Initial Statement of Reasons

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, effective system of regulation within the State.[2] To carry out this policy, the Legislature enacted the Radiation Control Law[3], which authorizes the California Department of Public Health (the 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 radiation workers.

To better protect 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 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. Digital radiography is not addressed because a national consensus on the quality assurance standards had not yet been established by either the medical or health physics communities at the time these proposed regulations were developed.

The regulations interpreting, specifying, or implementing the Radiation Control Law are in title 17, California Code of Regulations, section 30100 et seq. The proposed changes are explained as follows:

Section 30305.1, Quality Assurance General Provisions, establishes the quality assurance requirements that apply to each user who uses X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, or veterinary medicine.

A user, in part, is defined in Section 30100(aa) as any person who has registered as possessing a radiation machine so installed as to be capable of producing radiation, or who otherwise possesses such a machine that is subject to registration. The term, person, is defined in section 30100(l), and means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency

[1] Health & Safety Code section 114840.
[2] Health & Safety Code section 114965(b).
[3] Health & Safety Code section 114960 et seq.

thereof, and any legal successor, representative, agent, or agency of the foregoing, other than the United States Nuclear Regulatory Commission, the United States Department of Energy, or any successor thereto, and other than Federal Government agencies licensed by the United States Nuclear Regulatory Commission, under prime contract to the United States Department of Energy, or any successor thereto. Thus, use of the term "user" and the reference to section 30305(a)(1) are necessary to clarify that this section applies only to users who use X-rays in the practice of medicine, dentistry, osteopathy, chiropractic, podiatry, or veterinary medicine, whether or not they have registered with the Department.

Subsection (a)(1) requires each user to assure that radiographic films are stored, handled, and processed, in accordance with manufacturers' recommendations. It further prohibits use of expired film for clinical purposes.

Because the development of visible images in radiographic films is a chemical process, film manufacturers specify the solutions, concentrations, temperatures, and immersion times needed to form and fix a quality image. Under-processing can occur with improper solutions, weak chemical concentrations, low temperatures, or insufficient immersion times. Under-processing will produce images with densities that are too low to completely render the latent X-ray image visible. In an attempt to obtain a darker image many users will then increase the X-ray exposure to the film (e.g. over-exposed), which will also increase the radiation dose administered to the patients. This additional radiation dose is considered harmful, since it would have been unnecessary if the user had assured that their films were processed according to the film manufacturers' specifications.

Compounding this public health and safety issue is that an over-exposed and under processed film can also lead to a misdiagnosis caused by the resulting poor quality images. Such a misdiagnosis can occur because overexposing and under-processing a film reduces its ability to translate differences in anatomic structures into the expected image contrasts. Incomplete image contrast reduces the ability to differentiate anatomic structures, which can lead to misdiagnosis. Not only can patients be exposed to unnecessary levels of radiation, they may also be injured as a result of the misdiagnosis. For these reasons, requiring users to assure that radiographic films are processed in accordance with the manufacturers' recommendations will protect the patient from unnecessary exposure to ionizing radiation and will help ensure that images are of diagnostic quality.

During storage, unprocessed films can become fogged if they are not protected from radiation, chemical fumes, heat, pressure, and humidity. To prevent this fogging, radiographic film manufacturers specify the conditions under which their films need to be stored. Even when properly stored, film will eventually fog over time. Therefore, manufacturers also recommend a date after which each box of film should no longer be used for clinical purposes.

During handling, unprocessed films can also become fogged if they are exposed to extraneous light. To prevent this fogging, manufacturers design radiographic films so they can be safely handled under filtered lights. Manufactures specify the lighting and filtration under which different types of radiographic film may be handled without becoming fogged.

Film fogging limits the range of contrasts that can be provided in a radiograph. This loss in contrast will reduce the image quality, which in turn can diminish the accuracy of a diagnosis. Therefore, requiring users to assure that radiographic films are stored and handled in accordance with the manufacturers' recommendations is needed in order to protect the public health and safety, by helping to ensure that film images can be of diagnostic quality.

