

Initial Statement of Reasons

Summary of the Proposed Regulations

This proposal would establish the qualification, authorization and renewal processes, including new application and renewal fees and continuing education requirements, for individuals who perform therapeutic X-ray system output calibrations and radiation protection surveys of therapeutic X-ray installations. It establishes the processes for previously authorized individuals to remain authorized and identifies the standards for limiting, revoking or suspending the authorizations. This proposal also establishes who may perform patient radiation dose rate measurements on fluoroscopic X-ray equipment. Definitions are added for clarifying terms used in the proposed regulations. Nonsubstantial changes are also proposed.

Authority and Reference

The California Department of Public Health (Department) is proposing to adopt, amend, or repeal, as applicable, the regulations identified below under the authority provided in sections 114975, 114980, 115000, 115060, 115080 and 131200 of the Health and Safety Code (H&S Code). This proposal implements, interprets and makes specific sections 114965, 114970, 115000, 115060, 115080, 131050, 131051 and 131052 of the H&S Code.

Policy Statement Overview

Problem Statement: Existing regulations state that only Department-approved individuals may perform therapeutic X-ray system output calibrations and radiation protection surveys of therapeutic X-ray installations, and that radiation dose rate measurements must be performed on fluoroscopic X-ray equipment. However, the regulations fail to specify the qualifications and processes for authorizing those individuals, and fail to identify the qualifications of individuals making radiation dose rate measurements on fluoroscopic X-ray equipment. The lack of specificity in the regulation hampers its efficacy and ability to ensure the competency of personnel whose responsibilities include ensuring patient safety.

Objectives: Broad objectives of this proposed regulatory action are to:

- Ensure individuals verifying that therapeutic X-ray equipment can safely, accurately, and effectively irradiate cancerous tissue during human radiation therapy are qualified and competent.
- Provide well-defined procedures that allow an individual to obtain and maintain authorization to perform specific tasks related to fluoroscopic and therapeutic X-ray equipment.
- Specify the tasks that must be performed by or under a given level of supervision from authorized individuals.
- Specify actions by authorized individuals that may result in the Department revoking, suspending or limiting authorization.

- Ensure authorized individuals are aware of technological changes and maintain competency.
- Assure the long-term sustainability and enforcement of the standards created through the implementation of fees.

Benefits: Anticipated benefits, including nonmonetary benefits, from this proposed regulatory action are:

- Provide for continued protection of public health and safety, and worker safety, as established by the Legislature in H&S Code sections 114970 and 115000.¹
- Ensure that individuals are adequately trained and experienced to safely and competently perform tasks related to fluoroscopic and therapeutic X-ray equipment, thereby reducing unnecessary radiation exposure to the public during X-ray procedures.
- Specify the application and renewal processes and requirements that allow individuals to obtain and maintain authorization.
- Streamline the existing process to approve individuals to perform certain tasks regarding use of therapeutic X-ray equipment.
- Ensure that individuals are aware of technological advances impacting physics services for patient safety.
- Maintain an orderly regulatory pattern within the State and among the states pursuant to H&S Code section 114965.

Evaluation as to whether the proposed regulations are inconsistent or incompatible with existing state regulations: The Department evaluated this proposal and determined that, if adopted, it will not be inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing general regulations and those regulations specific to implementation of the RCL. Some inconsistencies in those specific regulations were found, and are addressed in this proposal. An Internet search of other state agency regulations was also performed. It was determined that no other California state agency regulations address the same subject matter.

Program Background

X-ray machines emit radiation. Radiation is used for healthcare purposes to diagnose injuries and diseases, including cancer. Radiation is also used to kill cancerous tissue or to slow its growth. Such treatment is called radiation therapy

¹ This short format "H&S Code section 114970" for a given Health and Safety Code section will be used throughout this document for brevity. For example, "H&S Code section 114970" means California Health and Safety Code section 114970.

and is conducted in facilities such as hospitals and cancer centers. The facility (i.e. the possessor of the radiation machine who is called a “registrant”) is responsible for complying with applicable laws and regulations.

Because X-ray machines emit radiation, the installation, or room in which the machine is housed, must be shielded to block the radiation from penetrating walls or surfaces. Radiation surveys are performed to ensure the shielding is sufficient so that the public, patients and workers are protected from unnecessary radiation exposure. The maintenance required to ensure these X-ray machines operate properly includes calibrations. Calibrations are quality assurance tests, measurements and calculations taken to establish how closely a machine’s settings meet the operating criteria established by the manufacturer. X-ray machines used for healthcare purposes require surveys and calibrations to minimize radiation hazards, to prevent harm to the public, workers or patients, and to ensure the equipment accurately delivers the intended radiation dose to cancerous tissue as prescribed by a physician.

Registrants, who wish to install, or already operate therapeutic X-ray machines, may only allow certain Department-approved individuals to perform radiation protection surveys of the installations and calibrations of therapeutic X-ray machines. However, existing regulations fail to specify how this approval process is performed and what qualifications a person must meet for approval. Thus, individuals are approved on a case-by-case basis resulting in time-consuming processes and issuance of authorizations based on inconsistent and subjective criteria. This subjective process fails to ensure individuals maintain knowledge of current and new technological changes in therapeutic equipment designs, radiation dose modeling, and radiation-related physics. The use of subjective criteria, the inability to ensure individuals remain competent, and insufficient funding of this approval process, hampers the regulation’s efficacy and ability to ensure the competency of personnel whose responsibilities include ensuring patient safety.

Also, registrants are required to make radiation dose rate measurements on fluoroscopic X-ray equipment, which is used for verifying the equipment continues to function consistently over time. However, existing regulations fail to identify the qualifications of individuals making those measurements. This proposal, as discussed below in the “Specific Discussion of Proposed Changes,” would require registrants to ensure that the individual who performs those measurements meet specific qualifications.

The use of X-ray machines for both diagnostic and therapeutic purposes is conducted both nationally and internationally. The Legislature established the State policy of being consistent, insofar as possible, with other states and the federal government so as to minimize duplication of regulation. (H&S Code sections 114965(c) & 114970(b).) In developing this proposal, the Department reviewed other states’ requirements pertaining to who may perform calibrations

of therapeutic X-ray systems and installation surveys for radiation protection, and who may make dose rate measurements on fluoroscopic X-ray equipment. What other states require is addressed below in the “Specific Discussion of Proposed Changes” as it pertains to a specific regulatory proposal.

Under this proposal, the Department’s approval process is formalized resulting in two pathways for approval and a process for renewal. The details of this proposal are discussed below in the “Specific Discussion of Proposed Changes.” One pathway for approval requires the individual to hold certification from an approved organization and may require specific work experience. The other pathway requires the individual to have completed a specific combination of education, training and work experience. All training and work experience used to qualify for approval must have been conducted in clinical therapeutic radiation facilities. An applicant following either pathway is required to provide three sample reports of work performed in the category for which the applicant is requesting approval.

The Department reviews the information provided by an applicant to verify that the applicant has completed the required education, training, work experience or holds the applicable certification. Sample reports received from the applicant are also reviewed by the Department before the application is approved or denied.

Broadly, this proposal would establish an oversight structure, as it relates to radiation measurements of radiation machines and installations used in the healing arts, as follows:

- Diagnostic medical physicist (DMP)
 - Must be Registrant-approved based on criteria specified in the definition of DMP.
 - May perform the tasks specified in section 30307(b) without supervision.
 - May perform tasks specified in section 30312(b)(4), (b)(5) and (b)(7)(C) only under the specified supervision level.
 - Department inspectors verify qualifications during inspection.
- Health physicist (HP)
 - Must be Department-authorized.
 - May perform the tasks specified in sections 30307(b) and 30312(b)(5) without supervision.
 - May perform tasks specified in section 30312(b)(4) only under the specified supervision level.
- Therapeutic medical physicist (TMP)
 - Must be Department-authorized.
 - May perform all tasks specified in sections 30307(b) and 30312(b) without supervision.

Although the Department currently refers to “approved” individuals, this proposal uses the term “authorized” to describe the same individuals. This change is

needed for consistency with existing regulations and results in no regulatory effect.

Authority

The RCL (H&S Code sections 114960 through 115273) authorizes the Department to develop programs necessary to evaluate the hazards associated with the use of sources of ionizing radiation, in order to protect public health and safety. The Department is the successor of the Department of Health Services and has the authority to regulate ionizing radiation under the California Public Health Act of 2006 (Chapter 214, Statutes 2006; SB 162, Ortiz).

Changes to the authority and reference citations note found at the end of sections 30306, 30307, 30312 and 30313 that are proposed to be amended reflect the numbering system implemented by the 1995 recodification of the Health and Safety Code, and the reorganization of the Department of Health Services into the Department of Health Care Services and the Department of Public Health, pursuant to SB 162. (Stats. 2006, ch. 241.) These changes result in no regulatory effect pursuant to 1 California Code of Regulations (CCR) section 100.²

Specific Discussion of Proposed Changes

The regulations that implement, interpret and make specific the provisions of the RCL are in Title 17, CCR sections 30100 through 30395 (17 CCR 30100-30395).

The proposed changes are explained as follows:

Amend **Section 30306, Definitions**, to identify and define terms used within this proposal and to clarify existing provisions. Existing subsections (a) through (p) are redesignated as follows to accommodate proposed terms and maintain a coherent structure, resulting in no regulatory effect:

- Subsections (a) through (d) – Subsection (b)(2) through (b)(5), respectively.
- Subsection (e) – Subsection (b)(7).
- Subsection (f) – Subsection (b)(10).
- Subsections (g) and (h) – Subsections (b)(13) and (b)(14), respectively.
- Subsections (i) and (j) – Subsections (b)(17) and (b)(16), respectively.
- Subsections (k) through (n) – Subsections (b)(18) through (b)(21), respectively.
- Subsections (o) and (p) – Subsections (b)(24) and (b)(26), respectively.

Proposed subsection (a) is needed for clarity, since some terms used in this proposal and existing regulations are found in section 30100.

² The short format “17 CCR 30100” for a given regulation found within title 17, California Code of Regulations will be used throughout this document for brevity.

Proposed subsection (b) is needed to introduce the defined terms, resulting in no regulatory effect.

Proposed subsection (b)(1) is needed to define the term as used in this proposal regarding educational activity for purposes of section 30313.35. Currently, regulations do not require an approved individual to renew approval or to maintain and enhance existing skills. The definition focuses on the provisions of continuing education credits (CECs) that will help ensure maintenance and enhancement of job-related skills. This proposal is based on the CEC requirements of individuals authorized under the Radiologic Technology Act (H&S Code section 27(f)) to apply X-ray to humans. Those requirements are specified in 17 CCR 30400 and 30403. Although authorization under this proposal does not allow the authorized individual to irradiate humans, obtaining CECs to maintain and enhance skills related to developments in technology, techniques and radiation safety issues reflects current industry standards. Authorized individuals ensure X-ray equipment used for medical purposes is properly adjusted and working correctly.

The Department recognizes that physics organizations currently evaluate and approve continuing education courses. These organizations have standards for ensuring that the continuing education is legitimate and accomplishes the purpose of maintaining competence and acquiring new skills. In lieu of establishing an additional review program, the Department proposes to use the existing expertise of these organizations by accepting the CEC courses and programs accepted by them. Individuals certified by the organizations listed in sections 30313.05(a)(1) or 30313.10(a)(1) whose CECs are accepted by the organizations listed in this subsection would meet the proposal so the individual would not need to complete additional CECs. See section 30313.35 for additional discussion of CECs.

The proposed definition specifies that the CECs must be in subjects related to medical or health physics, as applicable. This is because the X-ray equipment evaluated by a physicist is used to expose humans to radiation for diagnostic or therapeutic purposes. Education that is not related to medical or health physics or the application of X-rays to humans, and not approved by one of the organizations, does not ensure that the individual will improve upon or maintain the expertise needed to remain competent. Further, an individual may obtain CECs from any accepted organization specified, instead of being limited to one.

As proposed, a credit will equal 50 to 60 minutes of education and is based on industry standards used by the proposed acceptable entities and 17 CCR 30400(a)(4).

The following alternative was considered but rejected:

- Allow CECs approved by organizations other than the ones proposed.
This option was rejected because the Department was unable to identify

any other organization whose standards are related to medical or health physics.

Proposed subsection (b)(6) is needed to define the term as used in this proposal and to establish the qualifications of an individual who performs the tasks specified in section 30307(b)(3) and (b)(4). Those tasks determine the amount of radiation emitted by the fluoroscopic X-ray unit. That value is then used for quality control (QC) purposes by establishing the base operating parameters of the unit and to ensure it is operating consistently over time and usage. (17 CCR 30307(b)(2).) This QC test is a preemptive effort to prevent patients from receiving excessive radiation exposure due to malfunctioning equipment.

Currently, section 30307(b)(3) and (b)(4) does not address the qualifications of the person performing those measurements. Existing regulations only require the tasks be performed and used for QC. However, Department inspections commonly show that the facility's measurements are not performed properly, or are performed by individuals who have no training or education in how to take the measurements and determine whether those measurements are reasonable. If the measurements are not reasonable or valid, a determination that the fluoroscopic X-ray unit is operating consistently cannot be made. Therefore, this proposal would require that those measurements be made by persons who have received a certain level of education and training.

Proposed paragraph (A) requires a DMP to hold a bachelor's degree in one of the specified subject areas. This is based on and consistent with the requirements of other states such as Arizona, Colorado, Florida and Illinois. The Department believes that such an individual will have the basic knowledge to more completely understand the concepts related to the use of diagnostic medical physics in the healing arts so as to properly and accurately perform the specific tasks. Paragraph (B) requires the individual to have completed training and obtained work experience as proposed. The amount of time is based on and consistent with other states such as Arizona, Colorado, Florida, Illinois and New York.

Proposed subsection (b)(8) is needed to define the term as used in this proposal and to establish the availability of the supervisor. The term is based on the third sentence of existing section 30312(b)(4) regarding calibration and patterned on H&S Code section 106985(c)(1). See sections 30307 and 30312 for further discussion.

Proposed subsection (b)(9) creates an acronym and is needed to provide consistency and brevity.

Proposed subsection (b)(11) is needed to define the term as used in this proposal to identify the person performing the tasks specified in existing section

30312(b)(4), including the provisions addressing qualifications. See sections 30307, 30312 and 30313.05 for further discussion.

Proposed subsection (b)(12) creates an acronym and is needed to provide consistency and brevity.

Proposed subsection (b)(15) is needed to define the term as used in this proposal and to establish the availability of the supervisor. The term is based on H&S Code section 106985(c)(2). See sections 30307 and 30312 for further discussion.

