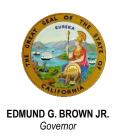


State of California—Health and Human Services Agency California Department of Public Health



NOTICE OF PROPOSED RULEMAKING

Title 17, California Code of Regulations

DPH-16-013 Posting of Radiologic Technology Act Authorizing Documents Notice Published: November 24, 2017

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 January 8, 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:

- By email: <u>regulations@cdph.ca.gov</u>. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-16-013 Posting of Radiologic Technology Act Authorizing Documents" in the subject line to facilitate timely identification and review of the comment;
- 2. By fax transmission: (916) 440-5747;
- 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-16-013 Posting of Radiologic Technology Act Authorizing Documents" author's name and mailing address.

AUTHORITY AND REFERENCE

The Department is proposing to amend Title 17, California Code of Regulations, section 30305 under the authority provided in sections 114975, 115000, 115060 and 131200 of the Health and Safety Code. This proposal implements, interprets and makes specific sections 114965, 114970, 115000, 115060, 131050, 131051 and 131052 of the Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of the Proposal

This proposal amends section 30305 to require medical X-ray facilities to post Radiologic Technology Act (RT Act) certificates and permits of personnel or to post a list containing the individual's name, the certificate/permit number and expiration date of the certificate or permit.

Policy Statement Overview

Problem Statement: Prior regulations required individuals who were certified and permitted to apply X-rays to people to post their certificate or permit where they perform X-ray procedures. However, some facilities refused to allow individuals to post their certificate or permit so they could not comply with the requirement. Further, facilities requested use of Internet online verification software for compliance with the posting requirements.

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

- Provide information to the public as to whether the person exposing them to X-rays meets certain qualifications.
- Clarify who is responsible for posting RT Act certificates and permits.

Benefits: Anticipated benefits from this proposed regulatory action are:

• Public confidence that persons exposing people to X-rays are qualified to do so.

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

Background/Authority

The Radiation Control Law (RCL) (Health & Saf. Code, § 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. The RT Act, codified in Health and Safety Code (H&S Code) §§106965 through 107120 and §§ 114840 through 114896, was enacted to protect the public and radiation workers from excessive or improper exposure to ionizing radiation. The regulations that implement, interpret and make specific the provisions of the RCL are in title 17, California Code of Regulations, §§ 30100 through 30395. The regulations that implement, interpret and make specific the provisions of the RT Act are in title 17, California Code of Regulations, §§ 30400 through 30468.

Under the RCL, the Department, in part, registers and inspects users of radiation machines (X-ray machines) including medical users. Under the RT Act, the Department, in part, certifies and permits those applying, or supervising the use of, X-ray to human beings, which include physicians, chiropractors, podiatrists, physician assistants, radiologic technologists and X-ray technicians. The application of X-ray to humans for diagnostic or therapeutic purposes is called radiologic technology (H&S Code § 114850(c)).

During the Department's inspection of a medical facility's X-ray machine use pursuant to RCL, Department inspectors verify that individuals performing radiologic technology are properly certified or permitted pursuant to the RT Act and conspicuously post their certificate or permit as required by 17 CCR 30404. This posting requirement was adopted in 1971 as part of the implementation of the RT Act and remained as adopted until October 11, 2013 (Register 2013, No. 41).

A number of events led both to amending § 30404 and to this proposal. Since 1971, the Internet's structure and use has greatly increased and is now integral to society and communication in general. A Certificate/Permit Search tool (http://rhbxray.cdph.ca.gov/) was added to the Department's Internet website in the mid-2000's and allows the public, facilities, and certified or permitted individuals to view up to date information on valid and current certificates and permits issued pursuant to the RT Act. However, that Internet search tool does not display any certificate or permit that is not current for any reason, or that has expired as of the last update of the date indicated on that webpage.

Although this search tool became publically available in the mid-2000's, under § 30404, individuals were still subject to the posting requirement. In August 2012, a facility requested they be allowed to use the online Certificate/Permit Search Tool as a primary source verification of current radiology related permits. Other facilities became aware of the request and personally contacted Department staff with the same request. To address these requests, the Department issued a general exemption to RT Act

¹ This short format "17 CCR 30100" for a given regulation found within title 17, California Code of Regulations will be used throughout this document for brevity.

certificate and permit holders from § 30404 provided certain conditions were met. That exemption also pointed out that the online Search tool had limitations and may be inaccurate. The issued exemption reminded the facility that the search tool was not intended to preclude a facility or patient from requesting to review original documents to verify an individual's qualifications.