Subsection (a)(2) requires each user to assure that intensifying screens, grids, viewers, and film processing equipment, chemicals, and solutions are stored, used, and maintained in accordance with manufacturers' recommendations.

Intensifying screens are fluorescent screens usually placed on each side of a radiographic film in order to intensify the exposure effects of the X-ray beam. Using screens allows less radiation to be used for exposing the film while still maintaining image quality. Since it is the intensifying screens that emit the light that provides a majority of the exposure to the radiographic film, it is essential that film-screen combinations used are matched in accordance to their manufacturers' recommendations. Because different brands and types of radiographic films can have different spectral sensitivities (e.g. blue, green or blue-green), screen manufactures specify the brands and types of films for which their screens are designed. Using mismatched screens (e.g. a blue-light emitting screen with a green-light sensitive film) will reduce the intensity of the light that can expose the film, which then makes it necessary to increase the X-ray exposure in order to obtain the needed image density. This increase in X-ray exposure will increase the patient's radiation dose, which is considered harmful because the increase of dose would have been totally unnecessary if proper film-screen combinations were used. Therefore, requiring users to assure that intensifying screens are used in accordance with the manufacturers' recommendations will protect the public health and safety by reducing the potential for unnecessary exposure to ionizing radiation.

Intensifying screens can become dirty during normal use. Because the surfaces of intensifying screens can be easily scratched, manufacturers recommend cleaning solutions and cleaning schedules for their screens. Dirty or scratched screens will introduce artifacts into a radiograph that can interfere with the diagnosis. Therefore, requiring users to assure that intensifying screens are maintained in accordance with the manufacturers' recommendations will help protect the public health and safety by reducing unnecessary radiation exposure and controllable adverse impacts on image quality.

Grids help absorb scattered X-rays that can interfere with the quality of a radiograph. Grids are manufactured to be used at specified distances from the X-ray tube. Using a grid at improper distances will reduce the intensity of the X-ray beam striking the film cassette, which then makes it necessary to increase the X-ray exposure to obtain the needed image density. This increase in X-ray exposure will increase the patient's radiation dose, which is considered harmful because it would have been totally unnecessary if the grid was properly used. Therefore, requiring users to assure that grids are used in accordance with the manufacturers' specifications will protect the public health and safety by reducing the potential for unnecessary exposure to ionizing radiation.

View boxes can become soiled during normal use and their lamps will eventually need replacing. For these reasons, manufacturers recommend specific cleaning procedures and specify the replacement lamps needed to maintain the designed performance level of film viewers. Improperly maintained film viewers can affect the accuracy of a diagnosis due to improper and inconsistent illumination of radiographic films. Therefore, requiring users to assure that film viewers are maintained in accordance with the manufacturers' recommendations will help protect the public health and safety by insuring that images can be adequately viewed for diagnostic purposes.

Manual film processing equipment consists of chemical tanks, tank covers, and film racks, and automatic equipment may include film rollers and tracks, all of which will become contaminated during normal use. For this reason, manufacturers recommend precautions to be used and cleaning procedures to be followed that will ensure that films can be processed with consistent quality. Also, automatic film processor manufacturers specify the cleaning and maintenance procedures that are needed in order to assure that quality images can be consistently produced from day to day. Since processing chemicals and solutions have limited shelf lives which can be affected by temperature, manufacturers specify the storage conditions and expiration dates for their chemical products. The strengths of film processing solutions become depleted because of use, contamination, and oxidation. Therefore, manufacturers recommend specific procedures for their storage, replenishment, and use. For all of the above reasons, it is necessary to require users to assure that film processing equipment, chemicals, and solutions are stored, used, and maintained in accordance with manufacturers' recommendations in order to insure that images are of diagnostic quality, and in order to protect the public health and safety.

Subsection (a)(3) requires each user to assure that a technique chart is provided for each X-ray machine.