Proposed subsection (b)(22) is needed to establish the broad scope of supervision for purposes of proposed terms “direct supervision” and “personal supervision” as it relates to performing tasks specified in sections 30307(b)(3) and (b)(4) and 30312(b)(4) and (b)(5). The definition is based on H&S Code section 114850(g) and 17 CCR 30417(b) and 30502 from the perspective that the supervisor is overseeing radiation measurements, not exposing a human being to radiation.

Proposed subsection (b)(23) is needed to define the term as used in this proposal to identify the person performing the tasks specified in existing section 30312(b)(5) and to cite the provisions addressing qualifications. See sections 30307, 30312 and 30313.05 for further discussion.

Proposed subsection (b)(25) creates an acronym and is needed to provide consistency and brevity.

Amend **Section 30307, Fluoroscopic Installations**, by correcting grammatical and capitalization errors to increase readability, comprehension and consistency. The proposal also clarifies what activities must be performed by whom.

Subsection (a) is amended to clarify who is responsible for ensuring fluoroscopic radiation equipment meets the specified criteria and for consistency with existing provisions, resulting in no regulatory effect.

Subsection (a)(4) is amended for consistency with the term “primary protective barrier” defined in section 30306(b), resulting in no regulatory effect.

Subsection (a)(4)(A) is amended to correct a grammatical error by the addition of one missing parentheses, resulting in no regulatory effect.

Subsection (a)(7)(A) is amended to change the phrase “section 30307” to “subsection” to clearly identify the referenced provision, resulting in no regulatory effect.

Subsection (b) is amended to clarify who must ensure the tasks are completed and for consistency with subsection (a) and existing provisions, resulting in no regulatory effect.

Subsection (b)(2) is amended to change the phrase “section 30307” to “subsection” to clearly identify the referenced provision, resulting in no regulatory effect.

Subsections (b)(3) and (b)(4) are amended to identify who may perform the specified measurements. Existing provisions only require that the measurements be made but do not address the qualifications of the individual performing the measurements.

As discussed regarding section 30306(b)(6), Department inspections often show that the facility’s measurements are not performed properly, or are performed by individuals who have no training or education in how to take the measurements and whether those measurements are reasonable. Thus, this proposal would require that the measurements be taken either by a qualified individual (i.e. a DMP, HP or TMP) or by an unqualified individual who is supervised by a qualified person, providing a level of confidence that the measurements are performed properly and the resultant radiation exposure value is reasonable.

This proposal specifies the level of supervision over the unqualified individual as being “supervision” as defined in section 30306(b)(22). The supervisor need only be available for consultation as needed by the individual being supervised. The supervisor remains responsible for that individual’s actions and the overall performance of the measurements. The Department believes that this level of supervision is adequate to ensure accurate measurements, since testing setup is not difficult to learn given adequate instruction, training and oversight from a DMP, HP or TMP.

The following alternatives were considered but rejected:

- Make no change since the regulation, as currently written, is clear and easy to follow. Several other states, such as Alabama, Alaska, Idaho, Kansas and Nevada, do not specify the qualifications of individuals responsible for taking radiation measurements. However, this alternative was rejected based on inspection experience showing that these measurements are often not performed accurately.
- Specify the level of supervision to be direct or personal supervision. This would require the supervisor to be either in the facility or to be physically present in the room where the measurements are taken. This alternative was rejected as too onerous, since the testing setup and measuring tasks can be easily detailed in documents.

Proposed subsection (c) is needed so that Department inspectors can verify that the individual performing the measurement meets the appropriate qualifications. The inspectors can also verify that the facility uses the appropriate value for the QC test required by subsection (b)(2) in evaluating the fluoroscopic unit's exposure consistency and that the tests were performed at the proper frequency. These verifications are needed to ensure that facilities use safe, functioning X-ray equipment.

Amend **Section 30312, Therapeutic X-ray Installations**, by correcting grammatical and capitalization errors in order to increase the readability, comprehension and consistency. The proposed regulations also clarify what activities may only be performed by authorized individuals.

Subsection (a) is amended to clarify who is responsible for ensuring therapeutic X-ray systems meet the specified criteria and for consistency with existing provisions, resulting in no regulatory effect.

Subsection (b) is amended to clarify who must ensure the tasks are completed and for consistency with subsection (a) and existing provisions, resulting in no regulatory effect.

Subsection (b)(1) is amended to change an out-of-date phrase to a phrase that is currently used in relation to therapeutic X-ray procedures, resulting in no regulatory effect.

Subsection (b)(4), first and second sentences are amended to improve clarity and maintain consistency with sections 30306(b)(24) and 30313, resulting in no regulatory effect.

Currently, subsection (b)(4), third sentence, requires that calibration be performed by or under the direct supervision of an approved person having met some level of training, experience and knowledge. However, adequacy criteria are not specified. This proposal's goal is to clarify what criteria the individual must meet for approval and the processes for obtaining the approval. Thus, the deleted phrase is replaced with "TMP" as defined in section 30306(b) to meet that goal. See sections 30313.10 through 30313.50 for additional discussion.

The level of supervision of the non-approved individual is not amended but the term "direct supervision" is proposed to be defined in section 30306(b)(8) in order to increase clarity.

However, it is not proposed to allow an HP or DMP to be fully authorized to perform and be responsible for calibrations. An HP or DMP may only function as a person being supervised by the TMP. This limitation is necessary because education and training in health physics does not address calibration of therapeutic X-ray systems used to treat cancer. Diagnostic medical physics

focuses on X-ray machines used for diagnostic purposes and the physics of lower radiation energies and not the more complex physics of high energy radiation from the use of therapeutic X-ray systems. The HP or DMP could apply for approval as a TMP if they meet the applicable qualifications.

Subsection (b)(5) is amended for the same reasons as discussed regarding subsection (b)(4). However, this provision focuses on performing a radiation protection survey of the installation, that is, the physical enclosure (e.g. room or building) in which the therapeutic X-ray system is housed. It does not address calibration of the actual machine.

Current language being removed focuses on the knowledge and skills necessary to determine proper shielding exists to protect the public, workers and patients from unnecessary exposure to the radiation emitted by the machine. However, it is unclear what knowledge and training is required for approval. This proposal's goal is to clarify what criteria the individual must meet for approval and the processes for obtaining the approval. Thus, the deleted phrase is replaced with "HP or TMP" as those terms are defined in section 30306. See sections 30313.10 through 30313.50 for additional discussion.

The existing supervision level specifies that the supervised individual must be under the direction of the approved person. To clarify what constitutes being "under the direction," the term "supervision," as defined in proposed section 30306(b)(22) is used to inform the supervisor that they remain responsible for the survey as performed by the supervised individual. This clarification does not change the level of supervision because the common definition of "direction," and the phrase "under the direction," contains the concept of being under management control, guidance or supervision, which is encompassed by the proposed term "supervision."

Subsections (b)(6) and (b)(7) are amended to improve clarity and maintain consistency with section 30306(b)(24), resulting in no regulatory effect.

Subsection (b)(7)(C) is amended to replace the deleted phrase with the proposed term identifying that individual. Also, the existing provision can be interpreted such that only that particular "individual who made the most recent calibration of the system..." may develop or approve spot check procedures. If that individual is not available for any reason, the facility could not comply with the requirement. The provision is amended to prevent such an interpretation and would allow any TMP, as defined in section 30306, to develop or approve the procedures.

