

Initial Statement of Reasons

Summary of the Proposal

This proposal would adopt, amend or repeal provisions of Title 17, California Code of Regulations (17 CCR) to address recommendations of the Radiologic Technology Certification Committee (RTCC) regarding the movement of a patient or equipment during fluoroscopic X-ray procedures; the recording of cumulative irradiation time or exposure during fluoroscopic X-ray procedures; the scope of practice of a certified radiologic technologist (CRT); and the experience requirement of individuals who provide training oversight to students during training in radiologic technology. Nonsubstantial changes are also proposed.

Policy Statement Overview

Problem Statement: The California Department of Public Health (Department) regulations implementing both the Radiation Control Law (RCL) and the Radiologic Technology Act (RT Act) do not clarify when the RT Act applies during fluoroscopic X-ray procedures; do not specify the scope of practice of CRTs; do not require radiation exposure times or dose be recorded for patient protection; and place an unnecessary experience requirement on individuals overseeing X-ray students during clinical training.

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

- Ensure patients receive the least amount of necessary radiation exposure during fluoroscopy procedures by limiting use of X-ray to qualified persons.
- Ensure facility staff understand radiation protection standards, so as to reduce unnecessary radiation exposure to patients, and how to protect themselves and others from radiation exposure.
- Ensure adequate oversight of students.
- Address RTCC's recommendations.
- Clarify the CRT scope of practice.
- Clarify what actions invoke the RT Act requirements.

Benefits: Anticipated benefits from this proposed regulatory action are:

- Prevent patients from receiving excessive radiation exposure due to facilities' use of unqualified individuals during fluoroscopy procedures.
- Reduce unnecessary radiation exposures to patients that occur due to a lack of understanding by facility staff of radiation protection standards.
- Reduce unnecessary radiation exposures to workers by ensuring they are educated on how to protect themselves and others.
- Ensure students receive adequate oversight by qualified persons when providing patient care during X-ray procedures.
- Reduce confusion as to the CRTs' scope of practice.

- Reduce confusion by clarifying when a person must hold certain RT Act authorizations.

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 the implementation of the RCL and the RT Act. An Internet search of other California state agency regulations determined that no other state regulation addresses the same subject matter.

Background/Authority

The RT Act codified in Health and Safety Code (HSC), sections 106965 through 107120 and sections 114840 through 114896 was enacted to protect the public from excessive or improper exposure to ionizing radiation. The RT Act requires that any individual who uses X-rays on human beings for diagnostic or therapeutic purposes meet certain standards of education, training, and experience. The Department (successor to the Department of Health Services) is authorized under the RT Act to promulgate regulations to implement the Act's provisions. (HSC §§ 131055 & 131200.¹)

Radiologic technology means the application of X-rays on human beings for diagnostic or therapeutic purposes. (HSC § 114850(c).) It is performed in hospitals, clinics, and private doctor offices, including mobile vans or vehicles.

Pursuant to the RT Act, the Department, in part:

- Certifies individuals as radiologic technologists in diagnostic, therapeutic, and mammographic X-ray use. An individual certified as a radiologic technologist is called a CRT. (17 CCR 30400(a)(9).)
- Certifies and permits licensed medical, osteopathic, podiatric, and chiropractic doctors to use diagnostic or therapeutic X-rays within the scope of their professional license. These individuals are called "licentiates of the healing arts" ("licentiates") as defined in HSC § 114850(h)(1). Once a licentiate is certified or permitted under the RT Act, they are called a "certified supervisor or operator" as defined in HSC § 114850(i); and
- Approves schools that provide the training courses required for obtaining a non-licentiate certificate or permit.

The RT Act also created the RTCC to assist, advise, and make recommendations to the Department for the establishment of rules and regulations necessary to insure the proper administration and enforcement of the RT Act. (HSC § 114855.) This advisory

¹ This short format "HSC § 131055" for a given Health and Safety Code section will be used throughout this document for brevity.

committee consists of six licensed physician and surgeons, a licensed podiatrist and chiropractor, two certified radiologic technologists, and a radiological physicist. (HSC § 114860.) Each member is appointed by the Department Director from at least three nominees for each position submitted by appropriate professional associations and societies. (HSC § 114855.) Lastly, any regulations proposed by RTCC shall be adopted by the Department only after consultation with the committee and approval by six affirmative votes of those present at an official meeting of the committee. (HSC § 114880.)

The RCL (HSC §§ 114960 et seq.) authorizes the Department to promulgate regulations regarding sources of ionizing radiation for the protection of the health and safety of the public and radiation workers. (HSC §§ 114965, 114970 & 115000.) As it pertains to use of X-ray for purposes of radiologic technology, the Department, under the RCL:

- Requires users who possess X-ray machines to register and renew that registration. (17 CCR §§ 30108 – 30146.) Users include hospitals, clinics, and physician, podiatric and chiropractic offices.
- Specifies, in part:
 - X-ray machine standards.
 - Radiation protection procedures.
 - Occupational and public radiation dose limits.
- Observe X-ray machine users to determine if the user safely uses radiation and whether the user is complying with both the RCL and the RT Act, and the regulations adopted under both laws.

The RCL focuses broadly on all uses of ionizing radiation sources (e.g. X-ray machines, radioactive materials) and the RT Act focuses narrowly on the use of X-ray for medical purposes. Both the RCL and the RT Act apply regardless of where radiologic technology is performed; how the organization providing it is structured; or who is providing it.

In October 2013, the Department adopted a number of RTCC recommendations. Since that adoption, RTCC has met and made additional recommendations in support of its advisory role to the Department. Therefore, this proposal addresses the following RTCC recommendations and other Department-determined needs regarding the administration of both the RT Act and the RCL.

RTCC Recommendation	Date of Meeting
<p>1. The scope of practice of certified radiologic technologists should be established and as stated in the American Society of Radiologic Technologists’ (ASRT) publication titled “Practice Standards for Medical Imaging and Radiation Therapy” for both Radiography and Radiation Therapy.</p> <p>See discussion of proposed section 30441.</p>	<p>October 29, 2014 (Reference 1.)</p>

RTCC Recommendation	Date of Meeting
<p>2. Air kerma received during fluoroscopic procedures should be documented in the patient’s record.</p> <p>See discussion of section 30307.</p>	<p>April 8, 2015 (Reference 2.)</p>
<p>3. Movement of the patient or equipment during use of fluoroscopic X-ray equipment by non-certified or non-permitted individuals should be allowed under certain conditions.</p> <p>See discussion of sections 30305.5 and 30450.</p>	<p>October 28, 2015 (Reference 3) & April 13, 2016 (Reference 4.)</p>
<p>4. As it pertains to student oversight, 17 CCR § 30417(f)(2) should be revised so that only those, except for a certified supervisor and operator (S&O), making the competency determination for purposes of the student moving from direct oversight to indirect oversight need to have at least two years of radiologic technology experience.</p> <p>See discussion of proposed section 30400 and 30417.</p>	<p>April 13, 2016 (Reference 4.)</p>

At the RTCC’s April 13, 2016 meeting, analyses containing draft regulations addressing the above RTCC recommendations were presented to the committee and the public for review and discussion. This proposal also addresses comments received at that public meeting.

Authority and Reference

The California Department of Public Health (Department) proposes to adopt, amend, or repeal, as applicable, sections 30252, 30305.5, 30307, 30400, 30411, 30417, 30418, 30423, 30441, 30450, 30456 and 30456.4 of 17 CCR, under the authority provided in sections 114870, 114975, 115000, 115060 and 131200 of the HSC. This proposal implements, interprets and makes specific sections 106965, 106980, 106985, 106990, 114850, 114870, 114995, 114970, 115060, 131050, 131051, and 131052 of the HSC.

DETAILED DISCUSSION OF EACH REGULATION

The regulations interpreting, specifying, or implementing the RCL and the RT Act are in 17 CCR sections 30100 - 30395 and sections 30400 - 30468, respectively. The proposed changes are as follows:

Amend **section 30252** to make corrections to the authority and reference citations note found at the end of the section to implement the numbering system established by the 1995 recodification of the HSC and to reflect the reorganization of the Department of Health Services into the Department of Health Care Services and the California

Department of Public Health, pursuant to Senate Bill 162. (Stats. 2006, ch. 241.) These changes have no regulatory effect.

Adopt **section 30305.5** to address RTCC's recommendation regarding movement of the patient or equipment during use of fluoroscopic X-ray equipment by non-certified or non-permitted individuals under certain conditions. At the April 2016 meeting, RTCC approved a staff recommendation (Reference 4b) clarifying Part 5 of its October 2015 recommendation based on staff's analysis indicating clarification was needed. The analysis also included draft regulation text that assumed clarification of the motion would be made and approved by RTCC. Attendees of the April 2016 meeting also expressed that the list of persons who may teach the radiation safety training, as found in the draft regulation text (f), should be reconsidered since the qualifications of a CRT(F) and PA(F) are not equivalent; and words like "manipulation" or "operation" were not consistent with the RTCC's recommendation.

After members' discussion and consideration of public comments, RTCC, as it pertains to its 5-part recommendation of October 28, 2015 (Reference 4b, p. 1), revised and approved Part 5 of that recommendation as follows:

An individual under the direct and immediate supervision of the S&O may assist the S&O in the real-time movement of the patient or equipment under fluoroscopy for purposes of re-centering to the area of clinical interest or for manipulating the patient for medical purposes necessitated by the procedure, provided a CRT is present in the room and is managing the radiation exposure and X-ray equipment and that the assistant shall have documented radiation safety training that includes training on the movement of the specific equipment and personal radiation protection required to be established by the facility.

After the public meeting of April 13, 2016 and before this proposal was published for public comment, the Department also received comments (References 7 & 8) regarding RTCC's recommendation.

The commenter (Reference 7) indicated that CRTs during fluoroscopy procedures, such as cardiovascular catheterization, perform in only one of the following roles:

1. Monitoring and documenting all actions of the surgical team.
2. Providing assistance outside the sterile field.
3. Assisting the physician directly while in sterile clothing.

Because this proposal (subsection (c)(2)) would create a new mandatory role for the CRT (i.e., monitoring radiation exposure and equipment movement by a non-permitted individual), the commenter believes a CRT should be limited to only one role during the procedure. Limitation is necessary because it could result in a patient receiving excessive and unnecessary radiation exposure since the CRT would be too busy fulfilling the other roles both inside and outside the procedure room. See discussion regarding subsection (c)(2).

The commenter (Reference 8), as it pertains to the analysis presented to RTCC at the April 2016 meeting (Reference 4b, p. 13), disagreed with proposed wording that appeared inconsistent with RTCC's part 5 motion, and provided different wording for consideration. Additional language was provided to clarify that the non-permitted individual is prohibited from establishing exposure factors; setting collimation; setting frame rate and pulse sequence settings; setting magnification modes; applying filters; setting exposure preset programs created by manufactures; resetting the fluoroscopic timers; and panning of the equipment. Panning, defined and examples given by the commenter, means moving the C-arm and/or table under live fluoroscopy for fluoroscopic positioning, a radiographic technique that is not just movement of the table or C-arm for re-centering purposes. A non-permitted individual could expose sensitive tissues such as the gonads, breast, and thyroid to radiation without understanding that such tissues are more easily damaged by radiation than tissue such as bone or muscle. Thus, the commenter indicated that panning is contrary to RTCC's motion. See discussion regarding subsections (b) and (c).

Lastly, the commenter expressed concern that a physician's need to have machine specific training for operating fluoroscopic equipment was not included in the analysis (Reference 4b), and felt it important to ensure physicians performing fluoroscopy procedures on their own are operating the unit so as to expose the patient and others to the least amount of radiation necessary. The commenter recommended that physicians should have a basic understanding of the exposure factors and exposure techniques available on the fluoroscopy unit to reduce the radiation dose to the patient. See discussion regarding subsection (d).

Subsection (a) is needed to inform all users of X-ray machines for radiologic technology purposes of the RT Act requirements. Current regulations implementing the RCL do not speak directly to, nor inform users of, the RT Act. Department inspectors continue to determine some users are unaware of the RT Act requirements. Though the RT Act applies regardless of the user's knowledge of that act, the Department believes its regulations should clearly inform the user so they can more easily comply.

Subsections (a)(1) and (a)(2) are needed to clearly define terms used in this proposal.

- Paragraph (1) is based on RTCC's October 2015 recommendations as revised at the April 2016 meeting and is needed to clarify who may or may not do certain tasks. Certification and permitting under the RT Act is invoked when a person administers or uses diagnostic or therapeutic X-ray on human beings (HSC §§ 106965 & 107110). Thus, the meaning in subparagraph (A) is broad and encompasses any person who is not certified or permitted pursuant to the RT Act. However, subsequent to RTCC's April 2016 meeting, it was determined that this broad meaning also includes an individual who holds a certificate or permit pursuant to the RT Act, but is not authorized to use fluoroscopy X-ray equipment. Thus, subparagraph (B) is needed to clearly indicate the broadness of the term as recommended by RTCC.