For consistent image quality it is essential that each operator of a given X-ray machine use the same examination techniques. If the techniques used for each examination are not consistent, it becomes very difficult to determine whether the causes of image quality problems are due to the X-ray machine or to film processing. Therefore, requiring users to provide a technique chart established for each X-ray machine helps

ensure that the image quality will be consistent, independent of the operator performing the examination.

The requirement to establish a technique chart for each machine is needed because output radiation levels can vary from machine to machine. Thus, it may be necessary to provide different exposure factors for various machines within a facility in order to standardize their outputs for any given view.

Subsection (a)(3) also requires that the technique chart include, for the views commonly performed with each machine, the following: patient size versus selectable exposure factors; source-to-image distance; grid data; film/screen combination; and, patient shielding, if appropriate.

Different views present unique subject contrasts that attenuate the X-ray beam differently. For example, in the chest; a view of the ribs requires a technique that will image the high density structures of bone, a view of the heart requires a technique that images the medium density structures of moving muscle, and a view of the lungs requires a technique that will image low density air spaces.

The requirement to include patient size is needed because the size of the patient has an effect on image density and contrast. The thicknesses of larger patients will absorb more X-rays from the beam, thus reducing the density of the image. Because the X-ray beam intensity at the film cassette is reduced more by larger patients, adjustments in the exposure factors are needed in order to maintain consistent image densities from patient to patient. The exposure factors that may be selectable for an examination include the X-ray tube voltage, the X-ray tube current, the duration of the exposure time, and the phototimer compensation. Because exposure techniques have a large impact on image densities and contrasts, it is critical that each operator of a given X-ray machine use the same exposure factors.

The source to image distance is the distance between the focal spot of the X-ray tube (i.e. the radiation source) and the film cassette. Including the source to image distance in the technique chart is necessary because changes in distance have a dramatic effect on the intensity of the beam at the film cassette, which will in turn impact the density of the image. Therefore, it is important that all operators of each X-ray system use the same distances prescribed for each of the more common views, in order to maintain consistent image densities.

Including grid data for specific views is required because the use of grids reduces the intensity of the X-ray's beam striking the film cassette, thus affecting the density of the image. Grids are used to absorb those X-rays scattered by the patient and other objects that would have exposed the film cassette. Although grids will decrease the beam intensity at the film cassette, they also have the effect of increasing the image contrast. Because different types of grids produce different degrees of these effects on the image, it is important that their use by all operators of each X-ray machine be consistent.

Including the type of film-screen combinations to be used for each view is also necessary in order to ensure consistent image densities and contrasts. Mixing film-screen combinations will produce images with different contrasts and densities, thus making it impossible to track the consistency of film processing. More importantly, using an incorrect combination of films and screens can result in unnecessary exposure levels to patients, and can result in image quality so poor that it leads to misdiagnosis. Therefore, this requirement is needed to protect against injury due to misdiagnosis, and to protect the public from unnecessary exposure to ionizing radiation.

The requirement that users assure that technique charts indicate the views for which patient shielding can be used is needed to help protect radiosensitive organs from direct exposure to the primary X-ray beam. Radiosensitive organs include the lens of the eye, the thyroid glands, and gonadal tissues.

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

The requirements in this section can not be applied to those who practice dentistry because the small sizes of intraoral X-ray films prevent the sensitometric measurement of radiographic film characteristics with instruments that are available. Requirements that are within the feasibility of all dental radiographic installations are therefore proposed in a separate section. See proposed section 30311.1, Quality Assurance for Dental Radiography.

Applying these requirements to the practice of veterinary medicine would go beyond the scope authorized in AB 929 in that the public is not exposed to X-rays as patients during the practice of veterinary medicine.

The film processing quality assurance requirements applicable to users who develop mammograms can be more thorough than those standards that can be applied in general medical and dental radiography. This difference in standards is due to more limited types of film that can be used to perform mammography. Therefore, the quality assurance requirements for automatic film processors used to developed mammograms are currently addressed in existing section 30316.20.