Subsection (b)(7)(D) is amended for consistency with this regulatory action and to clarify who is to be consulted when spot check results are erratic or inconsistent with calibration data. Existing language is unclear as it appears to allow consultation with a non-approved individual who has been determined by the user, by use of unknown equivalency criteria, to be of equivalent competence

as the approved individual. To clarify this provision, that person is proposed to be a TMP, because the TMP is trained to design or approve the spot check procedures. Correction of a grammatical error is also made, resulting in no regulatory effect.

Amend **Section 30313, Special Requirements for Therapeutic X-ray Equipment Operated at Potentials of 50 kV and Below**, including the section title, for consistency with the changes made to, and the title of, section 30312. The change to the title results in no regulatory effect.

Subsection (a) is amended to clarify who is responsible for ensuring therapeutic X-ray systems meet the specified criteria and for consistency with existing provisions, resulting in no regulatory effect.

Subsection (b) is amended to clarify who must comply with the provisions specified, resulting in no regulatory effect. Subsection (b)(1) is amended to correct a capitalization error. This change results in no regulatory effect.

Adopt **Section 30313.05, Health Physicist Requirements**, to establish the qualifications an individual must have in order to become an authorized HP. This section clarifies the necessary expertise of the HP to perform the tasks specified in sections 30307(b)(3) and (4) and 30312(b)(5).

Subsection (a) is needed to specify what criteria must be met to be eligible for authorization. The reference to section 30313.15 is needed to identify the process for applying for authorization.

The Department believes that HPs should be authorized in order to ensure they are competent given the dangers associated with the use of X-ray equipment for radiation therapy as discussed above regarding Program Background. Requiring authorization would ensure that HPs are competent to perform their duties by requiring them to meet specific qualifications.

Additionally, authorization provides a basis for the Department to evaluate an HP's level of skill and competence and take corrective action against any HP who is placing the health and safety of a patient, worker or the public in danger. With these regulations, the Department would be able to identify and amend, restrict, suspend or revoke an HP's authorization pursuant to proposed section 30313.50.

Two pathways for authorization are proposed. The first pathway requires the individual to hold certification from an approved organization. The second pathway requires the individual to have completed a specific combination of education, training and work experience.

Subsection (a)(1) is needed to specify which organizations are acceptable for HP

authorization. The proposed organizations confirm the qualifications of individuals prior to awarding certification.

The American Board of Radiology (ABR) is considered a primary certifying board by the health and medical physicist industries. ABR certifies individuals who demonstrate they meet a specific standard of knowledge and skill relating to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that ABR be an accepted certifying board based on the industries' acceptance and since the education and training criteria for ABR certification in Diagnostic Medical Physics is consistent with the requirements of this proposal. Furthermore, ABR and the Intersocietal Accreditation Commission are certifying bodies approved for reimbursement by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The Intersocietal Accreditation Commission recognizes ABR certification as sufficient to ensure individuals are competent in the specialty in which they are certified. In addition, 34 states such as Massachusetts, Texas and Colorado accept ABR as a certifying body for HP or DMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

Health physics is the application of scientific principles to the protection of people from the hazards of radiation. The American Board of Health Physics (ABHP) is the certification board for the practice of professional health physics. ABHP certifies individuals who demonstrate they meet a specific standard of knowledge and skill related to radiation protection. The Department proposes that ABHP be an accepted certifying board based on the industry's acceptance and since the education and training criteria for ABHP certification is consistent with the requirements of this proposal. Other states such as Colorado, Florida, Georgia, Illinois, Texas or Utah accept ABHP as a certifying body for HP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

Medical physics is the application of physics concepts, theories and methods to medicine or healthcare. The American Board of Medical Physics (ABMP) is the certification board for the practice of clinical medical physics. ABMP certifies individuals who demonstrate they meet a specific standard of knowledge and skill related to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that ABMP be an accepted certifying board based on the industry's acceptance and since the education and training criteria for ABMP certification in Medical Physics and Diagnostic Imaging Physics is consistent with the requirements of this proposal. ABMP offered certification in Diagnostic Imaging Physics through July 2005. Although new certifications in that specialty are no longer available through ABMP, an individual may remain certified by ABMP in Diagnostic Imaging Physics by renewing according to ABMP's requirements. Other states such as Arkansas, Colorado, Florida, Georgia, Hawaii, Illinois, Indiana, Massachusetts, Michigan, Texas and Utah accept ABMP as a certifying body for HP or DMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

The Canadian College of Physicists in Medicine (CCPM) is considered a primary certifying board by the medical physics industry. CCPM certifies individuals who demonstrate they meet a specific standard of knowledge and skill related to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that CCPM be an accepted certifying board based on the industry's acceptance and since the education and training criteria for CCPM certification in Diagnostic Radiological Physics is consistent with the requirements of this proposal. Other states such as Colorado, District of Columbia, Florida, Illinois, Iowa, Massachusetts, Michigan, Minnesota and Oregon accept CCPM as a certifying body for HP or DMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

Subsection (a)(2) is needed to specify the amount and type of education, training and experience that an applicant must have to qualify for authorization using this second pathway. This proposal provides an alternate to the certification pathway described in proposed subsection (a)(1). The Department believes that any alternative to certification must require at least the same level of education and training as certification in order to ensure public and worker safety. Therefore, this proposal requires an HP to have a degree that matches the educational requirements of certification by ABHP or ABMP, and is consistent with those states identified above. This proposal requires that all education and experience be completed at least five years prior to the date of the application. Even though some states have a seven-year limit, the Department proposes a five-year limit to ensure that applicants are up-to-date regarding the rapidly changing technology used in X-ray systems today. This limitation is based on other states such as Texas, New York and Ohio.

Subsection (a)(2)(A) is needed to specify the required number of hours and areas of training. Subsection (a)(2)(B) is needed to specify the number of hours of work experience and the type of supervision an applicant must have in order to be considered for authorization using this pathway. These requirements are consistent with the requirements of the approved organizations. In addition, other states such as Arizona, Colorado, Delaware, Florida, Illinois, Iowa, Kentucky, New York and Utah have the same requirements.

There are two limitations proposed regarding an applicant's training and work experience. First, the number of hours of training cannot be applied to meet the work experience requirement. This ensures the applicant has training of least 2,000 hours and work experience of at least 2,000 hours.

Second, the work experience must be completed while working under the supervision of an HP or TMP. The supervisor can help reduce the possibility of a less experienced HP failing to identify a radiation safety hazard. Further, the experienced supervisor can provide practical advice based on experience, thereby helping to strengthen the supervised individual's skills and abilities. The

Department believes that the supervisor can substantiate an applicant's ability to competently perform as an HP. Therefore, a letter from the supervisor would be required as discussed in section 30313.15.

The following alternatives were considered but rejected:

- The Department considered requiring an HP to have a total of six years of education and experience similar to what is required by ABHP. However, this alternative was rejected since the requirement would be excessive based on the level of education or experience needed to perform the tasks identified in sections 30307 and 30312.
- The Department considered requiring all individuals to be certified by an approved organization in order to be eligible for authorization. This requirement would reduce the amount of work and associated costs that the Department would incur in verifying each applicant's education, training and work experience. However, this alternative was rejected as too restrictive. Requiring all applicants to be certified by an approved organization could limit the ability of some qualified HPs to be authorized due to personal financial constraints or a lack of interest in becoming a member of or retaining membership in an approved organization. The Department recognizes that there are qualified HPs in the population who choose not to obtain certification or maintain membership.

