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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

DPH-10-007 Health & Therapeutic Medical Physicist Authorization
Published: November 9, 2018

PUBLIC PROCEEDINGS

The California Department of Public Health (Department) is conducting a 45-day written public proceeding during which time any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in the Informative Digest/Policy Statement overview section of this notice.

PUBLIC HEARING

The Department has not scheduled a public hearing on this proposed action. However, the Department will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her duly authorized representative, no later than 15 days prior to the close of the written comment period.

WRITTEN COMMENT PERIOD

Any written comments pertaining to these regulations, regardless of the method of transmittal, must be received by the Office of Regulations by 5 p.m. on December 24, 2018, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Persons wishing to use the California Relay Service may do so at no cost by dialing 711.

Written comments may be submitted as follows:

1. By email: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "**DPH-110-007 Health and Therapeutic Medical Physicist Authorization**" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission: (916) 636-6220;
3. By Postal Service: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814;



4. Hand-delivered: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

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.

SUMMARY OF THE PROPOSAL

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.

INFORMATIVE DIGEST/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.
- Ensure that individuals are aware of technological advances impacting physics services for patient safety.
- Streamline the existing process to approve individuals to perform certain tasks regarding use of therapeutic X-ray equipment.
- 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 to 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 and is conducted in facilities such as hospitals and cancer centers. The facility (i.e. the possessor of the radiation machine and is called a “registrant”) is responsible for complying with applicable laws and regulations.

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.

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. Further, the cost of this process is not recovered through applicant fees resulting in diverting staff to perform this work. This impacts work efficiencies in other program areas. 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 would require registrants to ensure that the individual who performs those measurements meets 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.

Under this proposal, the process to obtain and renew authorization is formalized resulting in two pathways for approval and a process for renewal. 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 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 facility-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) and (b)(5) 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.

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. An internet search of other state agency regulations determined that no other state regulation addresses the same subject matter.

MANDATED BY FEDERAL LAW OR REGULATIONS

Currently, there are no existing federal regulations or statutes applicable to the regulations.

DOCUMENTS INCORPORATED BY REFERENCE

None.

OTHER STATUTORY REQUIREMENTS

None.

BUSINESS REPORTING REQUIREMENT

The Department has determined that this proposed regulation would require businesses to submit a report, and that the report is necessary for the health, safety, and welfare of the people of this state.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE

The Department has made an initial determination that the proposed 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. Thus, there will be no significant adverse economic impact on California businesses.

LOCAL MANDATE

The Department has determined that this regulatory action 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.

EFFECT OF HOUSING

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

EFFECT ON SMALL BUSINESS

The Department has determined that there would be an effect on small businesses, because they will be legally required to comply with the regulation, and may incur a detriment from the enforcement of the regulation.

FISCAL IMPACT ASSESSMENT

- A. FISCAL IMPACT ON LOCAL GOVERNMENT:** There will be an impact as described in item B.1 below.
- B. FISCAL IMPACT ON STATE GOVERNMENT:**
1. State agencies that hire health physicists (HPs) and therapeutic medical physicists (TMPs) and pay for authorizations and renewals would be subject to the proposal. However, such payment is within the agencies' discretion. The proposed application fee is \$312 for HP or TMP authorization. The renewal fee is \$267 payable every three years. Costs for continuing education (CE) credits widely ranges from \$5 to \$250 per credit. For 15 CEs every 3 years, the cost ranges from \$75 to \$3,750.
 2. The proposed application fee is \$312 and the renewal fee is \$267 payable every three years. Since the renewal fee of \$267 is for a period of three years, the annualized renewal fee is \$89 (\$267 divided by 3 and rounded). The applicant pool cannot be accurately estimated because it is unknown how many individuals will apply for authorization. The Department has previously approved 511

individuals. Therefore, 511 renewal applicants are assumed for the purpose of this estimate.

The Radiation Control Fund would receive an estimated one-time increase of \$136,437 (\$267 times 511) due to renewal fees, if all 511 previously approved individuals renew their authorization the first year, and \$45,479 (\$136,437 divided by 3) annually thereafter.

C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS: None.

D. COST IMPACT ON REPRESENTATIVE PERSONS OR BUSINESSES DIRECTLY AFFECTED: There will be a fiscal impact on private persons who wish to obtain the authorization. The cost for the one-time application fee is \$312. The renewal fee is \$267 payable every three years. The cost of complying with the CE requirement ranges widely from \$5 to \$250 per credit. For 15 CEs every 3 years, the cost ranges from \$75 to \$3,750.

E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS: None.

F. OTHER NON-DISCRETIONARY COSTS: None.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

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 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.

CONSIDERATION OF ALTERNATIVES

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.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

None.

CONTACT PERSON

Inquiries regarding the subject matter in this notice may be directed to Phillip Scott, Department's Radiologic Health Branch (916) 440-7978.

Inquiries regarding the regulatory process described in this notice should be directed to Dawn Basciano, Office of Regulations, at (916) 440-7367, or to the designated backup contact person, Linda Cortez (916) 440-7807.

AVAILABILITY OF STATEMENT OF REASONS AND TEXT OF REGULATIONS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address noted above, will be the location of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents be mailed to you, please call (916) 558-1710 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

FINAL STATEMENT OF REASONS

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the regulation text, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov.