.

1a.2 The definition of a Health Physicist is very loosely worded in the documentation that was provided.

Response: Due to comments, terminology and definition of Health physicist was revised to more closely relate to the regulatory tasks. These revisions were noticed through two additional comment periods resulting in no additional comments.

1a.3 The proposed definitions for what is a qualified medical physicist and health physicist is narrower than national organizations such as the TJC (The Joint Commission), ACR (American College of Radiology), and AAPM (American Association of Physicists in Medicine). This would essentially close the field to many practicing and non ABR (American Board of Radiology) certified physicists and inhibit their ability to earn an income. California is essentially proposing to over-regulate the field of medical physics.

Response: See the response to comment 1a.5.

1a.4 The proposal fails to account the fact that the TJC, and the ACR are continuing to expand their testing requirements for each modality in medical imaging and in therapy. Because of this, the proposal will increase the medical community’s workforce needs to comply with all regulations. This regulation over-steps many boundaries in maintaining the harmony we currently have with many hospitals and it will also drive up the costs of delivering medical physics to the community.

Response: See the response to comment 1a.5.

1a.5 The TJC allows for Assistant Medical Physicists (AMP) or Physics Technologists (PT), but this proposal does not. It places more liability on medical and health physicists, and makes them liable for a trainee, opening up physicists to legal actions. Sees no issues with AMPs or PTs performing as defined, since such personnel have never caused any life threatening or dangerous events to patients or healthcare workers.

Response: Due to comments, the proposal was revised to more clearly focus on the formalization of the authorization processes specific to existing section 30312(b)(4) and (b)(5). Those provisions, and continued in this proposal as revised, allow for individuals, such as AMPs and PTs, to function within the facility but requires such

individuals to be under supervision of the qualified individual. The supervising individual has an inherent responsibility to the facility to ensure that measurements taken by the supervised individual were done correctly and that the facility can rely on the obtained information. Further, this is a universal, inherent function of a supervisor and the act of supervising, and this responsibility exists within current regulation.

- 1a.6 The proposed rulemaking in its current form continues to compare some of the measure that this proposed law will take into effect are those that mirror that of Arizona. I am a registered medical and health physicist in Arizona and Arizona process is not discriminatory in the same manner as this bill is towards non-ABR certified medical physicists. Arizona is also not discriminatory to non-ABHP certified health physicists.**

Response: The commenter appears to imply the proposal is discriminatory to non-board certified individuals. However, this proposal clearly provides an approval pathway for non-board certified individuals, as discussed in the ISR.

- 1a.7 Provides the definition of a medical physicist as defined by the ACR and the AAPM and recommends they be used in the proposal. Opposes the proposal as being exclusive, discriminatory and economically drastic for all parties involved. The proposal will drive up the cost of physics services to medical institutions, increase the liability insurance rates for both institutions and physicists, and removes many fine non-ABR and non-ABHP certified physicists out of our workforce.**

Response: The department disagrees with the comments because the proposal clarifies existing requirements, and provides pathways for physicists not certified by the indicated organizations. However, the proposal was amended to remove requirements for diagnostic medical physicists.

- 1a.8 Does not agree with the proposal since the old system has been working for decades, recommends re-wording of the proposal, and asks for one instance of error that was life threatening.**

Response: The ISR provides the reasons why the proposal is made.

- 1a.9 & 1a.10. Expressed that physicists were given an insufficient amount of time to discuss the rulemaking package with CDPH. The public hearing location and date were also inconvenient. Recommends CDPH consult with the medical physics community and to hold a public hearing in Southern California.**

Response: As required under rulemaking law, the public was provided periods of time to review the proposal. Scheduling of public hearings so they are convenient for all expected attendees is difficult and cannot accommodate every situation. As stated in the ISR, CDPH did consult with medical physicists.

1b.1 The method in which this original communication was sent out was not universal so the physics community at large did not know about this proposed rulemaking.

Response: The proposal was mailed to all known approved individuals, known interested persons, and those facilities that would have been impacted. The physics community is broad but the Department's knowledge of the entire community is finite since the Department does not regulate all aspects of that community or all individuals associated with it.

1b.2 A qualified physicist does not need to be on site to supervise an assistant of a qualifying physicist on any questions that may arise. This very rule stands to put people out of work and certain institutions in a bind to find adequate diagnostic medical physicists.

Response: Existing section 30312(b)(4) and (b)(5) require certain tasks be performed by or under the applicable supervision level of a qualified individual. Thus, the rule has stood for many years. This proposal defines those supervision levels. However, the proposal was amended to remove requirements for diagnostic medical physicists.

1b.3 If only board eligible physicists and physicists who have graduated from an approved program in the last five years can become licensed/authorized, what about my colleagues and I who graduated 17-40 years ago. This proposed rule-making would essentially put us out of business.

Response: The proposal addresses such individuals. However, the proposal was amended to remove requirements for diagnostic medical physicists, focusing only on formalizing the authorization processes for purposes of section 30312(b)(4) and (b)(5).

1b.4 In addition to the board certification and board eligibility section of the proposed rule-making, there is the requirement for a health physicist to have completed their graduate education within the last 5 years, plus have 2000 hours of supervised experience under a supposed qualified individual. A grandfathering scheme for both Diagnostic Medical Physicists and Health Physicists needs to be in place.

Response: Due to this and other comments, the proposal was amended to remove requirements for diagnostic medical physicists, and the concepts addressing health physicists were changed for consistency with the regulatory tasks. The proposal was also revised to more clearly identify the grandfathering methodology.

1b.5 The regulation states that it is up to the department's discretion to see who can and who cannot be licensed; as such does that mean that the state will create near impossible stipulations in order for me to get licensed? There has to be a

grandfathering law in place. The ACR has a clear and defined grandfathering clause for qualified medical and health physicists.

Response: See the response to comment 1b.4.

- 1b.6 Request names and roles/titles of the people involved in authoring this rule-making. Although physicists may have been consulted, physicists in my position were not. The source of CDPH's information is biased and favors the individuals who were consulted. Unsure if CDPH colluding with certain physicists to put other physicists out of work/business is legal.**

Response: The names of those consulted with were provided to the commenter.

- 1b.7 Please define "Annual" physics testing. The ACR and TJC state that as long as the equipment is tested within a 14-month window, then the test is considered annual. The FDA also has a 14-month rule in place. Patient care should take precedence over physics testing; it can be challenging for hospitals to fit us in so that we may test ER CT scanners.**

Response: The Department is unsure why defining "annual" is necessary for the physicist authorization process. It is likely the commenter is referring to provisions in section 30307(b)(3) and (4), current requirements that were initially adopted in 1980, and minimally amended in this proposal for consistency with the proposed authorization process. The comment is rejected, though retained for future rulemaking, as it is outside the scope of this proposal since the comment addresses machine standards or the testing of machines.

- 1b.8 The therapy physicist does not have the expertise nor the education in the field of diagnostic medical imaging to be able to train or supervise a health physicist. Most health physicists have never performed diagnostic tests, nor even have equipment to do so. Therapy medical physicists are not the same as diagnostic medical physicists; the ABR separates the two certifications.**

Response: See response to comment 1b.4.

- 1b.9 Health physicist should be defined better, i.e. can health physicists only test radiographic and fluoroscopic machines or are they in fact allowed to test advanced modalities. Unsure if a graduate physics degree is necessary to test radiographic and fluoroscopic units. CDPH needs to consider the widespread costs this would incur on individual radiology departments at smaller community hospitals.**

Response: See response to comment 1b.4.