The requirements in this section do not apply to manual processing. Manual processing is significantly more labor intensive in that it requires constant operator attendance during the process which can take approximately fifteen minutes per examination. Automatic film processing, depending on the particular equipment, takes up to three minutes per film and does not require the attendance of an operator during the process. The time required to establish and determine the operating levels for manual processing can take five times longer than that needed for automatic processing. Quality control in manual processing can be achieved by means of the proper processing procedures

proposed in section 30305.1, Quality Assurance General Provisions, because the operator has constant control of the developing process.

Since operators do not have constant control over automatic film processors it is essential to monitor the processor's operating levels in order to maintain consistent quality in the processed images. Requiring the user to assure that the operating levels of automatic film processors are monitored will help ensure that images will consistently be of diagnostic quality.

When unmonitored changes in the operating levels of automatic film processors are great enough to render diagnostically useless images, the examination will need repeating. These repeated exposures to the patient are considered harmful since they would have not been necessary if the operating levels of the processor had been monitored and corrected. Unmonitored processors can under-process radiographic films that will produce images which have densities too low to completely render the latent X-ray image visible. In an attempt to obtain a darker image with higher densities, the user may increase the X-ray exposure to the film, which will also increase the radiation dose administered to the patient. This additional radiation dose is considered harmful since it would have been unnecessary if the user monitored and adjusted the processor's operating levels. Compounding these harmful effects is the resulting loss of the film's ability to translate differences in anatomic structures into the expected image contrasts. Limiting the range of an image's contrast will reduce the ability to differentiate anatomic structures, which can lead to misdiagnosis. Not only will patients be exposed to unnecessary levels of radiation, they can also be injured as a result of misdiagnosis. For these reasons, requiring users to assure that the operating levels of automatic film processors are monitored will help protect the public health and safety from unnecessary exposure to ionizing radiation.

Subsection (a)(1) requires users to assure that each processor used to develop clinical radiographs is adjusted and maintained to meet the manufacturer's processing specifications for the highest speed radiographic film used clinically.

Radiographic film manufacturers specify the processing conditions needed to develop images that will render the optimum sensitometric characteristics of the film. In order to produce these radiographic images with automatic processors, it is therefore necessary to establish processor operating levels that will meet the processing conditions specified by the film manufacturer.

Because high speed films are more sensitive to changes in processing, changes in the operating levels of an automatic film processor will affect the image quality of high speed films before it does slow speed films. To assure that image quality can be maintained for all radiographic films regardless of speed, it is necessary to monitor changes in the image quality of the highest speed film developed in the processor. For this reason, it is necessary that a processor's operating level is established using the highest speed radiographic film developed for clinical use. Once established, it is then

possible to determine if a processor is consistently operating within the limits proposed in subsection (a)(2).

Subsection (a)(2) requires the users to assure that the automatic film processor is operating within specified limits each day before clinical films are processed. To be able to maintain consistency in day-to-day operation of a film processor, it is necessary to monitor operating levels each day films are processed. This daily monitoring must be performed before any clinical films are developed in order to assure the quality of all clinical films. The established method for monitoring processor activity is to expose a fresh radiographic film with a calibrated 21 step sensitometer. After developing this sensitized film in the processor being monitored, the optical densities of the sensitometric steps are then measured with a calibrated densitometer.

Subsections (a)(2)(A)-(C) establish the operational control limits for automatic film processors used to process clinical films. These operational control limits are the key to processor quality control. Three qualities of the sensitometric film are monitored to determine changes in the activity of a processor. These three qualities are: the base-plus-fog density, which indicates the film's minimum response to processing; the mid-density, which indicates speed; and, the density-difference, which indicates contrast. The mid-density and density-difference operating limits of plus or minus 0.15 are similar to those established in section 30316.20, Quality Assurance Testing Requirements for the Use of X-Ray in Mammography. However, the base-plus-fog operating limit is different than that established for mammography films.