- Paragraph (2) is needed for consistency with the RT Act by identifying to whom radiation is administered and to clarify who is moved for purposes of subsections (b) and (c).

Subsections (b) and (c) are needed to implement RTCC's 5-part recommendation, are based on their approval of the draft regulation text (d) and (e) (Reference 4b, p. 12), and revised to address their April 2016 revisions and public comments.

- Subsections (b)(1), (c)(1) and (c)(2), consistent with RTCC's approval of the draft regulation text (d)(1), (e)(1) and (e)(2), are needed to implement RTCC's recommendation.
 - Regarding the public comment identified as Reference 8, summarized above, the RTCC's revised part 5 of its recommendation addresses the submitted comments.
- Subsections (b)(2) and (c)(4), addressing what the non-permitted individual may not do, includes in its prohibition actions that directly impact the radiation exposure of patients. RTCC, and meeting attendees, continually expressed concern that doing such actions requires an understanding of the radiation consequences to the patient and that these actions should only be under the purview of individuals who have demonstrated that understanding, evidenced by being certified or permitted to use fluoroscopy equipment pursuant to the RT Act.
 - Regarding the public comment identified as Reference 8, summarized above, the proposal addresses the commenter's concern as to what the non-permitted individual may not do. See the additional discussion below regarding subsection (c)(4).
- Subsection (c)(2) requires certain qualified individuals to be physically present during the procedure performing certain functions. The RTCC felt it imperative that, because the S&O is focusing on the performance of the medical procedure, certain qualified individuals should be present to assist the S&O by managing the patient's radiation exposures and the actions of the non-permitted individual, for overall safety and radiation protection of the patient and those in the procedure room. In response to the public comment identified as Reference 7 regarding limiting an RT to one role when a non-permitted individual is assisting during procedures:
 - The Department rejects the recommendation to limit the specific roles a CRT in the procedure room may be asked to carry out. The Department believes that doing so would greatly inhibit the overall performance of the individuals involved with the procedure; would limit the S&O's medical judgement; is impractical because the proposal is not limited to cardiac catheterization procedures; and is best left to the facility's and S&O's judgement on how individuals in a procedure room work together to accomplish the procedure's goal in the best interest of the patient. Further, it would be impractical to identify all roles a person plays during a given procedure; which ones they may or may not perform; and when they may or may not be performed. It is impractical due to the innumerable and variable individual interactions that occur between personnel involved

during a medical procedure. Lastly, if the CRT is outside the procedure room when the non-permitted person is performing the actions in subsection (c), then subsection (c)(2) is not met.

- The commenter believes that the actions the non-permitted individual may perform could be interpreted to include “panning” as defined by the commenter, and constitutes positioning of the patient for radiographic purposes, contrary to RTCC’s recommendation. The commenter infers that panning should be included in those actions the non-permitted individual is prohibited from doing. This recommendation is discussed below regarding subsection (c)(4).
- Subsection (c)(3), consistent with RTCC’s approval of the draft regulation text (e)(3), is needed to implement RTCC’s recommendation.
- Subsection (c)(4), consistent with RTCC’s approval of the draft regulation text (e)(4), is needed to implement RTCC’s recommendation. Regarding the public comment identified as Reference 8 about “panning,” the Department agrees clarity is needed because the described practice does occur. The commenter’s recommendation is consistent with RTCC’s continual concern that actions with radiation consequences to the patient should only be under the purview of individuals who have demonstrated an understanding of the risks to patients from such actions, as evidenced by being certified or permitted to use fluoroscopy equipment pursuant to the RT Act. Subsection (c)(4)(C) is proposed to address this practice and clearly state that the non-permitted individual is prohibited from performing the action.

Subsections (d) and (e) are needed to implement RTCC’s recommendation; are based on its approval of the draft regulation text (f) and (g) (Reference 4b, pp. 13-14); and revised to address member and public comments made at the April 2016 meeting.

Development of this proposal was guided by the following goals:

- Ensure patient and operator health and safety.
- Ensure consistency with the RT Act and the RCL, and regulations adopted under those laws.
- Ensure that a qualified person oversees, or provides training to, unqualified persons, as evidenced in HSC § 106975(b), 17 CCR 30417(c) and 30418(d)(2).
- Provide maximum flexibility within statutory provisions.

Subsection (d):

- Requires the user to provide specific training. This is needed to implement RTCC’s revised recommendation that the non-permitted individual have radiation safety training that includes training on the movement of the specific equipment and personal radiation protection.
- Requires the instruction to be no less than 120 minutes in length. Some RTCC members felt that the facility should be allowed to determine the instruction’s length or that the length should be much less since what the non-permitted individual is allowed to do is minimal movement of the equipment or patient.

Other members felt that the length of time was appropriate. RTCC approved the proposal.

- The Department believes the length of time is appropriate. The overall protective goal for completing this instruction is not limited to the individual's protection but is for the protection of all individuals in the vicinity of the radiation source and, above all, the patient. Protection is not limited to radiation protection but includes protection from physical injury to the patient or others by incompetent use of, or unfamiliarity with, the equipment. An individual can quickly comprehend the basic radiation protection concepts of reducing their exposure time, increasing their distance from the radiation source, and placing shielding material between themselves and the radiation source. However, putting those concepts into practice, such as being aware of radiation levels and its' hazards, the importance of personnel monitoring equipment and how to use them, and to reach competency in manipulation of the specific equipment, all require more than just a few minutes of discussion. The Department agrees that the actions being allowed are minimal in nature and believes the length of instruction time is the minimum needed to reach the overall protective goal as evidenced in the curricula timeframes specified in sections 30424(a)(1)(A), 30425(a)(1)(A), and 30427(a)(1).
- Requires the instruction be provided by instructors who meet specific qualifications; this is needed to ensure that qualified persons oversee or provide training to unqualified persons. The proposal identifies those persons who have met a level of education, training, and experience as specified in current regulation to adequately instruct, evaluate and determine that a person is able to safely manipulate the equipment and grasps radiation protection concepts. The proposal also allows the user to designate instructors who do not hold the cited authorization. The proposal, for assistance to the user in applying the criteria, provides an example of a professional who would meet the criteria. This criterion is based on 17 CCR 30418(d)(2), used by an approved school (17 CCR 30400(a)(5)) for ensuring instructors are deemed qualified to teach specific didactic subjects. The user, pursuant to proposed subsection (e)(3), must maintain documents demonstrating the individual meets the specified criteria.
 - Qualifications for the specific instructor are specified in:
 - For the radiologic technologist fluoroscopy (RTF) permit, section 30423.
 - For the physician assistant fluoroscopy (PAF) permit, section 30456.4.
 - For the radiology supervisor and operator (S&O) certificate, section 30466(a)(6).
 - For the fluoroscopy S&O permit, section 30466(a)(2).
 - During the RTCC's April 2016 meeting, a member of the public felt that the qualifications for holding the PAF permit was not necessarily equivalent to what a CRT, holding the RTF permit, learns during X-ray school training. The commenter recommended the proposal be reconsidered. The