1b.10 The proposed regulation states that fluoroscopy units cannot be utilized until an authorized/licensed medical physicist tests the equipment. This would impact rural hospitals or hospitals that we may cover and we are incapable of attending to in an expeditious manner. This is not a practical route for fluoroscopy units; maybe allow 1 week.

Response: The Department appreciates the comments regarding fluoroscopic X-ray equipment standards. However, the comments are outside the scope of this proposal and are rejected for purposes of this proposal. The Department will retain this comment for future rulemaking efforts addressing equipment standards.

1b.11 Remove the requirements for 7/78” Lucite for fluoroscopy dose measurements and accept the guidelines from the AAPM, ABR, equipment manufacturers and CMS and allow the use of copper phantoms.

Response: See response to comment 1b.10.

1b.12 The proposal only addresses authorizing therapy medical physicist, not diagnostic medical physicists, does that mean that diagnostic physicists do not need to be authorized?

Response: The comment is correct. As revised, the proposal would not address diagnostic medical physicists.

2.1 Recommends revising “Diagnostic medical physicist” (DMP) definition for consistency with “Therapeutic medical physicist” (TMP) definition, creating new sections addressing qualification requirements, reducing training hours and adding (for DMP) board certifications, and allowing work as part of an accredited medical physics residency to apply to the requirements. Further, different professional certifications and supervision scenarios need to be considered and the type of “training” needs to be specified.

Response: The recommendations were partially accepted and rejected in that the proposal was revised to remove all DMP provisions, restructuring some sections for clarity, making definitions more consistent, and providing for residency programs within qualification requirements. See also responses to comment 2.6.

2.2 Recommends deleting or revising 30307(a)(4)(A) since it is addressed in 21CFR1020.32, and it is difficult to determine if the lead equivalence is met.

Response: See response to comment 1b.10.

2.3 Recommends clarifying section 30307(a)(7)(A)1. regarding use of

copper-based setup, to drive the exposure rates up, allow use of larger (thickness) phantoms to meet this requirement. Provides information useful for amending these equipment standards.

Response: See response to comment 1b.10.

- 2.4 Regarding section 30307(b)(3) and (b)(4), recommends HPs obtain specific training and education on testing of fluoroscopic systems prior to performing this test, and clarify what “immediately” means regarding actions taken after alteration or replacement of a major component. Recommends requiring service documentation be retained.**

Response: Regarding HP training and education, the Department agrees, revised the proposal based on the material the commenter provided for purposes of comment 2.1, and conducted an additional 15-day comment period. See also the response to comment 2.8.

Regarding clarification of “immediately,” the comment is outside the scope of this proposal because it addresses testing of equipment, and is rejected for purposes of this proposal. The Department will retain this comment for future rulemaking efforts.

Regarding service documentation, the comment was accepted and an additional 15-day comment period was conducted. However, see also the response to comment 1b.4.

- 2.5 Recommends restructuring section 30307(c) and adding retention of service documentation.**

Response: Due to comments, 30307(c) was deleted. See also the response to comment 1b.4.

- 2.6 Recommends revision of sections 30313.05 to address both HPs and DMPs performing therapeutic medical physics surveys. This section appears to be intended for both HPs or DMPs who perform therapy physics calculations. The title should accommodate both HPs and DMPs and the criteria for training appears to be excessively high if it meant to be related to didactic coursework. Training should also be specific to therapeutic medical physics.**

Response: Because all provisions relating to DMPs and HPs were removed, the comment to revise the title of § 30313.05 to accommodate DMPs and HPs was rejected. However, the title was revised to reflect the restructuring and terminology changes made due to this and other comments, as discussed previously. Additional 15-day public comment periods were conducted during which no additional comments on this revision were received.

2.7 Therapeutic Medical Physicist Requirements should be the same criteria for 30313.05 and proposed 30307.5. The didactic hours should be reduced and training should include residency programs. Provided suggested revision.

Response: The commenter suggested numerous revisions to accomplish their recommendation, generally reorganizing the initially proposed provisions into more specific topics. In deleting provisions relating to HPs and DMPs, restructuring provisions, and changing terminology, the recommendation to add new § 30307.5 (for DMPs), § 30307.7 (for HPs) is rejected since the HP and DMP provisions were deleted. As it pertains to TMP requirements, TMP provisions were revised so that terminology more accurately related to the regulatory tasks.

The recommendation to include residency programs was accepted but clarified as to how both completion and partial completion of such a program would count towards the training and work experience requirements. However, the recommendation to reduce the number of hours was rejected to maintain consistency with other states as discussed in the ISR, pages 14 through 15, and with the identified certification organizations. Additional 15-day public comment periods were conducted during which no additional comments on the revisions were received.

2.8 Recommends the title and content specify it is intended for persons performing therapy physics surveys. DMPs should be included.

Response: Due to this and other comments, DMP provisions were removed, and terminology revised to more closely address regulatory tasks.

2.9 – 2.14 Recommends sections 30313.20 through 30313.40 include Diagnostic Medical Physicists.

Response: See response to comment 2.8.

2a.1 The March 2019 draft redefines “Diagnostic Medical Physicist” in a manner that is inconsistent with other regulations, accrediting body, and professional definitions. The new regulations should be harmonious with current conventions to avoid confusion at hospitals when defining the medical physicists’ scope of services; situations could arise where unqualified individuals are allowed to perform evaluations outside their expertise.

Response: See response to comment 2.8.

2a.2 The requisite training and certification does not match the regulatory task. There are three distinct tasks to be performed which require different skill sets: Fluoroscopy Machine Surveys, Therapy Machine Calibrations, and Therapy Shielding Surveys. This regulatory draft allows 4 categories of individuals to perform these three distinct tasks: Certified Diagnostic Medical Physicist,

Certified Therapeutic Medical Physicists, Certified Health Physicists, and Non-Certified Trained Individuals. Because the tasks require different skill sets, the requisite training or certification must be specific for each task.

Response: See response to comment 2.8.

2a.3 I recommend rewording 30313.04 to remove the non-certified individuals and include board certified DMPs to match existing professional standards.

Response: See response to comment 2.8.

2a.4 The “exposure controls” can be misinterpreted as the foot pedal or hand switch to activate fluoroscopy – which is not a major component and does not affect the overall dose rate entering the patient. I would recommend substituting “automatic exposure rate control system” for exposure controls”.

Response: See response to comment 1b.10.

3.1 Fluoroscopy units are mostly surveyed by a DMP, I suggest state approval for all DMPs and to use AAPM’s definition for qualified diagnostic medical physicist and add an alternative pathway.

Response: See response to comment 2.8.

3.2 A bachelor’s degree is not sufficient to be a qualified diagnostic medical physicist (DMP). A bachelor’s degree cannot even qualify for an AAPM full membership. Recommend changing qualifications to: (A) Holds a master’s degree in medical physics, health physics, a physical science, engineering, or applied math from an accredited college or university; and (B) Has completed 2,000 hours of training and 2,000 hours of work experience in evaluating and testing diagnostic X-ray systems.

Response: See response to comment 2.8.

3.3 With regard to § 30307. Fluoroscopic Installations, I suggest the use of a metal plate in simulating a typical patient as the phantom as many other states are currently using.

Response: See response to comment 1b.10.

4.1 & 11.1 Requested public hearing to address the proposed rulemaking on Health and Therapeutic Medical Physicist Authorization.

Response: A public hearing was held on December 28, 2018.

4.2 & 11.2 We are concerned that a number of provisions either lack clarity or would have unintended consequences.

Response: The comment lacks details on which provisions lack clarity.

4a.1 The Southern California Chapter of the AAPM (AAPM-SCC) supports the comments provided by the national AAPM signed by Bruce Thomadsen and Melissa Martin.

Response: See responses to comments from commenter 11a.