Adopt **Section 30313.10, Therapeutic Medical Physicist Requirements**, to establish the qualifications an individual must have to become an authorized TMP. This section specifies what conditions a TMP must meet in order to perform the tasks specified in sections 30307(b)(3) and (b)(4) and 30312(b)(5) and (b)(7).

Subsection (a) is needed to specify what criteria must be met to be eligible for authorization. The reference to section 30313.15 is needed to identify the process for applying for the authorization.

The Department believes that TMPs should be authorized in order to ensure that they are competent, given the dangers associated with the use of X-ray equipment for radiation therapy. Requiring authorization allows the Department to establish specific requirements and review an applicant's qualifications prior to issuing authorization. The authorization ensures TMPs are competent to perform their duties without harming the public. TMPs making inaccurate calculations, improperly calibrating therapeutic X-ray equipment or improperly performing their required physics duties can cause substantial harm (up to and possibly including death) of a patient or worker.

Additionally, authorization provides a basis for the Department to evaluate a TMP's level of skill and competence and take corrective action against any TMP who is placing the health and safety of a patient, worker or the public in danger.

With these regulations, the Department would be able to identify and amend, restrict, suspend or revoke a TMP's authorization pursuant to proposed section 30313.50.

Two pathways for authorization are proposed. The first pathway requires the individual to hold a certification from an approved organization. The second pathway requires the individual to have completed a specific combination of education, training and work experience.

Subsection (a)(1) is needed to specify which organizations are acceptable for TMP authorization. The proposed organizations confirm the qualifications of individuals prior to awarding certification.

The American Board of Radiology (ABR) is considered a primary certifying board by the medical physicist industry. ABR certifies individuals who demonstrate they meet a specific standard of knowledge and skill relating to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that ABR be an accepted certifying board based on the industry's acceptance and since the education and training criteria for ABR certification in Therapeutic Medical Physics is consistent with the requirements of this proposal. Furthermore, ABR and the Intersocietal Accreditation Commission are certifying bodies approved for reimbursement by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). The Intersocietal Accreditation Commission recognizes ABR certification as sufficient to ensure individuals are competent in the specialty in which they are certified. In addition, 34 states such as Massachusetts, Texas, and Colorado accept ABR as a certifying body for TMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

The American Board of Medical Physics (ABMP) is considered a primary certifying board by the medical physics industry. ABMP certifies individuals who demonstrate they meet a specific standard of knowledge and skill related to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that ABMP be an accepted certifying board based on the industry's acceptance and since the education and training criteria for ABMP certification in Radiation Oncology Physics is consistent with this proposal. ABMP offered Radiation Oncology Physics certification through July 2005. Although new certifications in that specialty are no longer available through ABMP, an individual may remain certified by ABMP in Radiation Oncology Physics by renewing according to ABMP's requirements. Other states such as Arkansas, Hawaii, Indiana, Massachusetts, and Michigan accept ABMP as a certifying body for TMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

The Canadian College of Physicists in Medicine (CCPM) is considered a primary certifying board by the medical physics industry. CCPM certifies individuals who

demonstrate they meet a specific standard of knowledge and skill related to radiation-producing equipment used to diagnose or treat human beings. The Department proposes that CCPM be an accepted certifying board based on the industry's acceptance and since the education and training criteria for CCPM certification in Radiation Oncology Physics is consistent with the requirements of this proposal. Other states such as Colorado, District of Columbia, Florida, Illinois, Iowa, Massachusetts, Michigan, Minnesota and Oregon accept CCPM as a certifying body for TMP authorization, approval or licensing. Therefore, this requirement is consistent with those states.

Subsection (a)(2) is needed to specify the amount and type of education, training and experience that an applicant must have to qualify for authorization using this second pathway. This proposal provides an alternative to the certification pathway described in proposed subsection (a)(1). The Department believes that any alternative to certification must require at least the same level of education and training as certification in order to ensure public, worker and patient safety. Therefore, this proposal requires a TMP to have a degree that matches the educational requirements of certification by ABR, ABMP or CCPM, and is consistent with those states identified above. This proposal requires that all education and experience be completed at least five years prior to the date of the application. Even though some states have a seven-year limit, the Department proposes a five-year limit to ensure that applicants are up-to-date regarding the rapidly changing technology used in X-ray systems today. This limitation is based on other states such as Texas, New York and Ohio.

Subsection (a)(2)(A) is needed to specify the required number of hours and areas of training. Subsection (a)(2)(B) is needed to specify the number of hours of work experience and the type of supervision an applicant must have in order to be considered for authorization using this pathway. These requirements are based on and consistent with the requirements of the organizations specified in subsection (a)(1).

There are two limitations proposed regarding an applicant's training and work experience. First, the number of hours of training cannot be applied to meet the work experience requirement. This ensures the applicant has training of at least 2,000 hours and work experience of at least 2,000 hours, establishing a strong breadth of knowledge, skills and abilities. Second, the work experience must be completed while working under the supervision of a TMP. The supervisor can help reduce the possibility of a less experienced TMP failing to identify a radiation safety hazard. Further, the experienced supervisor can provide practical advice based on experience, thereby helping to strengthen the supervised individual's skills and abilities. This provides a level of confidence as to the applicant's ability to competently perform as a TMP.

The following alternatives were considered but rejected:

- The Department considered requiring all individuals to be certified by an

approved organization in order to be eligible for authorization. This requirement would reduce the amount of work and associated costs the Department would incur in verifying each applicant's education, training and work experience. However, this alternative was rejected as too restrictive. Requiring all applicants to be certified by an approved organization could limit the ability of some qualified TMPs to be authorized due to personal financial constraints or lack of interest in becoming a member of or retaining membership in an approved organization. The Department recognizes that there are qualified TMPs in the population who choose not to obtain certification or maintain membership.

- The Department considered approving ABHP as one of the organizations proposed in subsection (a)(1). This alternative was rejected since ABHP's training does not include the necessary clinical component required in therapeutic physics education. The main focus of ABHP is on education and training for broad radiation protection instead of specific machine calibration and clinical work, which are critical to the role of a TMP. Therefore, individuals using only their ABHP certification to qualify for authorization may not be able to competently or safely perform the duties specified in section 30312(b)(4) and (7). Applicants only certified by ABHP may apply for authorization using the education, training and experience pathway.
- The Department considered authorizing TMPs based on reciprocity. Reciprocity would allow TMPs who are authorized, approved or licensed by another state after submitting to the Department an application and specific documentation, including a copy of their authorization, approval or license. This alternative was rejected since it would be very costly and labor-intensive for the Department to continually identify and confirm which states have TMP requirements that match the Department's regulations. To allow reciprocity, the Department would first have to identify which states have requirements matching the Department's and carry out additional rulemaking actions. Finally, the regulations of all states would need to be monitored to identify when another state's regulations become compatible or incompatible with the Department's TMP regulations.
- The Department considered requiring a user to maintain documentation confirming that a TMP working at the facility meets the requirements of sections 30313.05 or 30313.10. This alternative would make a user responsible for ensuring their TMPs meet the Department's requirements. This alternative was rejected since the authorization as proposed would allow the Department to take disciplinary action such as amending, restricting, suspending or revoking that authorization (see section 30313.50). This would help protect the public from unskilled TMPs performing therapeutic X-ray tasks.

Adopt **Section 30313.15, Eligibility for and Issuance of Health or Therapeutic Medical Physicist Authorization**, to consolidate and clarify the eligibility requirements and application process for obtaining an HP or TMP authorization.