Department reconsidered the proposal and rejected the recommendation. The Department believes the commenter misconstrues the role of the instructor in this proposal. The instructor's role is to impart to the non-permitted individual a basic understanding of the hazards of radiation exposure, how to protect themselves, others and the patient from radiation exposure, and to adequately manipulate the equipment only to carry out the minimal tasks specified in proposed subsections (b) and (c). The role is not to train the individual to reach the same competency level as the instructor or to qualify the individual for obtaining an RTF or PAF permit. The holders of both the RTF and PAF permit have met substantially similar qualifications specific to fluoroscopy equipment (17 CCR 30423(b) [as recodified in this proposal] & 30456.4(b)) that encompass education and training included in the proposed instruction, and have passed substantially similar written examinations to establish their competence. Thus, the Department believes holders of either the RTF or PAF permit are equivalent instructors for purposes of the instruction.

- Requires retraining at intervals not to exceed 12 months. Some RTCC members felt that the facility should be allowed to determine how often retraining should occur or that it should be every two years. Other members and members of the public felt that the length of time was appropriate. However, RTCC approved the 12-month interval.
 - The Department believes the retraining interval is appropriate. The interval is based on existing training requirements as found in sections 30333(d) and 30336.1(q), for industrial radiographers and radiographer assistants, and on the fact that many medical facilities, such as hospitals, require staff to annually complete safety training. Thus, facilities could easily incorporate this training into their educational requirement schedules.
- Informs users that certain persons need not complete all training components. This is needed for clarity and to account for those individuals who have already completed substantial education and training requirements and passed written examinations in radiation protection and radiologic technology. However, the following individuals, though the individual's education/training is extensive and may include training on fluoroscopy equipment and expected radiation levels from such equipment, would still need to receive the indicated instruction because the instruction is specific to the particular equipment they may personally use for purposes identified in proposed subsections (b) and (c).
 - Certified diagnostic radiologic technologists (RT) complete the didactic and clinical training as specified in 17 CCR 30421, which is generally 24 months in length.
 - Limited permit X-ray technicians (XT) complete:
 - For the chest, extremities, leg-podiatric, skull, and torso-skeletal permit categories, a minimum of 228 hours of education including laboratory experiments and clinical training as specified in 17 CCR 30424.

- For the Dental Laboratory permit category, a minimum of 125 hours of education including laboratory experiments and clinical training as specified in 17 CCR 30425.
- For the DEXA permit category, a minimum of 20 hours of education including laboratory experiments and clinical training as specified in 17 CCR 30427.
- For certified S&O's not holding the fluoroscopy S&O permit, passage of written examinations as specified in 17 CCR 30466(a)(3) and (a)(4), and, for those holding the X-ray Bone Densitometry (XBD) S&O permit, completion of training and instruction as specified in 17 CCR 30466(a)(5).

Subsection (d) also specifies what training must be provided.

- Paragraph (1) is needed to ensure the non-permitted person can safely set-up and manipulate the equipment by receiving equipment training and demonstrating they have reached a strong level of equipment familiarity. The need for training and demonstration to be on the same equipment the individual will be asked to manipulate is necessary because equipment design varies by manufacturer, model, and year of manufacturing. Failing to be familiar with the equipment results in increased procedure time, and can increase unnecessary radiation exposure to the patient and others in the vicinity of the X-ray source. Procedural and radiation exposure time can increase because of the individual's inability to quickly manipulate the equipment into the required orientation for obtaining a particular view or inability to orient the equipment over the appropriate area of clinical interest. The RTCC, at its April 2016 meeting, expressed this need by revising its recommendation to state that the training must include training on the specific equipment that would be used. (Reference 4, pg. 10.)
- Paragraphs (2) through (5) are needed to implement RTCC's recommendation as revised, and to ensure the non-permitted individual has a basic understanding of radiation protection. The instruction topics are based on the curricula identified in:
 - Section 30421(a), for prospective diagnostic CRTs;
 - Section 30422(a), for prospective therapeutic CRTs;
 - Section 30423(f)(1) (proposed to be redesignated to subsection (b)(1)), for obtaining the radiologic technologist fluoroscopy permit;
 - Sections 30424 & 30425, for prospective X-ray technicians; and
 - Section 30456(b)(1), for obtaining the physician assistant fluoroscopy permit.

Subsection (e) is needed to implement RTCC's recommendation. Paragraph (1) is needed to identify if an individual completed the required training. Paragraph (2) is needed to determine when that individual completed the training and establishes when refresher training, if necessary, must occur. Paragraph (3) is needed to determine if those providing the education and training are qualified. Paragraph (4) is needed to

provide the Department a minimum level of confidence that the non-permitted individual has reached an appropriate level of competency as determined by the qualified person, rather than just verifying that the individual was physically present during the training session.

Subsection (f) is needed to prevent an interpretation of the regulation that would allow the non-permitted individual to do more than what is specified. The definition of a non-permitted individual includes individuals who are already certified or permitted under the RT Act. Therefore, the sentence addressing these individuals is needed to prevent interpretation that the individual's current authorization is expanded, limited, or that they are excused from or have more obligations under the RT Act, the RCL, or the regulations adopted pursuant to those laws than what currently exists.

Subsection (g) is needed to implement RTCC's recommendation and intent, consistent with HSC § 106980(d), that only the certified S&O (the licensed physician and surgeon, podiatrist or chiropractor holding the appropriate authorization) may direct the non-permitted individual as specified in subsections (b) or (c). This also prevents interpretation that the certified S&O can be substituted. (Reference 4, pp. 6-7; Reference 4b, pp. 7-8 [supervision issues].)