4a.2 Requests proposed regulations and public comments be vetted through the Radiologic Technology Certification Committee.

Response: The request is rejected because this proposal is not within the statutory scope of that committee. The scope of that committee falls within the Radiologic Technology Act (Health & Saf. Code §27). This proposal is made under the statutory provisions of the Radiation Control Law.

5.1 I think "supervision" needs to be defined in the regulations.

Response: The proposal defines that word in section 30306 as discussed in the ISR.

6.1 Does the proposed language allow "Health Physicists" to perform the duties of Therapy Medical Physicists? Can they qualify to take the boards other than ABR in therapy medical physics or use an alternate pathway of a BS + 2000 hours of training and experience?

Response: The proposal is not a path to ABR certification, or other type of approval by some other organization. This proposal formalizes the Department's process for authorizing individuals to perform certain regulatory tasks. The proposal does clarify what tasks certain individuals can perform.

6.2 Training/experience is not well defined.

Response: The commenter fails to clarify how training and experience is not well defined, so the comment is rejected.

6.3 There's also a fee for becoming authorized and the authorization process is not well defined – there is no explanation for continuing to stay authorized or determining ongoing competence.

Response: The proposal addresses the authorization process, and how one remains authorized. The comment fails to state how that process is not well defined.

6.4 As written, this could allow unqualified individuals to practice and potentially impact the health and safety of the public.

Response: The comment fails to provide information on how the proposal would allow an unqualified individual to practice.

6.5 Does anyone need any Board Certification anymore? It does not appear as though the proposal is an improvement over the existing system. It does not make things safer, make the process easier and less costly.

Response: The proposal addresses board certification. The Department believes the proposal is an improvement over the existing, case-by-case, evaluation process in that it clarifies the process.

7.1 Is there a pathway for approved CA MQA physicists to be grandfathered into the second classification "HP"? In the proposed 30313.40 section, I see the pathway for prior approved therapeutic physicists and understand that they can grandfather into the "TP" classification. Since there are currently 2 lists maintained with the state, mammography and therapeutic, would it be appropriate to let us individuals who have been approved in mammography to also be grandfathered into the "HP" classification since I am assuming most of us that work in mammography physics are also doing general diagnostic physics such as rad, fluoro, and/or CT?

Response: This proposal would not create a pathway for a person approved under section 30315.52 (mammography physicist) to be grandfathered as an HP, or vis versa. As revised, the HP concept was changed for consistency with regulatory tasks and would now be called a therapeutic survey physicist (TSP). Such a pathway is not considered, and the recommendation to so establish a pathway rejected, because a mammography physicist's qualifications are based on federal law and regulation (Mammography Quality Standards Act of 1992 (Pub.L. No. 102-539); 21 CFR 900.12(a)(3)) addressing screening and diagnostic mammography, not therapeutic use of X-ray or the therapy installation's shielding needs. The individual's education, training, and experience may meet some of section 30315.52's standards, but qualifications specified in sections 30312 or 30315.52 must be separately evaluated. Even if the individual is performing physics services of the identified X-ray equipment, such performance might not meet the specific qualifications in those provisions.

7.2 If there is not, in my case since I've been working in diagnostic physics (no therapy) for 16 years and have performed 1000's of fluoroscopic evaluations, how would I document 2000/2000 hrs of training/work experience? Will there be a case by case approval process for the "HP" classification as I feel this is where I qualify?

Response: Due to this and other comments, the proposal was revised to remove all provisions related to diagnostic medical physics and to revise the HP terminology. However, if the individual meets the TSP's qualifications, then they would be approved for the regulatory tasks requiring approval.

- 7.3 Regarding section 30313.20, recommend adding “if applicable” after “name of instructor due to the fact that most CE certificates only list date, course category, course description, and units earned. Course instructor information may not be available.**

Response: The comment is accepted and the proposal was revised to allow for the name of the provider or the instructor.

- 7b.1 For fluoroscopic installations, should the language “at least once each year” be clarified and consistent with ACR and other regulating bodies? In the ACR CT accreditation program requirements document, it is stated “The medical physicist must evaluate the performance of each CT unit at least annually. ACR realizes that surveys cannot usually be scheduled on the anniversary date of the previous survey. Therefore, a period of up to 14 months between surveys is acceptable.” I propose that this same consideration for the ability to schedule annual evaluations should be allowed for fluoroscopic installations and annual evaluations/measurements should be valid if performed within 14 months.**

Response: See response to comment 1b.10.

- 8.1 Sent an electronic letter to CDPH fully concurring and supporting Marc Cramer’s comments, which is also attached.**

Response: See responses to comments from commenter 17.

- 9.1 Sent an electronic letter which contains Laura I. Thevenot’s comments.**

Response: See responses to comments 9.2 through 9.5.

- 9.2 The proposed regulations do not define “approved organization” or give specific requirements for education, training and work experience.**

Response: The proposal never uses the term “approved organization,” so a definition is not needed, and clearly gives specific requirements for education, training and work experience.

- 9.3 Believes these proposed regulations will allow diagnostic medical physicists (DMP) and health physicists (HP) to perform tasks that they are not trained to do, even under the supervision of a therapeutic medical physicist (TMP), which**

could risk the health and safety of patients. We recommend that this provision be removed.

Response: The recommendation was accepted by entirely removing the DMP provisions, and revising HP to TSP. No additional comments on the revisions were received from this commenter.

9.4 Recommends following ASTRO's Accreditation Program for Excellence (APEX), which requires that "all medical physicists ... possess or are eligible for certification in therapeutic medical physics by the ABR, the American Board of Medical Physics or the Canadian College of Physicists in Medicine." This is consistent with the definition of a Qualified Medical Physicist (QMP), defined by the AAPM.

Response: The recommendation goes beyond the Department's intent for this proposal, which is to clarify existing authorization processes, not to establish an authorization for all medical physicists. The proposal includes much of the recommendations on qualifications, and board certification but limits its applicability to only therapeutic installation surveys and therapy equipment calibrations. The concept of "eligible for certification" is entirely rejected since it is unclear who determines one is eligible; namely, the applicant, the facility, the board, or the regulator. Lastly, the proposal was revised to remove provisions related to diagnostic medical physicists for further evaluation.

This, and a number of other comments, recommend broadening the oversight of physicists by defining a QMP, or a qualified expert, concepts used or developed by a number of organizations, such as AAPM, and CRCPD. Under that concept, a graduate degree and board certification sets the minimum qualification. This proposal was not intended to regulate or oversee all aspects of medical or health physics, but to clarify existing regulations, section 30312(b)(4) and (b)(5), requiring certain regulatory tasks be performed by Department-approved individuals, and who performed the tasks in section 30307(b)(3) and (b)(4) regarding fluoroscopy equipment, was also included. Based on comments, proposed provisions regarding DMPs were entirely removed for further evaluation.

9.5 Recommends use of the QMP Registry maintained by the Conference of Radiation Control Program Directors (CRCPD) to confirm the qualifications of board-certified medical physicists.

Response: The comment addresses a verification process that need not be specified in regulation. The proposal would require applicants to submit specific documents, and staff can use the CRCPD, or the specific certifying organization, as a method of verification should the need arise.

- 10.1 Both the TJC and the ACR have requirements for physics training adequately covered, and almost all facilities with fluoro units are accredited as required for CMS reimbursement. There is no need for additional regulatory requirements by the State.**

Response: The proposal was revised to remove the DMP provisions, as they relate to fluoroscopy equipment, for further evaluation.