Subsection (a) is needed to inform the HP or TMP community how to become eligible for authorization. It also specifies the content of an acceptable application and establishes the eligibility criteria that an applicant must meet for the Department to consider the applicant qualified for authorization. Once an applicant meets the criteria and the Department determines there is no basis to deny issuance, the authorization will be issued.

Subsection (a)(1) is needed to identify and to allow contact with an applicant. This information would allow the Department to contact an applicant to request information, provide the status of an application or send other necessary communications.

Subsection (a)(2) is needed to uniquely identify an individual and to comply with Family Code section 17520, which addresses child support enforcement. This information is also needed to help the Department take disciplinary action, such as suspension, revocation, amendment or restriction of authorization.

Subsection (a)(3) is needed to specify which authorization(s) an applicant is requesting and to help clarify the reason an applicant submitted the application.

Subsection (a)(4) is needed to identify the documents and information an applicant must provide in order for the Department to determine if an applicant is qualified for authorization. If the applicant requests authorization by use of the education, training and work experience pathway, this proposal requires submittal of a written letter signed by the applicant's supervisor. The letter is needed since it confirms an applicant has the experience claimed on the application and, therefore, provides the Department a level of assurance that the individual is competent and can ensure public and worker safety. Subsection (a)(4)(A) is needed to identify the applicant's supervisor so the Department can contact the supervisor should concerns arise. The signature of the supervisor is needed to confirm that the supervisor agrees with the content of the letter. The date of the signature is needed to specify when the supervisor agreed with the content of the letter and to prevent submittal of fraudulent, backdated letters. Subsection (a)(4)(B) is needed to confirm that an applicant is the individual supervised and the subject of the letter. Subsection (a)(4)(C) is needed to identify the dates when an applicant obtained the experience to ensure the applicant's experience was obtained no longer than five years prior to the date of the application, as proposed in, and discussed regarding sections 30313.05(a)(2) and 30313.10(a)(2). Subsection (a)(4)(D) is needed to identify where the applicant worked to gain experience. It also provides a way for the Department to verify the applicant's work history should concerns arise. Subsection (a)(4)(E) is needed to provide an additional level of assurance from the supervisor that the

applicant meets the proposed requirements and that the applicant is competent to work independently as an HP or TMP, as applicable.

Subsection (a)(5) is needed to clarify that a fee must be submitted. (See section 30313.45 for the discussion of fees.)

Subsection (b) is needed to clarify 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 addressing the authorization of mammography medical physicists. This also maintains consistency with the 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.

The following alternative was considered but rejected:

- The Department considered proposing a renewal period of every two years. Some of the Department's regulations use a two-year renewal period. However, this alternative was rejected because the three-year renewal period is consistent with the authorization requirements of a mammography medical physicist. It is also consistent with several states such as Nevada, South Carolina and Virginia.

Adopt **Section 30313.20, Renewal of Health or Therapeutic Medical Physicist Authorization**, to specify how the authorization is renewed.

Subsection (a) is needed to specify that an authorization issued to an HP or TMP must be renewed, what must be submitted to the Department in order to renew, and when to submit it. The 30-day requirement is proposed for consistency with other sections which also address renewal procedures, such as sections 30403.5 and 30456.2(b).

Subsection (a)(1) is needed to specify the information needed in order to ensure that the renewal application can be matched to the Department's records and to contact the applicant, if needed.

Subsection (a)(2) is needed to specify the documentation needed to confirm the completion of required CECs. This provision also provides an exception needed for transitioning from existing provisions to this proposal. The exception creates a shorter authorization process for previously approved or authorized individuals. See section 30313.40 for further discussion.

Subsections (a)(2)(A) through (D) are based on existing section 30403.5, pertaining to renewal applications under the Radiologic Technology Act (H&S Code 27) and are needed to determine if the completed CECs meet the criteria in section 30306(b)(1). Subparagraph (A) is needed to identify if the approving organization is one specified in section 30306(b)(1)(A) or (B). Subparagraph (B)

is needed to allow the Department to contact an instructor to confirm that the training was completed by the renewal applicant or to request additional information, if concerns arise. Subparagraph (C) is needed to confirm that the training is in a specialty related to medical or health physics. Subparagraph (D) is needed to ensure that CECs were obtained within the three-year window required by section 30313.35. Subsection (a)(3) is needed to cover the costs in renewing authorization. (See section 30313.45 for discussion of fees.)

The following alternative was considered but rejected:

- The Department considered requiring all individuals who obtained authorization through the certification pathway to maintain their certification to remain authorized. However, this alternative was rejected as too restrictive. Requiring those individuals to maintain their certification could limit the ability of some qualified HPs or TMPs to renew their authorizations due to personal financial constraints or lack of interest in retaining membership in an approved organization. The Department recognizes that there are qualified HPs and TMPs in the population who choose not to maintain membership.

Adopt **Section 30313.25, Change of Name, Address or Social Security Number**, to ensure that the Department has the information needed to contact the authorized HP or TMP. Maintaining up-to-date contact information allows the Department to request information, to comply with the requirements of section 17520 of the Family Code (which also requires the accurate social security number), and to send an HP or TMP renewal information. Requiring the changes to be reported within 30 calendar days is based on sections 30335.6 and 30406, for consistency with existing processes.

Adopt **Section 30313.30, Application Deadlines for Health or Therapeutic Medical Physicist Authorization**, to clarify the Department's actions and processing timelines relating to applications. The Department believes that the public benefits in knowing what to expect when applying for authorization. This proposal is based on sections 30315.60 and 30405, for consistency with existing processes.

Subsection (a) is needed to clarify for which type of authorization the listed deadlines apply. Subsection (a)(1) is needed to establish when an application, information, document or fee is considered to be received by the Department. It is based on section 30405(a)(1). Subsection (a)(2) is needed to establish when written notification from the Department to an applicant is considered to have occurred. It is based on section 30405(a)(2).

Subsection (b) is needed to establish the maximum number of calendar days the Department has to inform the applicant of the status of their application. This is based on section 30405(b)(1) and (b)(2) to maintain consistency with existing

processes. Subsection (b)(1) is needed to clarify what is needed from the applicant to make the application acceptable. This subsection specifies what the applicant must submit to the Department and also the maximum number of calendar days the applicant has to reply. This is based on proposed section 30313.15 and existing section 30405(b)(1). Subsection (b)(2) is needed to specify how and when the Department will notify an applicant that authorization is granted. This is based on section 30405(b)(2) and (3).

Subsection (c) is needed to clarify when the Department deems an application abandoned by an applicant or no longer valid. It also informs an applicant that a new application may be submitted to reapply. The applicant is able to reapply because the original application was not denied due to the applicant being unqualified, but rather because the application did not include all items needed to determine if the applicant met the eligibility requirements. This is based on section 30405(e).

Adopt **Section 30313.35, Requirements for Continuing Education**, to specify the timeframe allowed and the required number and type of CECs to maintain authorization. The proposed three-year timeframe is based on section 30315.52(b) and for consistency with the renewal period of the ABR and several states such as New York, Michigan, South Carolina and Virginia. The number of CECs proposed for renewal is based on the requirements of section 30315.52(b) and for consistency with the requirements of other states such as Arizona, Nevada, Ohio, South Carolina, and Virginia.