Amend **section 30307** to address RTCC's recommendation regarding documenting, in the patient's record, air kerma received during fluoroscopic procedures. Prior to 1961, there were no uniform fluoroscopy X-ray equipment manufacturing standards. The Department, in 1961 adopted equipment and usage standards. In 1968, Congress enacted the Radiation Control for Health and Safety Act [Pub. L. 90-602] under which the U.S. Food and Drug Administration (FDA) established, in 1974, national uniform X-ray equipment standards.

Fluoroscopy X-ray equipment is designed to obtain dynamic images (e.g. motion-picture or video) resulting in higher patient radiation doses than general radiography X-ray equipment used to obtain static images. Because of these higher doses, skin-reddening, ulceration, and denudation can occur and require medical care and follow-up. To assist the physician or the fluoroscopist in keeping radiation doses as low as reasonably achievable (ALARA) during medical procedures, all fluoroscopic units, depending on the year of manufacture, must be equipped with either a cumulative timer with audible warning signal (Title 21, Code of Federal Regulations (21 CFR), section 1020.32(h)) that displays fluoroscopic irradiation time (FIT), or the ability to calculate and visibly display cumulative air kerma (CAK) (21 CFR 1020.32(k)). Both FIT and CAK are defined in 21 CFR 1020.30(b).

Currently, facilities using fluoroscopy equipment are not required to record FIT or CAK. RTCC recommended that these values should be recorded so that any injuries that do occur can be more effectively clinically managed by the physician. Also, the facility can use either value to evaluate the skill of fluoroscopists so as to keep radiation doses ALARA and to identify practices that will reduce radiation exposures during procedures

while accomplishing the medical goal. The Department agrees with RTCC and believes that this requirement would carry out the Legislature's policy to protect the public health and safety regarding exposure to ionizing radiation (HSC §§ 114840, 114965, & 114970(a)).

Because there is continued use of fluoroscopy equipment that meet either of FDA's standards (display of FIT or CAK), proposed subsection (d) would require recording of the value displayed by that equipment, as recommended by RTCC.

However, subsection (d) would, pertaining to equipment that displays only FIT, require the user to record the "total" fluoroscopic irradiation time. Fluoroscopic X-ray equipment under 21 CFR 1020.30(h)(1)(i) must provide a means to preset the cumulative irradiation time of the fluoroscopic tube. The maximum cumulative time of the timing device shall not exceed five minutes without resetting. A signal audible to the fluoroscopist shall indicate the completion of any preset cumulative irradiation-time. Such signal shall continue to sound while X-rays are produced until the timing device is reset. If a procedure requires an irradiation time that exceeds the preset five-minute time and the timer is reset, the value returns to zero so that the procedure can continue. Thus, though the total irradiation time can be longer than five minutes, the timer will not indicate how many times the timing device was reset. Therefore, this proposal would require recording of the "total" fluoroscopic irradiation time to capture the number of times the timing device was reset.

How a facility accomplishes that recording, digitally or manually, and where that value is retained, such as in the patient's record or a procedure log, is left to the facility's discretion for flexibility. However, if the recorded value cannot be tied to the specific patient who received the radiation, then the value is meaningless and the act of recording is useless. Thus, the last sentence of subsection (d) allows identification of the patient by name or an assigned number as determined by the facility, but the facility must ensure the value can be traced to the particular patient so as to perform any needed clinical management of the patient.

Amend **section 30400** to address RTCC's recommendation regarding student oversight and to make nonsubstantial corrections. Subsections (a)(8) and (a)(11) are amended to delete an unnecessarily cited subsection designator since both referenced certificates are issued pursuant to section 30440. This results in no regulatory effect. Subsection (a)(35) is amended to delete the two-year experience reference for consistency with the changes to section 30417. See that section for further discussion.

Amend **section 30411** to clarify that the conditional exemption in subsection (e) granted to an approved radiologic technology certification school accredited by the Joint Review Committee on Education in Radiologic Technology does not exempt the school from the statutory requirement to provide specified training. This clarification is needed to ensure schools understand they are subject to that legislative mandate regardless of the regulatory provision. This change has no regulatory effect.

Amend **section 30417** to address RTCC's recommendation regarding student oversight. Subsections (c) and (f) address the oversight of a students' training based on whether the student is following the path for certification as a CRT or for permitting as an XT. Subsection (f) dictates the qualifications and limitations of the person who works with a student.

Currently, when CRT or XT students begin clinical training, they must be under direct oversight (30400(a)(19)) of a qualified practitioner (QP) (30400(a)(35)) who has at least two years of radiologic technology experience, except that a certified S&O need not meet the two-year requirement (30417(f)(2)). As students learn to perform an X-ray procedure, they gain experience and comfort with the tasks necessary to obtain quality images; to protect themselves, patients and others from unnecessary radiation exposure; and reach a level of competency where they can perform the procedure without the physical presence (referred to as indirect oversight (30400(a)(23)) of the QP. The QP evaluates the student's competency (called competency determination) and documents this determination. For XT students, only a supervising licentiate (30400(a)(40)) may perform and document the competency determination. The student may then, from that point forward, perform the procedure under indirect oversight. (30417(c).)

Adopted in October 2013, as recommended by RTCC, these requirements were to ensure a practitioner who has gained a strong level of experience oversees the student. It was based on industry standards that required clinical staff to hold specific certification issued by, and registration with, the American Registry of Radiologic Technologists (ARRT). Under ARRT's structure at that time, a person who passed the appropriate examination was considered certified, and upon renewal of the certification, became a registrant, resulting in a two-year period between initial certification and registration. ARRT has since clarified its concepts of certification and registration to indicate that registration begins upon certification issuance.

At RTCC's October 28, 2015 meeting (Reference 3), comments made during the public comment period indicated that implementation of this two-year requirement was burdensome on schools in that many clinical sites used by schools did not have staff that met the two-year experience requirement. It was determined that the two-year experience requirement for QP's presented an onerous, unintended burden on a school's ability to affiliate with medical facilities (called an affiliated clinical site (ACS) [30400(a)(2)]) in which students obtain clinical training. Because it is common that the ACS's clinical staff are newly certified or permitted, with less than two years of working experience, the school could not affiliate, or no longer maintain affiliation with the medical facility, impacting student training by delaying attainment of the student's educational goals and increasing their educational costs.

RTCC considered this provision and recommended (Reference 4) that only those, except for an S&O, making the competency determination for purposes of the student

moving from direct oversight to indirect oversight need to have at least two years of radiologic technology experience. This would maintain consistency with industry standards and ensure that students receive adequate training oversight and be deemed competent only by experienced persons.