- 10.2 It is outrageous to require that the supervising physicist be responsible for the "acts and omissions" of those persons who assist us in collecting data. How could that even be possible without direct supervision onsite?**

Response: The proposal was revised to delete the indicated phrase as unnecessary to convey what is deemed to be supervision. Existing section 30312 directly places responsibility over assistants on the approved person, if the approved person uses others to comply with the regulatory requirement. The concepts of supervision, supervisor, supervised, and supervising are inherently understood in all aspects of societies, and healthcare in particular.

- 10.3 In the proposed change of 30307(a)(7)(D)(3) it states that the physicist must test the unit immediately after replacement of a major part. The service engineer is well trained in the art of servicing the equipment. Does that mean that the facility cannot use the fluoro until we come out? Lives may be lost because of this needless delay.**

Response: See response to comment 1b.10.

- 10a.1 Regarding section 30307(a)(7)(A)(1), recommends the fluoro phantom be less bulky and more convenient such as the aluminum penetrometer?**

Response: See response to comment 1b.10.

- 10a.2 Regarding section 30307(b)(3), testing fluoroscopy unit immediately after replacement of a tube or major part is unrealistic if that unit resides in a rural or even semi-rural area. I propose we allow the engineer who installs the major component to perform the dose measurements and relay them to the physicist for approval. He is certainly well-trained in the operation of the equipment and can easily perform those measurements.**

Response: See response to comment 1b.10.

- 10a.3 Regarding section 30307(b)(3), the definition of annual needs to be clarified. The MQSA allows for 14 month intervals between testing of mammography units.**

Response: See response to comments 1b.10.

10a.4 Regarding section 30307(c)(2), recording of the name of the person who makes the measurements can be an issue if the person has one main employer and does not wish to be identified to a competing facility. The supervising physicist can keep the record of that person for review by the inspector upon request.

Response: The proposal was revised to remove proposed 30307(c), though not because of this comment. The commenter's concern appears to be a business issue, not a regulatory issue. A facility's equipment testing records generally are never shared with other facilities.

10a.5 Combining the DMP and HP requirements into the HP section in 30313.05 is confusing. They may be combined for those who are essentially doing the same work, but otherwise the DMP and HP should have completely separate sections.

Response: See response to comment 2.8. However, the proposal was revised to address each classification in unique section numbers.

10a.6 The total number of hours is reduced from 4000 to 2000 hours in 30313.04, however, the revised rules for HP in section 30315.05 (a)(2)(A) and (B) appears to require 2000 hours for training and 2000 hour for work experience. Why?

Response: Due to this and other comments, the proposal was revised to remove all provisions related to DMPs for further evaluation, and restructured as discussed previously.

10a.7 Does 30313.15 exclude DMP?

Response: As originally proposed, yes, section 30313.15 excluded DMPs as explained in the ISR, page 4. A DMP would have been approved by the registrant, not the Department so that section excluded DMPs. However, the proposal was revised to remove all provisions related to DMPs for further evaluation.

10a.8 The possibility of reciprocity is not mentioned. Can a DMP licensed in Texas or Arizona be approved by California?

Response: See response to comment 10a.6.

10a.9 I suggest all rules applying to diagnostic physicists be removed. The ACR and the TJC have adequately handled the credentialing. The State's proposal is redundant and unnecessary.

Response: See response to comment 10a.6.

11a.1 We are concerned that a number of the provisions either lack clarity or would have unintended consequences.

Response: The comment fails to provide information on what lacks clarity or identifies the consequences.

11a.2 Believes the proposed regulations do not establish or acknowledge appropriate training for medical physicists and may unfortunately put at risk the protection of public health and safety, and worker safety, as established by the California Legislature in H&S Code sections 114970 and 115000.1.

Response: The Department disagrees the proposal places the public at risk. However, due to comments, the proposal was revised resulting in no additional comments.

11a.3 The AAPM strongly recommends adopting provisions, including definitions, of the Conference of Radiation Control Program Directors (CRCPD), Suggested State Regulations for Control of Radiation (SSRCR).

Response: See response to comment 9.4.

11a.4 The AAPM recommends modifying the proposed regulations by adopting AAPM's or CRCPD's definition of a "Qualified Medical Physicist" (QMP).

Response: See response to comment 9.4.

11a.5 Recommends designating individuals who do not meet the education and training requirements of QMPs as "Qualified Experts (QEs)" rather than as QMPs, as follows:

"Qualified Expert (QE)" "means an individual who is granted professional privileges based on education and experience to provide clinical services in diagnostic medical physics by the Agency."

This allows the QE to provide clinical services as specified by the CDPH. Provision of some clinical services, however, should be limited to only QMPs—i.e., those individuals with board certification. The AAPM believes this additional designation would give greater clarity to the definition of QMP and recognize the considerable achievement represented by board certification.

Response: See response to comment 9.4.

11a.6 Believes the proposed qualifications for a "diagnostic medical physicist" (DMP) are not adequate to ensure competency for a medical physicist who performs fluoroscopy system evaluations. Provides wording for revision.

Response: Due to this and other comments, the proposal was revised to remove all provisions related to DMPs for further evaluation.

11a.7 Recommends the definition of “Qualified medical physicist” as one who performs or directly supervises tasks specified in section 30307:

Response: See response to comment 11a.6.

11a.8 Remove Health Physicist definition. TJC requires DMPs to make these measurements or allows them to supervise properly trained individuals to make the measurements.

Response: See response to comment 9.4.

11a.9 Alternate pathway training is not defined as didactic or formal. This raises the concern that unqualified individuals may be allowed to perform these measurements and jeopardize the safety and health of the public.

Response: Due to the comment, the training pathway (for both the TSP and TCP) was revised to clarify what training is acceptable, and whether the training is didactic or something more formal. Additional 15-day public comment periods were conducted during which no comments on the revision were received.

11a.10 Recommends following AAPM’s MPPG Scope of Practice that fluoroscopy measurements be performed by or under the direct supervision of a QMP, with supervision being as defined by CMS as “direct”. Section 30307(b)(3) and (b)(4) should only be performed by or under direct supervision of a diagnostic QMP as defined in this response. The American Board of Health Physicists (ABHP) does not certify imaging physicists. Imaging and therapeutic physics, however, are not within the training and or scope of practice for a health physicist.

Response: See response to comment 9.4.

11a.11 Recommends following CMS’ definition of personal supervision.

Response: The recommendation is rejected. As proposed, the definition of personal supervision, section 30306(b)(11), is nearly identical to CMS’ definition, but excludes “qualified.” That word is not needed because the provisions using the defined term clearly indicate that the person providing supervision has, by virtue of obtaining the required authorization, is qualified.

11a.12 Recommends following CMS’ definition of direct supervision.

Response: The recommendation is rejected. Proposed section 30306(b)(7), direct supervision, is nearly identical to CMS’ definition but the word “immediate” is excluded.

CMS's definitions are established from a patient perspective, whereas this proposal is not. This proposal's perspective entirely excludes the patient, and focuses on testing or evaluation of a machine without the patient being present.

11a.13 Recommends using ACR's CT Accreditation Program's definition of "Facility" for purposes of direct supervision.

Response: The recommendation is rejected as the definition is unclear and is not unique to the common understanding of facility.

11a.14 Recommends using CMS' definition of "General supervision."

Response: The recommendation is rejected as the CMS definition fails to provide more clarity or understanding than proposed section 30306(b)(18). We believe the proposal provides a stronger understanding of the scope and nature of supervision than CMS' definition, and fully encompasses the CMS' definition.

11a.15 Remove 30307(a) for primary protective barriers. Primary protective barriers are addressed in federal regulations (21 CFR 1020.32), which are already referenced by the state of California.

Response: See response to comment 1b.10.

11a.16 Recommends updating section 30307 to include current detector technology for fluoroscopy systems.