The base-plus-fog density operating limit is increased from the plus 0.03 limit established for mammographic film processors to plus 0.05 for general purpose radiographic film processors. The increase in the base-plus-fog density operating limit is needed because mammographic films have one emulsion, while general purpose radiographic films have two emulsions. Dual emulsion films inherently have higher base-plus-fog levels than single emulsion films. In their Report Number 99 (Reference 1, p. 50), Quality Assurance for Diagnostic Imaging, the National Council on Radiation Protection (NCRP) also recommends the 0.05 base-plus-fog operating limit for general purpose radiographic film processors.

Subsection (a)(3) requires users to assure that tests are performed to determine the level of residual fixer retained in radiographic films. Residual fixer chemicals left on films after processing can render radiographs useless within five years due to chemical staining. For this reason, automatic processors wash the films to remove any residual fixer chemicals. To determine if radiographs can be useful for archival purposes, it is necessary to periodically test for the level of residual fixer retained in the film after the washing process. Film manufacturers offer kits that test for fixer retention levels. The requirement for performing a test every three months to determine that residual fixer retention is less than 5.0 micrograms per square centimeter is identical to that established in section 30316.20, Quality Assurance Testing Requirements for the Use of X-Ray in Mammography.

Subsection (a)(4) requires users to assure that tests are performed at intervals not to exceed six months, in order to determine that the increase in optical density in clinical films that is attributable to darkroom fog is not more than 0.05. This requirement is needed because film fogging will impact image quality by reducing the image contrast, which in turn can diminish the accuracy of a diagnosis.

These darkroom fog tests are required to be performed with the highest speed of each type of radiographic film used clinically. This requirement is necessary to minimize the risk of clinical films used in a facility being damaged because of darkroom fog. The test must be performed on the highest speed of film because higher speed films are more sensitive to the effects of darkroom fog than slower speed films. Types of medical radiographic films include, blue sensitive, green sensitive, single emulsion, and double emulsion films. Because each of these films responds differently to the effects of darkroom fog, each film type used clinically needs to be tested.

These tests are also required to be performed in the mid-density portion of the films, where the optical density is not less than 1.20. The mid-density portion of a clinical film is the most important for diagnostic purposes because the effects of darkroom fog become visually apparent at mid-density levels before there is an increase of optical density in the unexposed areas of radiographic films. The 1.20 optical density limit is different than the mammographic value established in section 30316.20. The mammographic standard was based on the U.S. Food and Drug Administration's Interim Regulations for Quality Mammography Standards, which has since been changed to 1.20 in their Final Regulations.[4]

The requirement for test films to be exposed on the counter top for one minute with the safelight on is needed to simulate the handling of clinical films under typical darkroom conditions. One minute is different than the exposure time required for mammographic facilities, as specified in section 30316.20(d)(1). The time required for mammographic facilities was established for single emulsion films. The one minute exposure time proposed here is for dual emulsion general purpose radiographic films, which are more sensitive to light than single emulsion films. The one minute exposure is also consistent with the time recommended in NCRP Report Number 99 (Reference 1, p. 47).

This proposal requires darkroom fog tests to be performed at intervals not to exceed six months. This requirement is needed because there are many changes that can occur which can cause an increase in darkroom fog to radiographic films. These changes include fading of safelight filters, improper safelight filter or bulb replacements, and problems in processor or darkroom maintenance. Ideally, tests for darkroom fog need to be performed whenever there is a change that could affect the levels of darkroom fog. However, it would be impossible for the Department to determine if or when these changes occurred. Therefore, it is more prudent to require the user to periodically perform these tests and to document the results for review by the Department, as

[4] February 6, 2002 (67 FR 5446) PART 900.12(e)(3)(i).

required in subsection (a)(6). Six months is consistent with the interval established in section 30316.20.

