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Director

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



EDMUND G. BROWN JR.
Governor

ACTION: Notice of Proposed Rulemaking
Title 17, California Code of Regulations

SUBJECT: Medical and Dental X-ray Quality Assurance, DPH-08-015

PUBLIC PROCEEDINGS: Notice is hereby given that the California Department of Public Health will conduct written public proceedings 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 this notice.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW: The Legislature of the State of California has found and declared that it is in the interest of public health to require that the people of this state be protected from excessive and improper exposure to ionizing radiation.¹ In this regard, the Legislature declared that it is the policy of the State of California to institute and maintain a regulatory program for sources of ionizing radiation so as to provide for an integrated and effective system of regulation within the State.² To carry out this policy, the Legislature enacted the Radiation Control Law (Health & Safety Code section 114960 et seq.), which authorizes the California Department of Public Health (Department), as a successor to the Department of Health Services pursuant to Health and Safety Code sections 131055 and 131200, to promulgate regulations regarding sources of ionizing radiation, for the protection of the health and safety of the public and for the protection of radiation workers. The regulations that implement, interpret, and make specific, the provisions of the Radiation Control Law are in title 17, California Code of Regulations, sections 30100 through 30395.

To better protect both the public and radiation workers from unnecessary exposure to radiation, and to reduce the occurrence of misdiagnosis, the Governor, during the 2005-2006 legislative session, signed into law Assembly Bill (AB) 929 (Stats. 2005, chapter 427). AB 929 requires adoption of regulations that require personnel and facilities using radiation-producing equipment for medical and dental purposes to maintain and implement medical and dental quality assurance standards that protect the public health

¹ Health & Safety Code section 114840.

² Health & Safety Code section 114965(b).

and safety by reducing unnecessary exposure to ionizing radiation, while ensuring that images are of diagnostic quality.

The purpose of these proposed regulations is to implement AB 929. The standards in these proposed regulations are limited to the use of radiographic film. Quality assurance standards for digital radiography have not yet been established by either the medical or health physics communities at the time these proposed regulations were developed.

The Department proposes to:

Adopt **Section 30305.1, Quality Assurance General Provisions**, to establish the quality assurance requirements that apply to each user who performs radiography for healing arts purposes.

Adopt **Section 30308.1, Quality Assurance for Radiographic Installations (Other Than Mammography, Dental, and Veterinary Medicine)**, to establish the quality assurance requirements that apply to users who develop clinical radiographs with automatic film processors in the practice of medicine, osteopathy, chiropractic, and podiatry. This proposed section does not apply to those who practice dentistry or veterinary medicine or perform mammography.

Adopt **Section 30311.1, Quality Assurance for Dental Radiography**, to establish the quality assurance requirements that apply to each user performing radiographic examinations using intra-oral film systems for dental purposes.

Authority: Sections 114975, 115000, 115060, 115061, 131051, 131052, 131055, and 131200, Health and Safety Code.

Reference: Sections 114965, 114970, 115000, 115060, and 115061, Health and Safety Code.

COMMENTS: 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 October 3, 2011, 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 to: regulations@cdph.ca.gov. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH -08-015" in the subject line to facilitate timely identification and review of the comment; or
2. By fax transmission: (916) 440-5747; or

3. By mail to: Office of Regulations, California Department of Public Health, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377; or hand-delivered to: 1616 Capitol Avenue, Sacramento, CA 95814. It is requested but not required that written comments sent by mail or hand-delivered be submitted in triplicate.

All comments, including email or fax transmissions, should include the author's name and U.S. Postal Service mailing address in order for the Department to provide copies of any notices for proposed changes to the regulation text on which additional comments may be solicited.

INQUIRIES: Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Leo Spencer of the Radiologic Health Branch, at (916) 440-7982 or Phillip L. Scott at (916) 440-7978.

All other inquiries concerning the action described in this notice may be directed to Miyoko Sawamura, Office of Regulations, at (916) 440-7690, or to the designated backup contact person, Linda M. Cortez at (916) 440-7683.

CONTACTS: In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-08-015.

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

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 by clicking on these links, in the following order: Decisions Pending and Opportunity for Public Participation, Regulations, Proposed.

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) 440-7683 (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.

FISCAL IMPACT ESTIMATE:

- A. Fiscal Effect on Local Government: There will be an impact as described in item D below.
- B. Fiscal Effect 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.
 - 2. The Department estimates that there will be no increase to the Radiation Control Fund. The Department currently possesses the equipment, supplies and inspectors needed to determine compliance with the proposed regulations. It is estimated that the time needed for inspections will not significantly increase.
- C. Fiscal Effect on Federal Funding of State Programs: None.
- D. All cost impacts, known to the Department at the time the notice of proposed action was submitted to the Office of Administrative Law, that a representative private person or business would necessarily incur in reasonable compliance with the proposed action: The Department estimates that approximately 8,000 businesses will be impacted. However, the actual impact is likely less because an unknown portion of medical X-ray facilities use digital imaging capture systems instead of film-screen capturing systems that require photographic film processing. These proposed regulations do not apply to digital imaging capture systems, but to medical X-ray facilities using photographic film, whether by use of automatic film processing equipment or by manual film processing.

The impact will be on those businesses that provide medical X-ray services using automatic film processing without a current quality control program. Initial costs for each business providing medical X-ray services using automatic film processing without a quality control program are estimated to be less than \$2,000. These costs, found through internet search, are for the purchases of sensitometers, densitometers (\$1,650), step-wedges (\$135), and film for quality control tests (\$90 [3 boxes times \$30 per box]). Ongoing costs for each of these businesses should be around \$100 annually, for film.

It is estimated that there will be no costs for individuals.

The impact on dental X-ray facilities cannot be estimated because the proposal would impose minimal, but unknown, procedure changes. However, it is likely that there will be no impact.

E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

DETERMINATIONS: The Department has determined that the regulations 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 made an initial determination that the 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.

The Department has determined that the regulations would not significantly affect the following:

1. The creation or elimination of jobs within the State of California. The proposal may result in the creation of jobs but its extent cannot be estimated.
2. The creation of new businesses or the elimination of existing businesses within the State of California. The proposal may result in the creation of new businesses but its extent cannot be estimated. The proposal should not result in the elimination of existing businesses.
3. The expansion of businesses currently doing business within the State of California. The proposal may result in the expansion of businesses currently doing business with the State of California but its extent cannot be estimated.

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

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

ADDITIONAL STATEMENTS AND COMMENTS: In accordance with Government Code Section 11346.5(a)(13), 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 the action is proposed or would be as effective and less burdensome to affected private persons than the proposed action.

No hearing has been scheduled; however, any interested person or his or her duly authorized representative may request in writing, no later than 15 days prior to the close of the written comment period, a public hearing pursuant to Government Code Section 11346.8. For individuals with disabilities, should a public hearing be scheduled, the Department will provide assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette, or computer disk. Note:

The range of assistive services available may be limited if requests are received less than ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Linda M. Cortez, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, or call (916) 440-7683, or use the California Relay Service by dialing 711.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

DPH-08-015

Date: JUL 08 2011



Ron Chapman, MD, MPH
Director