Response: See response to comment 1b.10.

11a.17 Remove 30307 (b) (2) weekly output testing. Inspections conducted by the state of California have not correlated non-compliant exposure rates as measured by inspectors with failing weekly output checks. We understand the state is already considering removal of this requirement.

Response: See response to comment 1b.10.

11.a18 Recommend adding QMP, in lieu of HP and TMP, throughout the proposal, with specific credentials.

Response: See response to comment 9.4.

11a.19 Regarding section 30313.10, recommends deletion of subsection (2). The AAPM supports residencies in medical physics as the pathway to professional qualification and supports board certification of medical physicists as a pre-requisite for becoming a QMP. The AAPM believes that requirements of nationally recognized certification bodies should be deferred to regarding

appropriateness of training and experience for measuring fluoroscopy output and therapeutic output.

Response: It appears the comment recommends deletion of § 30313.10(a)(2), so that only individuals certified by one of the certifying organizations (subsection (a)(1)) may perform activities specified in § 30312(b)(4) and (b)(7). This is the outcome comment 13.3 warns against and why the 1993 proposed legislation was vetoed. The recommendation is rejected as it would remove individuals who are otherwise qualified from providing their services. As it relates to measuring fluoroscopy output, proposed changes to § 30307(b)(4) were deleted due to this and other comments. Additional 15-day public comment periods were conducted during which no comments on the revisions were received.

11a.20 Radiation protection of surveys of therapeutic X-ray installations should remain with the Therapy Physicist. Radiation protection surveys of therapeutic X-ray installations require an evaluation of shielding integrity and we believe those surveys should remain with the Therapy Physicist approved to provide that calculation and supportive safety data.

Response: The proposal, as revised, does what is recommended.

11a.21 A QMP should be recognized as qualified to perform a therapy safety survey and write the report with no further review. This is tested on ABR exams.

Response: See response to comment 9.4.

11a.22 Clarify language regarding imaging equipment used in therapy that is not mounted on an accelerator. We believe there could be varying interpretations of the current language in the proposed regulations. For example, we believe it is not clear if CT scanners and C-arms used exclusively for therapy simulation and imaging fall under this regulation, or if a diagnostic physicist would be required for annual calibrations.

Response: See response to comment 1b.10.

12.1 In principle, supports the proposal. Regarding supervision levels, recommends using CRCPD [Conference of Radiation Control Program Directors, Inc.] definitions. We had some concerns about imaging equipment that is used for simulation in therapy departments. In the new language, it is not quite clear if they would fall under the therapy or diagnostic language. And we also had some concerns about the training levels and hours that were outlined in the regulations that aren't quite in agreement what, we, as professionals currently do.

Response: See responses to comments from commenters 4, 4a, 11, 11a, and 24.

- 13.1 Concerned that there is no recognition of prior listing or authorization for medical physicists commonly referred to as the grandfather option in this proposed regulation. As written, the regulation suggest that all medical physicists must reapply and meet the required criteria. Not all currently practicing physicists would necessarily be approved under the current requirements.**

Response: The Department disagrees. Section 30313.40 provides the process for previously approved or authorized individuals. It appears the commenter defines grandfathering to mean the previously approved person remains approved indefinitely and never needs to obtain the authorization under this proposal. As proposed, such individuals have three years after the effective date of the regulations to submit an application for obtaining the authorization. However, that submittal would need to include a copy of the previously issued approval, not documentation of meeting the education, training, and experience requirements. If the individual fails to meet that timeline, then they would have to submit such documentation. Due to this and other comments, references to previously approved persons was clarified.

- 13.2 Has no issue with raising the entry level, however, a regulation that does not explicitly allow these individuals to continue practicing the profession of many years should not be adopted until corrected.**

Response: See response to comment 13.1.

- 13.3 Among other things, a clear case could be made to challenge a regulation in court when it prevents, currently California list approved and practicing physicists from performing their job. It potentially places their employers at risk should any litigation arise that is linked to an event that is later found to have occurred under the guidance of a medical physicist who originally qualified for state approval but now no longer meets the requirements. It was for this reason among others that Governor Pete Wilson was lobbied by hospital groups and vetoed the last attempt to establish a credentialed physicist licensing program in the 1990s. The precedent for creating the grandfather clause for medical physics is clear.**

Response: The proposal would not prevent previously approved persons from performing duties for facilities, nor does it create a liability issue. The commenter refers to 1993 proposed legislation, Assembly Bill 251, that would have established licensure for medical physicists. The Governor vetoed that bill because it did not provide such a pathway. This proposal does provide a pathway. See also the response to comment 13.1.

- 13.4 When the RHB followed the guidance of the NRC in establishing the qualified or authorized medical physicists' designation, the NRC recommended such a**

provision which the RHB followed. Specifically, I refer you to 10 CFR 35.57(a) which details the exception for individuals already identified as medical physicists prior to 2002, 2005, and 2009. Additionally, paragraph C under the same section notes that such individuals may also act as preceptors for other physicists. This is a time limited clause, over time these physicists will retire and the issue will become moot. It may also be that many of these physicists choose to practice elsewhere rather than incur the costs of and effort of continuing education requirement or to write a check every three years. But those who choose to stay and fight could quickly offset any revenue the Department expects with the cost of litigation.

Response: Regarding reference to the U.S. Nuclear Regulatory Commission (NRC), those federal regulations address medical use of radioactive material, and each authorized medical physicist (AMP) is identified on the issued license only after the specific licensee has submitted to NRC the individual's training and education (T&E), and NRC has determined the individual's T&E meets the applicable requirements. It is not the individual who applies to NRC to become an AMP, but the licensee. The AMP is authorized only for the specific license on which their name appears. That AMP cannot be an AMP for a different licensee, unless the individual is listed as an AMP on the other licensee's specific license.

For radiation machines, the regulatory structure is less limiting. This proposal clarifies the existing process in section 30312(b)(4) and (b)(5) of which the registrant is not part of. This structure is common in healthcare professions, such as for those who perform or supervise radiologic technology (Radiologic Technology Act, HSC §27). The Department cannot stop a physicist from choosing to practice in another state.

14.1. The proposed regulations do not define “approved organization” or give specific requirements for education, training and work experience.

Response: The proposal never uses the referenced term so defining the term is unnecessary. The proposal clearly states specific qualifications a person must have for approval.

14.2 We are concerned that the proposed regulations will allow diagnostic medical physicists (DMP) and health physicists (HP) to perform tasks that they are not trained to do, even under the supervision of a therapeutic medical physicist (TMP), which could risk the health and safety of patients. We recommend that this provision be removed.

Response: See response to comment 2.6.

14.3 Recommends adoption of the ASTRO's Accreditation Program for Excellence, which requires that “all medical physicists ... possess or are eligible for certification in therapeutic medical physics by the ABR, the American Board of

Medical Physics or the Canadian College of Physicists in Medicine.” This requirement is consistent with the definition of a Qualified Medical Physicist (QMP), defined by the AAPM.

Response: See response to comment 9.4.

14.4 ASTRO also recommends the use of the QMP Registry maintained by the Conference of Radiation Control Program Directors (CRCPD) to validate the qualifications of board-certified medical physicists.

Response: See response to comment 9.5.

14a.1 Additional changes should be made to distinguish the qualifications of the different types of medical physicists including diagnostic medical physicists, health physicists, and therapeutic medical

Response: See response to comment 2.6. Also, the provisions regarding types of physicists was restructured as recommended.

14a.2 We align ourselves with the new comments submitted by the AAPM and recommend that revisions be made to these proposed regulations.

Response: See responses to comments from commenter 24.