At the same time those requests were being considered and the exemption issued, the Department was in the process of revising § 30404 to address an issue found during medical X-ray facility inspections. It was found that some X-ray facilities would not allow the X-ray technologist/technician to post their certificate or permit since the facility was not the responsible party for posting the certificate or permit. Thus, the X-ray technologist/technician responsible for posting their certificate or permit could not comply with the requirement.

Due to these events, § 30404 was amended, effective October 11, 2013, to require the certificate or permit holder to provide their certificate or permit, or a copy thereof, to the X-ray facility. During that rulemaking effort, the public was informed that the Department intended, in a future rulemaking effort, to require the X-ray facility to post the certificate or permit. Thus, this proposal is carrying out that intent.

To ensure the public has access to information on whether an individual who takes their X-rays, or supervises the X-ray technologist or technician, is authorized to do so, this proposal would require the X-ray facility to either post an individual's certificate or permit or to post a list containing specific information. This proposal also clarifies that the responsible party for posting the certificate or permit or list is the "user" as defined in § 30100, and not the RT Act certificate or permit holder, as required prior to October 11, 2013.

The regulations interpreting, specifying, or implementing the RCL are in 17 CCR §§ 30100 through 30395. The proposed changes are:

Amend **section 30305** to require users to display certificates and permits issued pursuant to the RT Act or to post a list containing specific information from those documents.

EVIDENCE SUPPORTING THAT THE PROPOSED REGULATORY ACTION IS COMPATIBLE WITH EXISTING STATE REGULATIONS

The Department has evaluated this proposal as to whether the proposed regulations are inconsistent or incompatible with existing state regulations. After conducting a review for any regulations that would relate to or affect posting of Radiologic Technology Act Authorizing Documents, the Department has concluded that no known statute or regulation conflicts with this proposed regulatory action.

MANDATED BY FEDERAL LAW OR REGULATIONS

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

FORMS INCORPORATED BY REFERENCE

None.

OTHER STATUTORY REQUIREMENTS

None.

BUSINESS REPORTING REQUIREMENT

None.

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.

FISCAL IMPACT ASSESSMENT

A. FISCAL IMPACT ON LOCAL AGENCIES AND SCHOOL DISTRICTS

There are no costs to local agencies or school districts for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

B. FISCAL IMPACT ON STATE GOVERNMENT:

- 1. State agencies using radiation sources are subject to the proposal. There will be an impact as described in item D below.
- The Department inspects and verifies the list and an individual's certificate or permit are available. However, because facilities already comply and Department inspectors already verify proper posting, there should be no impact on inspections.
- C. FISCAL IMPACTS ON FEDERAL FUNDING OF STATE PROGRAMS: None.
- D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED: If an individual gives a copy of their certificate or permit to the facility, there is no cost to the facility. Small facilities might only have a two page list costing \$0.20 to post. A large facility may have 500 names on their list which

equates to \$1.00 to post the 10 pages. However, because facilities already comply and Department inspectors already verify proper posting, there should be no impact on private persons or businesses.

E. OTHER NON-DISCRETIONARY COST OR SAVINGS IMPOSED UPON LOCAL AGENCIES. None.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a represented 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. If the small business fails to comply with the regulation, the small business may incur a detriment in the form of a civil penalty.

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 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:

- A. The creation or elimination of jobs within the State of California. The proposal will not impact the creation or elimination of jobs because it only addresses the requirement of posting certificates and permits or a list with specific information.
- B. The creation of new businesses or the elimination of existing businesses within the State of California. The proposal will not impact the creation or elimination of new or existing businesses within the state of California because it only addresses the requirement of posting certificates and permits or a list with specific information.
- C. The expansion of businesses currently doing business within the State of California. The proposal will not impact the expansion of businesses currently doing business within the state of California because it only addresses the requirement of posting certificates and permits or a list with specific information.
- D. The benefits of the regulation to the health and welfare of California residents, worker safety, and the state's environment. The proposal increases and

strengthens the health and welfare of California residents, and worker safety by providing the public the information to verify a person's qualifications to perform medical X-ray procedures.

CONSIDERATION OF ALTERNATIVES

The Department must determine 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 this action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

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

- Email dated July 21, 2015 from Lisa Russell to Phillip Scott containing email chain including request of August 7, 2012 from Lynn M. Lopes of Sutter Health Medical Staff & Physician Services.
- 2. Issued Exemption from 17 CCR 30404 dated October 1, 2012.

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.