Subsection (a)(5) requires users to assure that for any test result falling outside the criteria specified in this section, the problem or cause has been identified and corrective action has been taken. To assure that all clinical radiographs will be of diagnostic quality, this subsection also requires that corrective action be taken before processing further clinical radiographs. This requirement is needed to assure that any changes in the operating levels of an automatic film processor which can significantly affect the quality of clinical images can be detected and corrected before clinical films are processed. To achieve this level of quality control, the operating levels of a film processor must be tested at appropriate frequencies, the test results must be promptly analyzed to determine if films will be satisfactorily processed, and any identified problems must be corrected. Finally, follow-up tests must be conducted before further clinical radiographs are processed, to determine if the corrective actions taken were effective.

Subsection (a)(6) requires users to assure that records of the tests specified in this section (including the problems detected, corrective actions taken, and the effectiveness of those corrective actions) are maintained until the Department has completed its next routine inspection. Records of these tests are needed to enable the Department to quickly determine if a user needs technical assistance in maintaining a radiographic quality control program.

In addition, these records will help the user, their service representatives, and their health physicists to recommend more effective corrective actions for any recurring problems.

30311.1 Quality Assurance for Dental Radiography establishes the quality assurance requirements that apply to each user performing radiographic examinations using intra-oral film systems for dental purposes. Quality control standards directed specifically to dental radiography users are needed because those standards proposed in Section 30308.1 would require measurements that cannot be performed, due to the small size of dental intraoral film. The standards proposed in this section are within the capability of all dental radiographic installations and are based on those recommendations that are considered to be the most cost effective by the American Dental Association Council on Scientific Affairs[5].

Subsection (a)(1) requires dental users to assure that reference films which meet the interpreting dentists' criteria for image density, contrast, sharpness and overall quality have been selected. This requirement allows the quality of dental radiographs to be determined by the person interpreting the image. It also gives other dentists, dental

[5] Reference 2: Journal of the American Dental Association 2006;137:1304-12. Available at: http://jada.ada.org/cgi/reprint/137/9/1304

hygienists, and dental assistants a means to continually monitor for changes in image quality.

Subsection (a)(2) requires dental users to assure that clinical radiographs are compared to a reference film each day that clinical radiographs are processed. Requiring daily comparisons allows dental users to take corrective action before dental image quality has deteriorated to a level that could reduce the diagnostic quality of the film.

Subsection (a)(3) requires dental users to assure that corrective action is taken when there is a change in image quality. This requirement is the key to providing quality control in dental radiography. It is needed to protect dental patients from unnecessary exposure to radiation, and can reduce the occurrence of misdiagnosis due to poor quality clinical images.

Subsection (a)(4) requires dental users to assure that records of the corrective actions taken, and records of the effectiveness of those corrective actions, are maintained until the Department has completed its next routine inspection. Records of these tests are needed to enable the Department to quickly determine if a user needs technical assistance in maintaining a radiographic quality control program. In addition, these records will help the user and their service representatives in recommending more effective corrective actions for any recurring problems.

Subsection (a)(5) requires dental users to assure that corrective action is taken if the Department finds that patient exposure levels are outside of acceptable ranges. This requirement is needed because of the limited tests that are available to dental users for an effective quality control program in radiography. The small size of intraoral films prevents dental users from performing the tests proposed in section 30308.1 for other users who develop clinical radiographs with automatic film processors. However, State Radiation Control Agencies across the country have the ability to screen dental users for their patient radiation exposure levels. By comparing exposure levels found by the Department to the nationwide values, the Department can identify users needing optimization of their image processing. The Conference of Radiation Control Program Directors, Inc. publication[6], Patient Exposure and Dose Guide–2003[7], provides State

[6] The Conference of Radiation Control Program Directors, Inc. (CRCPD) is comprised of representatives from the radiation control programs of nearly all of the 50 states. The CRCPD assists the states in their efforts to protect patients from unnecessary radiation exposure. The CRCPD also provides a forum for centralized communication on radiation protection matters between the states and the federal government, and among the individual states. One method of providing assistance to the states is through technical publications. The publication, Patient Exposure and Dose Guide–2003, is intended to provide the states and other interested parties with national norms of entrance skin exposure (ESE) and dose values for routine radiography examinations as a basis for comparison in order to assist facilities in identifying the need for change.