ABHP and ABMP also require certified individuals to complete CECs to renew their certifications. Completion of CECs for maintaining ABHP or ABMP certification could be used to meet this proposal so an individual would not need to complete additional CECs. The Department believes that this continuing education keeps individuals current as clinical applications, technologies, and methodologies continue to change. See also proposed section 30306(b)(1) for additional discussion on CECs.

Adopt **Section 30313.40, Previously Approved or Authorized Health or Therapeutic Medical Physicists**, to specify a process for those HPs or TMPs previously approved by the Department on a case-by-case basis. Existing sections 30312(b)(4) and (b)(5) fail to clarify the process by which a person is determined by the Department to meet certain criteria, state the name of what is given to an individual signifying the Department's determination that the individual has met the criteria, and what that individual is called. Historically for this case-by-case process, the terms "approval," "approved," "authorize," "authorized" and "authorization" have been used interchangeably.

This proposal establishes terms (section 30306) and uses the term "authorization," consistent with the same concepts found in section 30315.60

regarding a similar process, so that only one term is used. This reduces confusion between Department staff and the healthcare industry.

Subsection (a) is needed to transition from existing processes to the proposed process by specifying what a previously authorized individual must do to remain authorized under the proposed process. The date the new process takes effect is based on the effective date of the regulation, if adopted. This date was chosen, as opposed to a date further in the future, to quickly move from a subjective based process to a performance based process. However, because the effective date of this proposal cannot be determined, the Department proposes to allow the Office of Administrative Law (OAL) to insert the date for clarity.

Subsection (a)(1) is also needed to specify the period of time for a previously authorized medical physicist to comply. Three years is proposed for consistency with the three-year validity period proposed in section 30313.15(b) and is consistent with existing section 30315.60(d). The provision addressing applications received after that three-year period is needed to clearly inform previously approved individuals of the consequences for not submitting a timely application. Because existing processes fail to include a renewal-type mechanism, or name or address change requirement such that an individual is not required to keep personal contact information current, the Department cannot determine how current existing contact information is for any individual. Therefore, this proposal will also assist the Department in building a more current file of approved individuals.

It is proposed that these individuals apply by use of section 30313.20 instead of section 30313.15. Section 30313.15 addresses the initial issuance of an authorization and requires the applicant to submit documents that, for previously approved persons, have already been reviewed and the individual deemed approved or authorized. Thus, using the process in section 30313.15 for previously approved persons is unnecessary because it duplicates prior document review. Therefore, section 30313.20 is used to transition previously approved individuals into the new process without duplication. Additionally, as provided in section 30313.20(a)(2), these individuals would not need to submit CEC information during the transition period. This is needed to reduce regulatory burdens during transition by maintaining the same level of compliance for all individuals regardless of whether they followed the existing process or must follow the new process.

Subsection (b) is needed to assist with obtaining and updating current personal contact information, to transition to the new proposed process, and to inform these individuals they are subject to proposed section 30313.50, if adopted. Currently, regulations fail to clarify whether an authorized individual can be disciplined or if the authorization can be limited, restricted, or revoked. Thus, this proposal is needed to inform these individuals their authorization is subject to

limitation or revocation and to ensure the Department can take action to stop incompetent or negligent individuals, thereby protecting the public health and safety. The provision regarding what provisions that the individual is subject to upon issuance of the authorization is needed to transition from the old process to the new process.

Adopt **Section 30313.45, Fees**, to specify certain fees.

Subsection (a) is needed to cover the costs of the following functions:

Initial Application – Description of Tasks (Table 1)

1. Processing applications and entering information into computer database, cashiering of payment, and correspondence with applicant as necessary;
2. Developing and providing training to staff on regulatory and program policy changes, researching and responding to internal and external stakeholders, including preparing written correspondence;
3. Developing and providing training to the Program Technician II (PT II) on regulatory and policy changes associated with the certification program area, and researching and responding to inquiries from internal and external stakeholders, including preparing written correspondence. Review applicant training as needed. Analyze laws, regulations and policy changes to determine program impact regarding changes to the existing certification application process or develop new application processes;
4. Conducting quality assurance of technical evaluations and compliance actions and evaluating/verifying submitted documentation.
5. Issuing documents;
6. Maintaining records; and
7. Workload Tasks as identified in Table 3.

Table	1.	Estimate	for	Application	Fee
Staff Classification performing task	Task #	Total Program Cost* (A)	Hourly Rate (A/1800**)	Estimated time to complete tasks	Staff Cost* per application (time X rate)
Program Technician II	1, 5 & 6	\$ 93,794	\$ 58.12	0.75 hour	\$ 44.00
Associate Governmental Program Analyst	3	\$144,582	\$ 88.81	0.75 hour	\$ 67.00
Associate Health Physicist	2 & 4	\$195,746	\$108.82	0.5 hour	\$ 54.00
Subtotal (C)					\$ 165.00
3 year Workload cost (Table 3) (D)					\$ 147.00
Estimated Application Fee*(C+D)					\$ 312.00
*Rounded					
**1800 hours used to account for staff-leave time.					

Subsection (b) is needed to cover the costs of the following functions:

Renewal of Authorization – Description of Tasks (Table 2)

1. Compiling, printing and mailing renewal billing notice;
2. Receiving and processing fee submittal;
3. Accessing records and verifying submitted information is consistent with existing information, and make changes as needed;
4. Revising and updating existing training to PT II on regulatory and policy changes associated with the certification program, and researching and responding to inquiries from internal and external stakeholders, including preparing written correspondence. Analyze changes in laws, regulations and policies to determine program impact regarding changes to the existing certification application process or revise application processes;
5. Verifying completion of required CE credits;
6. Contacting and corresponding with applicant as needed;
7. Issuing and mailing new authorization; and
8. Auditing validity of CEC, assisting in developing needed legislative/regulatory changes, compliance actions such as permit revocation/suspension, tracking compliance history, assisting legal staff on technical issues, and conducting quality assurance of program.

Table		2. Estimate		for Renewal		Fee
Staff Classification performing task	Task #	Total Program Cost* (A)	Hourly Rate (A/1800**)	Estimated time to complete tasks	Staff Cost per application (time X rate)	
Program Technician II	1, 5 & 6	\$ 93,794	\$ 58.15	0.75 hour	\$ 44.00	
Associate Governmental Program Analyst	3	\$144,582	\$ 88.81	0.25 hour	\$ 22.00	
Associate Health Physicist	2 & 4	\$195,746	\$108.82	0.5 hour	\$ 54.00	
				Subtotal (C)	\$ 120.00	
3 year		Workload	Cost	(Table 3) (D)	\$ 147.00	
Estimated		Renewal		Fee* (C+D)		\$ 267.00
*Rounded						
**1800		hours	used to	account for	staff-leave	time.

Workload Assumptions (Table 3) for use in Tables 1 and 2:

1. Current number of authorized medical physicists (MP): 511.
 - a. Proposal requires MPs to submit a renewal application within 3 years of the proposed regulation effective date to maintain authorization.
2. Estimated average number of new applicants per year: 24.
3. Proposed validity period: 3 years.
 - a. Estimated average number of applicants in 1st 3 years (i.e. MP Population): 194
 - i. $(511 + (24 \text{ new apps/year} \times 3 \text{ years})) / 3 = 194$.
 - ii. Though it is likely that a majority of the 511 MPs will submit the renewal application in the first year preceding the 3-year deadline, for purposes of this analysis, it is assumed 1/3 of the current MPs will submit each year.
 - iii. The number of 194 is used as this is the actual population for whom the tasks are performed and staff and services provided annually.
4. Task assumptions:
 - a. Name/address changes:
 - i. Assumes 10% of existing MP population. Due to stability of MP profession, higher estimate is unlikely.
 - b. Issuance of revised documents:
 - i. Corresponds to 4.a.i.
 - c. Research & Responses
 - i. Estimate based on staff experience and comparison to other similar existing processes.
 - ii. Assumes 50% of total tasks are performed by each job class due to nature of providing safe radiation therapy services. Radiation therapy can result in major injury or death within short time frames.
 - d. Fee related processing:
 - i. Same reason as 4.a.i.
 - e. Enforcement Actions:
 - i. Estimate based on staff experience.
5. Table 3 concludes with cost for the proposed 3-year validity period.
6. All dollar amounts rounded.