15.1 I don't think anyone would do fluoroscopy output measurements without knowing what they are doing only if they are out of State individuals who are not aware of specific requirements of the Title 17 requirements in California.

Response: See response to comment 2.6.

15.2 What happens to all State Inspectors that validate fluoroscopic output measurements who are not credentialed?

Response: Users of fluoroscopy equipment are required to make those measurements for purposes of equipment quality assurance and control. Inspectors do measure the output but for purposes of ensuring the output does not exceed regulatory values, not to validate the physicist's measurement.

15.3 What happens to all field service engineers who calibrate and make necessary output corrections and adjustments on fluoroscopy units who are not credentialed?

Response: See response to comment 2.6.

- 15.4 What happens to physicists who for decades have been doing diagnostic medical physics work including fluoroscopic output measurements making sure unites are in compliance with current California Title 17 requirements. Of course out of State physicist need to get to know current California Title 17 requirements.**

Response: See response to comment 2.6.

- 15.5 Agree with the CEU's but the State must develop pathway for physicists who have been performing these measurements and evaluations for years just like what ACR did.**

Response: The proposal addresses the concern.

- 15.6 Currently there are a number of physicists in California who have been approved by FDA and approved by the State to perform mammography unit evaluations under the MQSA Act. Most of these physicists are also involved in the diagnostic medical physics and are keeping up with their CEU's in all modalities including fluoroscopic units since they provide ACR Accreditation for CT, MRI, US, Mammography, etc....**

Response: Due to comments, provisions addressing DMPs were removed for further evaluation.

- 15.7 Additionally, current Title 17, 30307(a)(7)(D) (3) and (8) need considerable clarification and amendment. Currently, under these sections all fluoroscopic units in that c-arm configuration are treated as one. Whereas we have c-arms like, portable, interventional, bi-plane fluoroscopic units and o-arms. Measurements (Methodology, reference points) of maximum dose and patient dose (Average patient) need to be addressed and amended pertaining each configuration.**

Response: See response to comment 1b.10.

- 15a.1 The current proposed language of the regulations is highly favoring a select group of individuals that have a lot to gain and arbitrarily is totally disregarding other group of individuals who have years of extensive work experience in the field and are posed to lose their jobs without any consideration to be grandfathered into the program.**

Response: Due to comments, provisions addressing DMPs were removed for further evaluation. As revised, the proposal to formalize the authorization process remains focused only on clarifying existing processes.

15a.2 One of the most negative impacts and adverse consequences would be a total shortage of individuals who perform fluoroscopy surveys, not enough individuals to cover the State of California, this in turn would increase the cost of such surveys considerably which will be passed on to the patients, increasing the cost of healthcare unnecessarily to another level.

Response: See response to comment 15a.1.

15a.3 It would be desirable to repeal it as is or drastically amend it and propose an implementation timeline of 2026-2027 given equal, fair and ample time for interested parties to attain the required qualifications.

Response: See response to comment 15a.1.

**16.1 Recommends defining Supervision as follows:
*“Supervision means providing proper training of persons being supervised with respect to relevant aspects of radiation safety and other relevant technical aspects of activities being supervised, overseeing the technical content of the supervised activities being conducted, and providing consultatory expertise, guidance, and oversight upon-demand by those conducting the supervised activities.”***

Response: Though the recommendation was rejected, the term was revised to more clearly, and succinctly, state what supervision means. Additional comment periods were provided and no additional comment on the revision was received.

16.2 As an aside, we recommend updating Section 30307 Fluoroscopic Installations, which largely refers to image intensification systems and fluoroscopic screens, the latter of which have not been used for decades. We suggest the more generic reference to “image receptor”, which would include flat panel imagers, on which most modern fluoroscopic systems are based.

Response: See response to comment 1b.10.

17.1 I absolutely agree with the necessity to define the qualifications of individuals that make dose rate measurements on fluoroscopic imaging equipment. However, I see some problems in the proposed regulations and would like to submit suggestions for improving them. In particular, I strongly believe that medical physicists that conduct performance evaluations of fluoroscopy equipment should be board-certified or working under the supervision of a board-certified physicist. The proposed qualifications are insufficient to assure competence, as well as to ensure patient safety, given the responsibilities required of medical physicists performing such surveys.

Response: See response to comment 15a.1.

- 17.2 The definition of a “diagnostic medical physicist” (DMP) doesn’t align with other organizations’ definitions of medical physicists and it’s unnecessary to define a “diagnostic medical physicist” given that industry standards already exist for a “qualified medical physicist” (QMP). Provided a recommended definition of “qualified medical physicist.”**

Response: See response to comment 15a.1.

- 17.3 The definition of a “health physicist” (HP) in 30306 and 30313.05 is unnecessary. Health physicists are not necessarily qualified to perform the tasks required in sections 30307 and 30312, even if they meet the qualifications listed in the proposed regulation section 30313.05. I recommend removing the definition of health physicist entirely, removing section 30313.05, and removing mention of health physicists in sections 30313.15, 30313.20, 30313.25, 30313.30, 30313.35, and 30313.40. Individuals who consider themselves HPs would still be able to perform the duties listed in sections 30307 and 30312 if they meet the qualifications to do so.**

Response: See response to comment 2.6.

- 17.4 I recommend putting the qualifications of those who perform exposure rate measurements into section 30307(c) and changing the proposed regulations in sections 30307(b)(3) and 30307(b)(4) to the following:**
- (3) Fluoroscopic equipment shall be evaluated by an individual who meets the requirements in section 30307(c) within 30 days of installation and of any alteration or replacement of a major component such as the X-ray tube, exposure controls, imaging assembly, or the power source. Thereafter, annual performance evaluations shall be conducted by an individual who meets the requirements of section 30307(c). At a minimum, these evaluations shall include an assessment of the following:**

- (A) Exposure rate measurements in normal, high-level control, and CINE modes, when available**
- (B) Air-kerma rate accuracy (when applicable)**
- (C) High contrast resolution and low contrast detectability**
- (D) Tube potential/kilovolt peak (kV/kVp) accuracy**
- (E) Beam filtration (half-value layer)**
- (F) Beam alignment and collimation**

These performance evaluations would be very similar to those by the TJC and the CRCPD Suggested State Regulations as I mentioned earlier. The CRCPD Suggested State Regulations have a 30-day timeframe for performance evaluations following installation or replacement of a major component, and annually thereafter.

Response: See responses to comment 2.6, and, for testing of equipment, comment 1b.10.

- 17.5 Allowing any individual, only under “supervision” (and therefore not under “direct supervision” or “personal supervision”) of a DMP, HP, or TMP to perform exposure rate measurements is very dangerous. I believe the intent of this proposed regulation is to allow for a medical physicist in-training to be able to perform exposure rate measurements but I fear this will lead to wholly unqualified individuals doing so instead. This would allow a medical physicist or medical physics groups to hire personnel without any education, training, or experience whatsoever and have them acquire the measurements. Additionally, it is inappropriate for a HP or TMP without applicable training and experience in diagnostic medical physics to perform the measurements.**

Response: The proposal addresses when and the type of supervision a person must be under. See also the response to comment 15a.1.

- 17.6 I recommend moving the qualifications to section 30307(c) as follows:
(c) Users shall maintain for inspection records that indicate the date and values obtained for all measurements required by subsection (b)(3). These performance evaluations shall be completed by:**

(1) A QMP that has met both the following qualifications:

(A) Has earned a master’s and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and

(B) Holds a valid certificate in:

- 1. Diagnostic medical physics, diagnostic radiological physics, or radiologic physics from the American Board of Radiology; or**
- 2. Diagnostic imaging physics from the American Board of Medical Physics; or**
- 3. Diagnostic radiological physics from the Canadian College of Physicists in Medicine; or**

(2) An individual that has met both the following qualifications:

(A) Has earned a master’s and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and

(B) At least 2,000 hours of work experience and 4,000 hours of combined training/experience in evaluating and testing diagnostic X-ray systems.