To address RTCC's recommendation, subsections (c) and (f) and the definition of "qualified practitioner" found in section 30400(a)(35) are amended or repealed as follows:

- Section 30400(a)(35) – The definition is revised to repeal the two-year requirement as recommended by RTCC and to make nonsubstantial changes.
- Subsection (c) – Phrases are added and repealed to address RTCC's recommendation. An additional change regarding XT student competency determination is proposed that was not addressed by RTCC and is discussed further below.
- Subsection (f) is repealed because its provisions are addressed by the revisions being made to both subsection (c) and section 30400(a)(35), making subsection (f) unnecessary.

As it pertains to XT students, the competency determination may be made only by a supervising licentiate (SL) (30400(a)(40)). (30417(c).) This limitation was initially adopted because a majority of the affiliated clinical sites used by limited permit X-ray technician schools have a limited number of QPs, most of which are supervising licentiates. Thus, the provision mirrored common practice. However, the Department believes that this limitation should be modified to allow any QP, not just the SL, to determine the XT student's competency, provided the QP (except for an SL), as currently required in subsection (f)(2), has at least two years of radiologic technology experience. This maintains consistency for both CRT student oversight (e.g. QP is a CRT or SL) and XT student oversight (e.g. QP is an XT, CRT or SL) and provides schools more flexibility in affiliating with clinical sites for student training without compromising patient safety.

Subsection (g) is redesignated as subsection (f) to maintain a coherent structure.

Amend **section 30418** to delete expired dates and ensure grammar is correct, resulting in no regulatory effect.

Amend **section 30423** to delete expired provisions, ensure grammar is correct, clarify that the type of school being referred to is the school defined in 17 CCR 30400(a)(39), redesignate provisions to maintain a coherent structure, and correctly identify the website location where incorporated documents can be obtained, resulting in no regulatory effect.

Adopt **section 30441** to address RTCC's recommendation regarding establishing the CRT's scope of practice. RTCC recommended that:

The scope of practice of certified radiologic technologists should be established and be as stated in the ASRT's publication titled "Practice Standards for Medical Imaging and Radiation Therapy" for both Radiography and Radiation Therapy.

The need to establish this scope of practice became evident through previous RTCC meetings, public comments at those meetings, contact by facilities, and discussions regarding a CRT's authorization to inject contrast material under HSC § 106985. At RTCC's October 2013 meeting, staff presented its analysis of what the CRT's scope of practice was under the RT Act and requested RTCC's assistance. (Reference 9.) RTCC established a subcommittee to review the issue, and present its report and recommendation for consideration. (Reference 9a, p. 17.) This subcommittee presented an interim report at the RTCC's April 2014 meeting (Reference 10, p. 25) and submitted its final report at the October 2014 meeting. RTCC based its recommendation on that report. (Reference 1, p. 17.)

At the RTCC's April 2016 meeting (Reference 4), staff presented an analysis and draft regulations (Reference 4a) for consideration. That analysis indicated that the ASRT document (dated June 16, 2013 for Radiography; June 19, 2011 for Radiation Therapy) contained both scope of practice statements and clinical performance standards for facilities. It was determined that those standards applicable to facilities were not needed to establish the scope of practice. The draft regulations as presented excluded those standards since they did not focus on what a CRT is authorized to do under the RT Act. RTCC approved the draft regulations.

As compared to the draft regulations approved by RTCC (Reference 4a, pp. 11-13), this proposal contains differences as follows:

- Subsection (a) – The phrase "Subject to subsection (c)" is added and needed to ensure a CRT is aware of the supervisory structure as identified. The Department continues to receive questions from CRTs, hospitals and other medical facilities regarding this regulatory structure. This informs such facilities of this legal structure and should reduce confusion in the industry.
- Subsection (b) – The phrase "In addition to subsection (a)" is changed to the same opening phrase as found in subsection (a). This change was made to remove duplication between the original phrase and the phrase "certified radiologic technologist." The acronym "CRT" is defined in 17 CCR 30400(a)(9) and is a broad term that includes a CRT holding certification in either diagnostic or therapeutic radiologic technology (17 CCR 30400(a)(17) & (a)(42), respectively). Thus, the phrase "In addition to subsection (a)" was duplicative as to who subsection (a) applied; it applies broadly to any CRT. However, subsection (b) applies specifically to a certified therapeutic radiologic technologist (17 CCR 30400(a)(11)) and the indicated activities may not be performed by a certified diagnostic radiologic technologist. Therefore, the original phrase was changed to remove duplication and to inform the CRT and industry of the supervisory structure, as discussed regarding subsection (a).

ASRT's documents (References 5, 5a, 5b, 5c, 5d, 6 & 6a) present concepts, beliefs and information from a private organization's perspective and do not account for federal or state laws and regulations. Thus, ASRT's documents serve as a guide for appropriate practice as deemed by the organization and clearly state that their standards are superseded by federal and state laws, accreditation standards necessary to participate in government programs, and lawful institutional policies and procedures. Therefore, this proposal, though similar to and based on ASRT's Standards, ensures consistency with the RT Act and the Radiation Control Law (HSC §§ 114960 et seq.).

Subsections (a) and (b) are needed to address RTCC's recommendation and the provisions are based on the ASRT's publications "Practice Standards for Medical Imaging and Radiation Therapy" for both Radiography and Radiation Therapy (herein after called "Radiography Standards" and "Therapy Standards," or, collectively, "ASRT's Standards"), as recommended by RTCC. (Reference 5, pp. R6-R7; Reference 5a, pp. RT6-RT7.) Certification as a radiologic technologist is issued separately for diagnostic purposes and therapeutic purposes. (HSC § 114870(b)(1).)