[7] Reference 3: Conference of Radiation Control Program Directors, Inc. Publication E-03-2, Patient Exposure and Dose Guide – 2003, page 21. Table A-1, Technique/Exposure Guides for the Dental Bitewing Projection.
See http://www.crcpd.org/Pubs/ESERePublishedApr03.pdf

Programs with the national norms of exposure values for routine radiography examinations to use as a basis for these comparisons. The guide includes the diagnostic reference levels, defined by national and international radiation protection organizations as the first and third quartile points of measured distributions of exposure levels, intended to serve as norms for comparison. The dental exposure guide for bitewing projections provides the range of exposures that will produce, in the judgment of a panel of experienced dental radiologists, acceptable quality radiographs. Therefore, requiring a user who exceeds the X-ray exposure levels specified in this subsection to take corrective action will help ensure that dental users are using proper film processing techniques.

Alternative Standards

Quality assurance standards for digital radiography were intended to be included in these proposed regulations. However, at the time of this proposal, there has not been a consensus by any of the nationally recognized medical physics or radiology associations as to the standards to be applied to quality assurance in digital clinical X-ray imaging.

Adopting quality assurance regulations similar to those standards used in the states of New York, New Jersey, Texas, and Washington was initially considered. However, it was discovered that each of these states implement their quality assurance requirements with user guides. These state guidelines provide recommended requirements that may not be applicable to all medical and dental X-ray users. Further, California law prohibits enforcing guidelines or standards that implement, interpret or make a law specific unless those guidelines or standards have been adopted as regulations. Because of the diversity of specialized applications, modalities, systems, and components employed by the various medical and dental X-ray users, many of those guidelines could not be adopted into general standards that would apply to all healing arts users.

The Department next considered adopting the quality assurance requirements for the Use of X-ray in Mammography (i.e. section 30316.20), into the standards to be applied to medical and dental users. However, many of the mammography standards proved to be impractical for adoption, for the following reasons:

- Requiring each user to consult with health physicists to annually review their quality assurance program would not be feasible, due to the large number of medical and dental users and the limited number of health physicists. Currently there are more than 30,000 X-ray facilities registered with the Department and less than 100 diagnostic X-ray health physicists approved by the Department. Each health physicist would need to average more than 300 additional surveys per year to fulfill this requirement.

- Requiring each user to use a phantom to evaluate the consistent operation of their entire imaging system was determined to not be feasible because there are

no standardized phantoms established for the many different types of examinations that are performed in clinical radiography.

- Requiring the performance of darkroom fog tests was found to be beyond the scope of those users not required to perform densitometric tests. The evaluation of the adverse image quality effects of darkroom fog is meaningful only in the mid-density portion of a radiographic image. Darkroom fog tests performed by those users not possessing a densitometer would therefore not result in meaningful measurements. For this reason, the requirement for darkroom fog tests was limited to those who would be required to make daily sensitometric measurements, i.e. those users developing clinical radiographs with automatic film processors for other than dental or veterinary use.

- Requiring each user to develop a quality assurance manual was determined to be unnecessary. The proposed regulations will require each user to follow manufacturers' published recommendations for the use and maintenance of all components used in the X-ray imaging system, to develop operating technique charts, and to meet outcome based requirements for image quality. In addition, developing such a manual would be an unnecessary burden on the significant number of users in private offices with only one person operating the X-ray equipment.

Finally, the Department gave strong consideration to distributing step wedges to all registered dental users, for monitoring film processing levels. However, requiring the use of a step wedge provided by the Department could become unenforceable in the future if the Department could not acquire or distribute the required quantities at nominal cost.

STATEMENTS OF DETERMINATIONS

The California Department of Public Health ("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. Thus, there will be no significant adverse economic impact on California businesses.

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 regulation 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 there would be an effect on small business because they will be legally required to comply with the regulation and may incur a detriment from the enforcement of the regulation.

Alternatives were considered and are discussed in the Initial Statement of Reasons.