Table 3.	Annual	Workload	Task	Estimates
Task Performed	(A) Number of tasks performed annually	(B) Time needed to perform task (hour)	Classification of person performing task	Annual Cost (A x B x hourly rate from table 1 & rounded)

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Health & Therapeutic Medical Physicist Authorization
January 2018

Name & Address Changes;	50	0.25	PT II	\$ 727.00
Issuance of Revised Documents	50	0.25	PT II	\$ 727.00
Research & Respond to staff, public, applicant, medical physicist inquiries	150	0.5	PT II (50%) HP (50%)	\$2,181.00 (PTII) \$4,081.00 (HP) Total = \$6,261.00
Perform Fee related processing	50	0.5	PT II	\$1,453.00
Enforcement Actions	2	2	HP	\$ 435.00
Annual	Workload	Cost	(C)	\$9,602.00
Estimated	annual MP	population	(1 st 3 years)(D)	194
Annual	Workload Cost	per MP(E)	(C/D = E)	\$ 49.00
Cost per MP	per 3-year	validity cycle	(E x 3)	\$ 147.00

Subsections (c) and (d) are needed to inform individuals that they are subject to a penalty fee for failure to pay the renewal fee and to inform them of the consequences when authorization is not renewed. This consequence is needed to encourage individuals to renew their authorizations on time so that facilities can continue to use their services, and Department staff can issue timely renewed authorizations. Subsection (c) is needed to encourage timely submittal of renewal applications and is based on existing sections 30145(i), 30231(d), 30409(d), and 30535(f) for consistency with existing processes.

Subsection (d) is also needed to inform individuals of the consequences of not paying the renewal fee, via the renewal process. This provision is needed to ensure only those individuals who maintain and update skills and knowledge by completing continuing education remain authorized. This provision occurs automatically when the Department does not receive the renewal application, including the fee and documents of obtained continuing education. It is based on H&S Code section 107085, though not exactly the same, and section 30408(f) for

consistency with existing processes. This proposal, as compared to H&S Code section 107085, clarifies that to reinstate the authorization both the payment of fees and submittal of the reinstatement application must occur within five years from the date of suspension, which is the day following the fifth anniversary of the expiration date. H&S Code section 107085 requires the reinstatement application to be submitted by the day following the fifth anniversary of expiration date but allows payment of the fee to occur within the following six months of that anniversary, extending the whole process to five years and six months. This proposal ties payment and application submittal to one date. The proposal is also needed to clarify how an individual can reinstate their authorization. The five-year limitation is proposed to maintain consistency with existing processes and other states.

Subsection (e) is needed to inform individuals that fees are nonrefundable because the fees cover the costs of performing tasks. Refunding fees would place cost burdens on regulated persons that do not require the services of an authorized person, such as persons only using general diagnostic radiographic equipment. This subsection is also needed to inform individuals that fees can be revised as provided in H&S Code section 100425.

Adopt **Section 30313.50, Grounds for Amendment, Restriction, Suspension or Revocation of Authorization**, to specify the reasons for taking certain actions. This section is based on H&S Code section 107070.

Subsection (a) is needed to inform authorized HPs and TMPs that such authorizations are subject to amendment, restriction, suspension or revocation. Subsections (a)(1) through (a)(9) are needed to inform authorized HPs and TMPs which types of actions would cause the Department to take action against the authorization.

Subsection (a)(1) is needed to clarify that all information provided by an applicant must be true and accurate. False or inaccurate information may cause the Department to authorize an unqualified individual, thereby placing public, worker, and patient safety at risk.

Subsection (a)(2) is needed to clarify that an applicant must provide information that only pertains to the actual applicant. If the applicant is authorized, only the authorized HP or TMP may use the authorization.

Subsection (a)(3) is needed to specify that those who are granted authorization must act in a manner that meets professional standards of the industry so as to consistently ensure public, worker, and patient safety.

Subsection (a)(4) is needed to specify that for violations of specific laws, action will be taken against an authorized HP or TMP. Those who break these laws may place public, worker, and patient safety at risk.

Subsection (a)(5) is needed to specify that an authorized HP or TMP must follow the lawful enforcement of radiation safety laws and regulations. These laws are in place to protect public, worker, and patient safety.

Subsection (a)(6) is needed to ensure an authorized HP and TMP understand the types of crimes that will affect their authorization status. Those who are convicted of a specific type of crime may place public, worker and patient safety at risk.

Subsection (a)(7) is needed to specify that an authorized HP or TMP must complete all corrective actions mandated by the Department to remain authorized. HPs or TMPs who do not comply may place public, worker, and patient safety at risk.

Subsection (a)(8) is needed to ensure an authorized HP and TMP understand that the Department will also take action against the individual if another entity takes action against their certification, or authorization.

Subsection (a)(9) is needed to ensure that an authorized HP and TMP understand that the fees due to the Department must be paid to maintain a valid authorization as explained in sections 30313.15, 30313.20 and 30313.45. The fees are needed to cover the costs for the Department to issue and renew authorizations.

STATEMENTS OF DETERMINATIONS

The Department has determined that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

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.

The Department has determined that because an HP or TMP may provide services to facilities as a small business provider there would be an effect on small businesses because they will be legally required to comply with the regulation.

The Department has determined that the regulations will have no impact on housing costs.

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the proposed regulatory action, or would be more cost-effective to affected private persons.

ECONOMIC IMPACT ASSESSMENT

The Department analyzed whether and to what extent this proposal affects the following:

1. **The creation or elimination of jobs within the State of California.** This proposal is not likely to eliminate jobs since this approval process only clarifies an existing process, and may create new jobs but creation of new jobs is not likely to be significant because this proposal only develops processes for an HP and TMP to become authorized, and applies to a limited pool of individuals.
2. **The creation of new businesses or the elimination of existing businesses within the State of California.** This proposal is not likely to eliminate existing businesses but may create new businesses to provide authorized individuals required continuing education (CE) courses. Creation is not expected to be significant due to the small pool of individuals needing to obtain CE and that existing CE courses are widely available.
3. **The expansion of businesses currently doing business within the State of California.** Existing CE providers may see business expansion from those required to obtain CE to renew authorization. Expansion is expected to not be significant due to the small pool of individuals needing to obtain CE and that existing CE courses are widely available.
4. **The benefits of the regulation to the health and welfare of California residents, and increases worker safety.** This proposal significantly increases the benefits to the health and welfare of California residents and worker safety because it ensures that users of therapeutic X-ray equipment can safely and competently keep a patient's radiation exposure to a minimum and protect operators, and other workers, from receiving unnecessary radiation exposure. This proposal would not affect the state's environment because the proposal would establish the qualifications an individual needs to have to perform therapeutic X-ray system output calibrations and does not impact X-ray machine standards.