Subsection (a) is based on and corresponds directly to the ASRT's Scope of Practice as stated in the ASRT's Standards, except as follows:

- Paragraph (1):
 - Though not addressed by the ASRT's Standards on which RTCC's recommendation were based, this provision is based on ASRT's revised Standards dated June 26, 2016 (Reference 6, pp. R5-R6; Reference 6a (pp. RT5-RT6)). The Department believes such a goal – to provide optimal patient care – is inherent in healthcare and is the intent of both the Legislature (H&S Code 114840) and the RTCC (HSC § 114855); that is, protection of the people from excessive and improper exposure to ionizing radiation and ensuring the proper administration and enforcement of the RT Act. Thus, this provision is needed to clearly inform all CRT's of that expectation placed on them by virtue of certification, the industry, and most importantly, the public.
- Paragraph (4) includes the phrase "for applicable procedures" to clarify that informed consent may not apply in all instances. This is based on ASRT's revised Standards dated June 26, 2016. (References 6 (pp. R5-R6) & 6a (pp. RT5-RT6).)
- Paragraph (7) clarifies the term "ALARA" as found in ASRT's standards to ensure consistency with the regulatory definition as cited.
- Paragraph (8) corresponds to ASRT's Standards regarding intravenous access and medications.
 - However, because ASRT's Standards are not intended to address state laws and regulations, this proposal ensures consistency with H&S Code 106985 and informs CRT's they may only perform venipuncture per that law.
- Paragraph (9):
 - The term "medications" is defined. It is based on:
 - HSC § 11014(b) for the term "drug" defined for purposes of the Uniform Controlled Substances Act (HSC § 11000 et seq.); and

- ASRT's Advisory Opinion Statements regarding medication injection through existing vascular access (Reference 5b, p. 1), and medication injections by radiologic technologists (Reference 5c, p. 1).
- ASRT's definition provides examples of two types of medications: contrast material and radiopharmaceuticals. Contrast material is a pharmaceutical used to increase visualization of tissues such as blood vessels so they can be seen on an X-ray image. As proposed, contrast material is included in the definition. However, the proposal excludes radiopharmaceuticals (i.e. radioactive drugs) because injection of radiopharmaceuticals is reserved to individuals who perform nuclear medicine technology (NMT) (HSC § 107150) and meet the requirements of 17 CCR 30500-30543. Thus, the proposal limits the term "medications" for consistency with those provisions. This proposal is not implying that a CRT who is also certified in NMT may not inject radiopharmaceuticals. If the individual is certified both as a CRT and a "certified technologist, nuclear medicine" (17 CCR 30500), the individual is authorized by their NMT certificate (17 CCR 30533) to inject radiopharmaceuticals. However, such injection must be in accordance with 17 CCR 30500-30543.
- Additionally, paragraph (9) limits the CRT scope of practice, regarding performing specific vascular access procedures, for consistency with HSC § 106985(f). A review of the legislative adoption and amendments to HSC § 106985 (Reference 4a, pp. 4-8) indicated legislative cautiousness, from a CRT having no role in identifying, preparing or administering (i.e. injecting) medications to allowing performance of more than just those activities as now specified in HSC § 106985, provided certain conditions exist or are met. However, certain acts continued to be prohibited. Thus, this proposal clarifies what acts are and are not authorized.
- Paragraphs (13) and (14) include the phrase "as applicable" to clarify the actions that may or may not be performed by the CRT because of the variable nature of the types of duties a CRT is assigned within a facility.
- Paragraph (15), corresponding to item 1 of the scope of practice as stated in ASRT's Standards, is needed for consistency with the RT Act and to identify those regulation sections under which certificates and permits are issued.
 - Additionally, ASRT's reference to performance of "noninterpretive fluoroscopic procedures...." is excluded since a CRT holding the permit issued pursuant to section 30451 authorizes the CRT to perform such procedures. Thus, the phrase is duplicative and not needed.
- Paragraph (18), as compared to the draft proposal approved by RTCC (Reference 4a, p. 12 [30441(a)(17)]), excludes the phrase beginning with the word "including" and ending with the word "procedures." This exclusion is based on ASRT's revised Standards since that phrase is not needed to identify what activities may be included "during all aspects of radiologic procedures." Assisting or transporting patients is an inherent activity that occurs when performing radiologic procedures.

Subsection (b) is based on and corresponds directly to the ASRT's Scope of Practice as stated in the ASRT's Standards (References 5, 5a, 6 & 6a), except that paragraph (7) clarifies that participation in brachytherapy procedures is subject to the cited license. This is needed because certification in radiologic technology does not extend to authorize the holder use of radioactive material or imply the holder is qualified for medical use of radioactive material. Brachytherapy means a method of radiation therapy in which radioactive sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application. (Title 10, Code of Federal Regulations, Part 35.2 incorporated by reference in 17 CCR 30195(a).) Such use is subject to the Radiation Control Law, its regulations, and the conditions of use under that issued license.

Subsection (c) is needed to clearly inform CRTs, the industry, and facility staff of the regulatory structure under which a CRT performs. The Department continues to receive questions from CRTs, hospitals and other medical facilities regarding this regulatory structure. This informs such facilities of this legal structure and should reduce confusion in the industry. This structure is dictated by the RT Act and clarified in regulation as follows:

- HSC § 106965(a):
 - It is unlawful for any person to administer or use diagnostic or therapeutic X-ray on human beings unless the person is certified or has been granted a limited permit, acts within the scope of that certificate or permit, and is acting under the supervision of a licentiate of the healing arts.
- HSC § 106980(a), in part:
 - A CRT may only use X-ray equipment under the supervision of a certified supervisor or operator².
- HSC § 114850(g)
 - "Supervision" means responsibility for, and control of, quality, radiation safety, and technical aspects of all X-ray examinations and procedures.
- 17 CCR:
 - Section 30460:
 - This is the broadest category of licentiate authorization and allows the holder to use or supervise X-ray use without restrictions, except as limited by the individual's healing arts license.
 - Radiology S&O may supervise a CRT, XT, or students.
 - It is issued only to licensed physician and surgeons who practice as radiologists or radiation oncologists.
 - Section 30461:
 - These permits are narrow authorizations as indicated and limited by the holder's healing arts license. For example, a podiatrist or chiropractor can obtain any of these permits but the permit does not expand what is legally authorized as a podiatrist or chiropractor.

² As implemented, the phrase "certified supervisor and operator" is used in current regulation and is defined in 17 CCR 30400(a)(10).

- Fluoroscopy S&O may supervise a diagnostic CRT with fluoroscopy permit, or students using fluoroscopy.
- Radiography S&O may supervise diagnostic CRT, XT, or students using radiography equipment.
- Dermatology S&O may, limited to the treatment of diseases and tumors of the skin, supervise therapeutic CRT, or an XT holding the permit category of dermatology X-ray therapy (no longer issued but there are persons holding a current permit in this category), or students operating therapeutic X-ray equipment.
- XBD S&O may supervise diagnostic CRT, XT holding an XBD permit, or students operating an XBD unit.

Amend **section 30450** to address RTCC's recommendation regarding movement of the patient or equipment during use of fluoroscopic X-ray equipment by non-certified or non-permitted individuals under certain conditions. See also the discussion of section 30305.5.

