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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations

DPH-17-009 Radiologic Technology Act Regulations: RTCC Recommendations
Published: June 21, 2019

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 August 5, 2019, 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-17-009 Radiologic Technology Act Regulations: RTCC Recommendations**" 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.

All submitted comments should include the regulation package identifier, “**DPH-17-009 Radiologic Technology Act Regulations: RTCC Recommendations**” author’s name and mailing address.

INFORMATIVE DIGEST

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.

PROGRAM 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 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

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

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>
<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>

RTCC Recommendation	Date of Meeting
<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.

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.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

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.

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.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impact that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

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.

STATEMENTS OF DETERMINATIONS

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.

RESULTS OF THE ECONOMIC IMPACT ANALYSIS

The Department has determined that the regulations affect the following as described:

- A. The creation or elimination of jobs within the State of California.** No effect is expected because it clarifies current practices.
- B. 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.

C. The expansion of businesses currently doing business within the State of California. No effect is expected because it clarifies current practices.

D. 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.

FISCAL IMPACT ESTIMATE

A. FISCAL IMPACT ON LOCAL GOVERNMENT: There will be an impact as described in item D below.

B. FISCAL IMPACT ON STATE GOVERNMENT: There will be an impact as described in item D below.

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

D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED:

RTCC Recommendation	Assessment
<p>Section 30305.5.</p> <p>Movement of the patient or equipment during use of fluoroscopic X-ray equipment by individuals not authorized under the RT Act should be allowed under certain conditions.</p>	<p>A facility is not required to implement subsections (b) through (g). A facility can implement either: only subsection (b); subsections (c) through (g); or subsections (b) through (g).</p> <p>Assuming a facility only implements subsection (b), a savings of about \$20 per hour of fluoroscopy usage could result only if a lesser paid person is used in lieu of a higher paid person. Actual savings varies based on wages paid.</p> <p>Assuming a facility only implements subsections (c) through (g), a savings of about \$20 per hour of fluoroscopy usage could result only if a lesser paid person is used in lieu of a higher paid person.</p>

	<p>However, that savings is offset by about \$91 to \$203 annually, due to re-allocation of existing staff or use of a qualified non-staff person, to provide the required training. Actual savings varies based on wages paid.</p> <p>The above conclusions apply for a facility implementing subsections (b) through (g).</p>
<p>Section 30307(b).</p> <p>Air kerma (a measurement of ionizing radiation) received during fluoroscopic procedures should be documented in the patient's record.</p>	<p>No cost or savings.</p>
<p>Section 30417.</p> <p>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, 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>Savings is likely but are not easily estimated due to significant variation between a school's physical location and the clinical site's physical location; the student's physical residence distance to a clinical site or the school's location; whether a facility wants to affiliate with the school; and the clinical site's staff availability and experience.</p>
<p>Section 30441.</p> <p>The scope of practice of certified radiologic technologists should be established and be as stated in the ASRT publication titled "Practice Standards for Medical Imaging and Radiation Therapy" for both Radiography and Radiation Therapy.</p>	<p>A facility could save about \$80 per day if a facility uses a qualified CRT in lieu of a higher qualified individual, such as a registered nurse, for administering medications during radiologic procedures. However, savings varies widely due to facility workloads, discretion, and union contract and liability insurance provisions, and is limited to radiologic procedures.</p>

- E. MANDATE ON LOCAL AGENCIES OR SCHOOL DISTRICTS:** None.
- F. OTHER NONDISCRETIONARY COSTS:** None
- G. FISCAL IMPACT ON LOCAL AGENCY OR SCHOOL DISTRICT REQUIRING REIMBURSEMENT PURSUANT TO 17500 ET SEQ.:** None

ALTERNATIVES CONSIDERED

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

ALTERNATIVES STATEMENT

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.

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

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.

CONTACT PERSON

Inquiries regarding the subject matter in this notice may be directed to Phillip Scott, Department's Environmental Management 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 .