

Initial Statement of Reasons

Summary of the Proposal

This proposal would require users of X-ray machines, for radiologic technology purposes, to post Radiologic Technology Act (RT Act) certificates and permits of personnel or to post a list containing the individual's name, and the certificate/permit number and expiration date of the individual's certificate or permit.

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.

Policy Statement Overview

Problem Statement: Prior regulations required individuals who were certified and permitted to apply X-ray 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 preventing the individual from complying with the posting 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 it, 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 30395.¹ The regulations that implement, interpret and make specific the provisions of the RT Act are in 17 CCR 30400 through 30468.

Under 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 a medical facility's inspection of 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 posted their certificate or permit as required by 17 CCR 30404. This posting requirement was adopted in 1971 (former § 30411, Register 71, No. 17; redesignated to § 30404; Register 85, No. 34) 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 lead 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.

Though 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 primary source verification of current radiology related permits. (Reference 1.) Other facilities became aware of the request and personally contacted staff with the same request. To address these requests, the Department issued a general exemption to RT Act certificate and permit holders from § 30404 provided certain conditions were met. (Reference 2.) 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.

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.

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 their 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 an individual's 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 their 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.

DETAILED DISCUSSION OF EACH REGULATION

Amend Section 30305, adopted pursuant to the RCL, to require users to display certificates and permits issued pursuant to the RT Act or a list with specific information. This requirement will allow both patients and state inspectors to readily determine if an individual performing X-ray procedures is certified or permitted by the Department to perform those procedures.

Proposed subsection (e) requires the user, the person who possesses the radiation machine, to publicly display specified documents at the installation where an individual performs, or supervises the performance of, radiologic technology. The need for this provision is discussed above.

This proposal does not prescribe the physical location where an individual's certificate or permit or list must be displayed. Because the configuration of hospitals, private physician practice offices, orthopedic offices, podiatry offices, etc. widely varies, this proposal would require the document or list to be "publically" posted to allow flexibility in where the posting is presented. For example, a hospital radiology department is usually housed within a specific area of the hospital building with its own waiting room and the posting could be in that room. Displaying of an individual's certificate or permit may also occur in the X-ray procedure room itself, which is typical of private or group medical practice offices.

Proposed subsection (e)(1) specifies the documents that the user is required to display. These documents are copies of each individual's certificate and permit required under the RT Act. These certificates and permits are issued by the Department to authorize an individual to perform certain X-ray activities.

Proposed subsection (e)(2) provides an option for the user to display a list of information based on the documents specified in subsection (e)(1). This option may be more convenient for those users who have the services of a large number of certified and permitted individuals. The Department believes that displaying the list will be as effective as displaying a copy of each certificate.

Proposed subsection (e)(2)(A) specifies the information required on the list. The individual's name indicated on the issued document is needed to identify who the certificate or permit was issued to. The certificate or permit number indicated on the issued document is needed to identify the specific type of certificate or permit. And, the expiration date indicated on the certificate or permit is needed to determine if the authorization is current. This information is the same information as provided on an individual's certificate or permit. Thus, patients can verify a person on the list shows up on the Department's website, providing additional confidence that a person is authorized. The Department's website contains a search tool to verify an individual is certified or permitted: <http://rhbxray.cdph.ca.gov/>. The font size is designated at 12 points to ensure the document is visible and readable to a person with compromised vision, viewable at arm's length.

Proposed subsection (e)(2)(B) specifies the text needed to ensure that displaying the list will be as effective as displaying a copy of each certificate. The public should be informed that an individual's certificate or permit can be viewed so the public can have peace of mind regarding the individual's authorization. The list also allows the public to verify an individual's information on the Department's website. The font size is designated at 14 points to more easily draw a person's attention to the list.

The authority and reference citations are amended, resulting in nonsubstantial changes, 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 SB 162. (Stats. 2006, ch. 241.)

Documents Relied Upon (References)

1. 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.

Consideration of Reasonable Alternatives

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

STATEMENTS OF DETERMINATIONS and ECONOMIC IMPACT ASSESSMENT

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 jobs 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 creation or elimination of jobs 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.

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.

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