Response: See response to comment 15a.1.

- 17.7 Recommends a minimum degree a medical physicist should obtain is a master’s degree. Proposes a third pathway to meet the requirements as follows:**

(3) An individual that has met both the following qualifications, and only conducts fluoroscopic equipment performance evaluations under the supervision of a QMP that meets the qualifications under (1):

(A) Has earned a bachelor's or higher degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and

(B) Documented experience in a clinical environment performing at least 10 fluoroscopic equipment performance evaluations under the direct supervision of an individual that meets the qualifications under (1) or (2). The requirement of conducting at least 10 fluoroscopic equipment performance evaluations under the direct supervision of a board-certified medical physicist is similar to the initial requirements for medical physicists to perform mammography equipment evaluations at any facility and CT performance evaluations at facilities accredited by The Joint Commission.

Response: See response to comment 15a.1.

18.1 The proposal specifically lists the qualifications for health physicist and therapeutic medical physicist, which is a great improvement. However, there has been a lack of qualification for diagnostic medical physicist. In my opinion, the state should have similar qualification and continued education requirement for diagnostic medical physicists, such as board certification and so on.

Response: See response to comment 15a.1.

18.2 In section 30307, the proposal added that " Measurements of the table top or patient exposure rate shall be made by or under the supervision of a DMP, HP or TMP at least once each year for units with automatic exposure control, ..." First of all, without a clear qualification of DMP, it will be practically difficult for the state inspector to determine whether the measurement was done by a proper person. Secondly, I personally do not think those test should be done by a HP or TMP, as they are not trained in this specific field of diagnostic imaging, which is also very different from their standard working environment.

Response: See response to comment 1b.10.

19.1 I strongly support the general idea of having regulations requiring medical physicist qualifications to perform medical physics tasks within California. As a busy, consultant, board certified diagnostic medical physicist, we are constantly in competition with un-qualified individuals who sell themselves as medical physicists when in fact they are not. They provide sub-standard work, are unaware of the regulations governing fluoroscopic and CT equipment in the state, and patient care is affected as a result. As a professor of mine would always say, "the state requires you to have a state license if you want to cut

someone's hair, but if you want to calibrate a radiation therapy treatment machine capable of killing someone in minutes, we're still the wild-west." The current system does not prioritize patient care and must be improved.

Response: The department appreciates the support.

- 19.2 The proposed regulations do not specify the qualifications required to be a Diagnostic Medical Physicist (DMP). The states of Texas, Florida, and Hawaii all require board certification in an appropriate sub-specialty of medical physics to be approved. The CRCPD Suggested State Regulations specify a board-certified medical physicist. AAPM provides a definition of a qualified medical physicist and I have included it on page 2 (Attached the AAPM definition of a Qualified Medical Physicist).**

Response: As proposed, DMP qualifications were specified in section 30306(b)(6). However, provisions specific to DMPs were removed, due to comments, for further evaluation.

- 19.3 The certification programs for therapeutic and diagnostic medical physics do not cross-train in the other specialties. Therefore, a therapeutic medical physicist should not be qualified to test a fluoroscopy system, in the same way that a diagnostic physicist isn't qualified to perform therapeutic medical physics.**

Response: See response to comment 15a.1.

- 19.4 The proposed regulations should include requirements for physicists testing CT systems as well as fluoroscopy.**

Response: The recommendation to address CT (computed tomography) systems is rejected because it is already addressed in Health and Safety Code sections 115111 and 115112, via the accreditation requirements of certain approved organizations. See also the response to comment 1b.10.

- 19a.1 Recommends medical physicists have a master's degree. Fluoroscopic procedures are responsible for the highest individual patient doses and their performance testing or supervision of less-qualified individuals should not be left to individuals who do not meet the industry accepted definition of a qualified medical physicist.**

Response: See response to comment 15a.1.

- 19a.2 The requirement to have "At least 1,000 hours of work experience in diagnostic medical physics under the supervision of a TMP" in Section 30313.05(a)(1)(B)(2) should instead be under the supervision of a qualified Diagnostic Medical**

Physicist. By definition, Therapeutic Medical Physicists are not board certified in Diagnostic Medical Physics and therefore should not be supervising anyone in diagnostic medical physics.

Response: See response to comment 15a.1.

19a.3 The requirement to be a HP must include a graduate degree.

Response: See response to comment 1b.4 and the restructuring change discussed previously.

20.1 The proposed regulations have several significant problems and supports comments by the AAPM.

Response: See response to comments from commenter 11.

20.2 Recommends a QMP to evaluate Diagnostic Imaging Equipment, particularly fluoroscopic equipment.

Response: See responses to comments 1b.4 and 9.4.

20.3 Recommends that radiation therapy equipment calibration be performed by an ABR or equivalent recognized board, physicist.

Response: Section 30312(b)(4), calibration of radiation therapy equipment, and § 30312(b)(7), use of spot check procedures, require calibration, or development of the spot check procedures, by either an individual certified by one of three certifying organizations including ABR, § 30313.10(a)(1), or approved by the Department, § 30313.10(a)(2). Thus, the proposal requires that the radiation therapy equipment calibration be performed by an ABR or equivalent recognized board physicist, as recommended, or a physicist approved by the Department under § 30313.10(a)(2).

20a.1 Supports AAPM's letter and requests CDPH consider the proposals written in the letter. The final proposed regulations for medical and health physicists need to have the correct delineations of the categories of Board Certification available to medical and health physicists. These categories need to be clearly defined.

Response: See response to comments from commenter 11.

20a.2 Recommends that ABR certified physicists enrolled in Maintenance of Certification be considered currently qualified without additional documentation. All the ABR certified physicists enrolled in MOC must keep their continuous education and experience current at all times.

Response: Due to this and other comments, the proposal was revised as recommended.

20a.3 Training provided by Qualified Medical Physicists should be provided by physicists certified in the appropriate categories.

Response: The proposal, as it pertains to non-board certified individuals (sections 30313.07(a)(3) & 30313.15(a)(3)), requires documentation of training, which is evaluated to ensure qualified persons provide training to applicants. Thus, the proposal addresses the comment.

20a.4 Physicists certified by the ABR, the American Board of Medical Physics or the Canadian College of Medical Physicists have all had to provide documentation of their training to enter the Board certification process and therefore should not need to provide this documentation of original training again.

Response: See response to comment 20a.2.

21. I am addressing the issue of non-grandfathering clause for physicists that are currently working in the profession to access Radiographic, Nuclear medicine, MRI, CT and other imaging equipment. Groups of individuals who have years of extensive work experience in the field are posed to lose their jobs and income.

Response: The proposal, as revised, provides a grandfathering process.

21.1 Request to repeal this proposed rulemaking or propose an implementation time of 2026-2027.

Response: The recommendation was rejected because, as revised, the proposal clarifies existing regulatory provisions for authorizing certain individuals to perform specific regulatory tasks.

22. The proposal would exclude a group of medical physicists that are qualified to perform fluoroscopic surveys. Grandfathering in certain individuals or to not implement the current language until existing Health Physicists, that I have depended on for over a decade, have the opportunity to obtain the required qualifications.

Response: See response to comment 1b.4.