Subsection (b) is amended to establish an acronym used in proposed subsection (c) to reduce the volume of words in subsection (c). This results in no regulatory effect.

Subsection (c) is needed to address RTCC's recommendation and clarifies that authorization granted by certain permits or as certain qualified persons (CRT or XT) is not required, provided the individual complies with the cited provision. This implements RTCC's recommendation and clearly connects provisions adopted under the RT Act found in subchapter 4.5 (commencing at section 30400) and the provisions adopted under the RCL found in subchapter 4.0 (commencing at section 30100). The need for this connection was identified by staff and presented to RTCC (Reference 4b, p. 7) because RTCC's recommendation commingles concepts of radiation use, users, and safety issues within the statutory authorities of both the RCL and the RT Act.

Further, under regulations implementing the RCL, all radiation users must have a current copy of the subchapter 4.0 provisions (17 CCR 30255(b)(2)) but not subchapter 4.5 provisions (RT Act regulations). Though users can obtain a hardcopy or access the internet version containing provisions of both subchapters, confusion occurs often because the RCL regulations include broad safety procedures, require performance of tasks by undefined persons, and contain differing terminology from the RT Act provisions. Thus, clearly connecting related provisions increases consistency and clarity, allowing radiation users to more easily understand the relationships between the provisions and to fulfill their responsibility for radiation protection.

The last sentence of subsection (c) is needed to clearly inform the industry that the proposal does not grant more than what is stated or allow any person to perform tasks that constitute a violation of the RT Act. For further discussion, see section 30305.5.

Amend **section 30456** to address RTCC's recommendation regarding movement of the patient or equipment during use of fluoroscopic X-ray equipment by non-certified or non-permitted individuals under certain conditions. Subsection (d) is needed for the reasons stated regarding section 30450(c). The acronym "RTF," as used in proposed subsection (d), established in existing subsection (b) and refers to the "Radiologic Technologists Fluoroscopy" permit issued pursuant to section 30450. See also the discussion of section 30305.5.

Amend **section 30456.4** to correctly cite where a document can be found. Subsection (c), second sentence, states that the check-off document is found in the publication identified in subsection (a)(1). However, there is no subsection (a)(1) and the referenced publication is found in subsection (b)(1). Thus, the reference to subsection (a)(1) is changed to subsection (b)(1) for clarity, resulting in no regulatory effect.

References (Documents relied upon by the Department pursuant to Gov. Code Sec. 11346.2(b)(3)))

1. RTCC meeting minutes of October 29, 2014.
2. RTCC meeting minutes of April 8, 2015.
3. RTCC meeting minutes of October 2, 2015.
4. RTCC meeting minutes of April 13, 2016.
- 4a. Handout for RTCC April, 13, 2016 meeting: CRT Scope of Practice.
- 4b. Handout for RTCC April, 13, 2016 meeting: Movement recommendation.
- 4c. Presentation for RTCC April, 13, 2016 meeting: Student supervision at clinical sites.
5. *The Practice Standards for Medical Imaging and Radiation Therapy: Radiography Practice Standards*. ASRT, Effective June 16, 2013.
- 5a. *The Practice Standards for Medical Imaging and Radiation Therapy: Radiation Therapy Practice Standards*. ASRT, Effective June 19, 2011.
- 5b. *The Practice Standards for Medical Imaging and Radiation Therapy: Advisory Opinion Statement – Medication Injection Through Existing Vascular Access*. ASRT, Effective June 16, 2013.
- 5c. *The Practice Standards for Medical Imaging and Radiation Therapy: Advisory Opinion Statement – Medication Injection by Radiologic Technologists*. ASRT, Effective June 16, 2013.
- 5d. *The Practice Standards for Medical Imaging and Radiation Therapy: Advisory Opinion Statement – Injecting Medication in Peripherally Inserted Central Catheter Lines or Ports with a Power Injector*. ASRT, Effective June 16, 2013.
6. *The Practice Standards for Medical Imaging and Radiation Therapy: Radiography Practice Standards*. ASRT, Effective June 26, 2016.
- 6a. *The Practice Standards for Medical Imaging and Radiation Therapy: Radiation Therapy Practice Standards*. ASRT, Effective June 26, 2016.
7. Email from Teri Braun-Hernandez to Lisa Russell & Phillip Scott dated 8-20-16 regarding RT role during cardiovascular, cathlab and hybrid imaging.

8. Email from Teri Braun-Hernandez to Lisa Russell, dated 4-27-16, as forwarded by Lisa Russell to Phillip Scott, et al, dated 4-28-16 regarding Fluoroscopy Analysis from RTCC meeting 4/2016.
9. Presentation for RTCC's October 23, 2013 meeting: Scope of Practice – Radiologic Technologist.
- 9a. RTCC meeting minutes of April 8, 2015.
10. RTCC meeting minutes of April 2, 2014.

ALTERNATIVES CONSIDERED

Alternatives considered in this proposal are discussed or addressed in the detailed discussion of each regulation.

STATEMENTS OF DETERMINATIONS and ECONOMIC IMPACT ASSESSMENT

The Department, based on the following, 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.

- A facility could see a savings if a lesser paid person is used in lieu of a higher paid person as it pertains to movement of fluoroscopy equipment or the patient during fluoroscopic X-ray procedures.
- Allows a facility implementing the proposal to use existing personnel to provide proposed training.
- Recording of data and its retention is minimal and uses a facility's existing information technology systems.
- Makes it easier for approved schools to affiliate with clinical facilities.
- By specifying the CRT scope of practice, a facility can fully utilize a CRT's expertise in radiologic technology.

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 the regulations affect the following as described:

1. **The creation or elimination of jobs within the State of California.** No effect is expected because it clarifies current practices.
2. **The creation of new businesses or the elimination of existing businesses within the State of California.** No effect is expected because it clarifies current practices.
3. **The expansion of businesses currently doing business within the State of California.** No effect is expected because it clarifies current practices.
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 users of X-ray equipment have met specific training, education and experience requirements. Competency of such users ensures operators can safely and competently keep a patient's radiation exposure to a minimum and protect themselves, and other workers, from receiving unnecessary radiation exposure. This proposal would not affect the state's environment because the radiation energy emitted from the use of X-ray

equipment dissipates to normal atomic structures without environmental contamination.

The Department has determined that there would be an effect on small business subject to these regulations because small businesses would be required to comply with the regulations.

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

The Department must determine that no reasonable alternative considered by CDPH 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 and equally effective in addressing RTCC's recommendations.