23.1 When changes to regulations pertaining to radioactive materials were previously announced and/or proposed, there were numerous communications and workshops for the licensees. In this case, numerous facilities were unaware of the proposed changes that will impact either their direct employees or consultants that are hired to advise and perform measurements on their

fluoroscopy units. I would propose either a longer comment period, after these facilities receive the announcements and allowed to comment, and/or a longer phase-in period for the new regulatory requirements.

Response: It appears the commenter is referring to facilities using fluoroscopy X-ray equipment. As proposed, this proposal would have established who could perform the tasks specified in section 30307(b)(3) and (b)(4). All facilities having such equipment were included in the mailing of the public notice. However, due to comments, the proposal was revised to remove such provisions for further evaluation.

23.2 I am not board certified, but started performing dose measurements on x-ray and fluoroscopy (diagnostic) units over 20 years ago after receiving training both in a formal classroom environment and on-the-job training. I have continued to provide fluoroscopy measurements since that time. The proposed regulatory changes do not contain a “grandfathering” clause for the diagnostic medical physicists to allow facilities to continue to use someone with over 20 years of experience.

Response: See response to comments 2.6 and 15a.1.

23.3 The proposed 30307 allows for individuals to perform the fluoroscopy output measurements without meeting the proposed criteria, as long as they have a letter from a HP, TMP or DMP stating they have done at least 10 units under their personal supervision and they are competent to perform the measurements moving forward under supervision. Perhaps this could be deemed as a “temporary grandfathering”, but is only really valid as long as the supervising HP, TMP or DMP is still willing to supervise. What if the supervising HP, TMP or DMP retires or is deceased? The person performing the measurements would now need to find another supervising HP, TMP or DMP.

Response: See response to comment 2.6.

23.4 The proposed regulations offer an alternate pathway to approval with the residency requirement. While the original alternate pathway called for training and experience within 5 years of applying for approval, this was stripped out of the proposal and replaced by a Medical Physics residency requirement. What if training was done at a job and not a residency program. Do all of the hours need to be obtained in residency? As written, someone may have obtained 2 hours in a residency program and the remainder outside the program. What is the intent of this part?

Response: As revised, the proposal allows, not requires, work obtained during a residency program to count towards the required number of hours. The intent is to allow residency program work to be applied to the required hours.

- 23.5 Another reason listed for the changes to the regulations was to “Maintain an orderly regulatory pattern within the State and among the states...” While the changes to the regulations would bring California up to par with other states with physicist licensure, the proposed changes do not include any reciprocity between states. This may exclude others wanting to provide fluoroscopy beam measurements whom have been licensed by another state, but do not meet the CA criteria. Please consider either adding a true “grandfather” clause for the HP/TMP state approvals and facility approvals for DMPs.**

Response: See the response to comment 2.6.

- 23.6 The title Health Physicist (HP) pertains to both radioactive materials and radiation producing machines. If the HP nomenclature is to remain, there should be a clear definition when the changes are announced to all radiation tube registrants so as to avoid confusion over scope of duties and approval for a Health Physicist. It should be made obviously clear that these regulatory changes only apply to fluoroscopy measurements and shielding measurements with therapeutic installations. The person does not need to be approved to perform other Health Physics duties.**

Response: See the response to comment 24.1.

- 24.1 We believe that the proposed regulations, as modified from the initial draft, still do not establish or acknowledge appropriate training for medical physicists and may, unfortunately, put at risk the protection of public health and safety, as established by H&S Code Sections 114970 and 115000.1**

Response: Due to this and other comments, the proposal was revised by removing provisions related to DMPs, clarifying the grandfathering process, and to focus on formalizing the authorization process specific to section 30312(b)(4) and (b)(5). The revisions were publically noticed and no additional comments received.

- 24.2 The AAPM believes that achievement of Board Certification objectively demonstrates that sufficient training has occurred and that competency has been established. Providing additional documentation to the State regarding hours of training is an unnecessary burden for both physicists and State regulators for Board certified Medical Physicists.**

Response: See response to comment 20a.2.

- 24.3 Certification Boards have established requirements for continuing education credits. Providing ongoing documentation to the State regarding hours of continuing education credits is an unnecessary burden for both physicists and State regulators for Board Certified Medical Physicists.**

Response: See response to comment 20a.2.

- 24.4 Suggest modifying section 30313.04 Diagnostic Medical Physicist Requirements to board certified by: (A) The American Board of Radiology in Diagnostic Medical Physics or Radiological Physics or (B) American Board of Medical Physics in Diagnostic Imaging Physics or (C) Canadian College of Physicists in Medicine in Diagnostic Radiological Physics to section 30313.04.**

Response: See response to comment 24.5.

- 24.5 Suggest modifying section 30313.05 Health Physicist Requirements to board certified by: (A) The American Board of Radiology in Diagnostic Medical Physics, Nuclear Medical Physics, Therapeutic Medical Physics or Radiological Physics or (B) American Board of Medical Physics in Diagnostic Imaging Physics, Nuclear Medicine Physics, Radiation Therapy Physics, or Medical Health Physics or (C) Canadian College of Physicists in Medicine in Diagnostic Radiological Physics, Nuclear Medicine Physics, or Radiation Oncology Physics or (D) The American Academy of Health Physics (previously The American Board of Health Physics), including a minimum of three years relevant experience in the appropriate subfield of medical health physics.**

Response: Due to this and other comments, the proposal was restructured, terminology revised and the initially proposed provisions regarding DMPs and HPs were deleted. See also the previous discussion regarding Restructuring Changes.

- 24.6 Suggest modifying section 30313.10 Therapeutic Medical Physicist Requirements to board certified by: (A) The American Board of Radiology in Therapeutic Medical Physics or Radiological Physics or (B) American Board of Medical Physics in Radiation Oncology Physics or (C) Canadian College of Physicists in Medicine in Radiation Oncology Physics.**

Response: The comment was accepted and the proposal revised. No additional comments on the revision were received. See also the other responses to commenter 24.

- 25.1 Corrected error in the list of names of medical physicists from California who participated in the preparation of the comments submitted by the American AAPM.**

Response: The Department appreciates the correction. The correction contained no additional or specific comments on the proposal.

ALTERNATIVES DETERMINATION: In accordance with Government Code Section 11346.9(a)(4), the Department has determined that no alternative would be more effective in

carrying out the purpose for which the regulation is proposed; or would be as effective and less burdensome to affected private persons than the proposed regulation; or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

This determination is based on the following:

- Statutory policy (HSC §§ 114965(c)), in part, requires the State of California, in furtherance of its responsibility to protect the public health and safety, to institute and maintain a regulatory program for sources of ionizing radiation so as to provide for a system consonant insofar as possible with those of other states.
- The RCL's purpose is to effectuate that policy, in part, by providing programs to promote an orderly regulatory pattern within the State, and among the states, with respect to use and regulation of sources of ionizing radiation. (HSC § 114970(b).)
- Existing regulatory provisions requiring certain activities be performed by or under a specific level of supervision of Department-approved persons (17 CCR 30312(b)(4), (b)(5), & (b)(7)) were adopted in 1973 (Register 73, No. 36).
- As initially implemented and currently used, the existing approval process follows common and well-known approval processes, including processes used by physicist certifying organizations identified in the proposal.
- Thirty-six of 49 states either license or approve physicists in a manner nearly identical to the proposal.
- The proposal retains the existing process, is consistent with 36 other states and private certifying organizations, and implements statutory policy.
- Alternatives considered and rejected were presented for public consideration, and no comments on the alternatives were received.
- The CDPH received no comments identifying more effective, less burdensome, or more cost-effective alternatives to the proposal.

IMPOSITION OF LOCAL MANDATE

The Department has determined that the regulation would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code, nor are there any other nondiscretionary costs imposed.

IMPACT ON BUSINESS

The Department has determined that the regulations would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.