

# Radiation Safety In Dental Practice

A study guide and excerpts from The California Radiation  
Control Regulations pertaining to dental practice

Radiation Safety Protection Program template





# Radiation Safety In Dental Practice | A Study Guide

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# Introduction

Licensed dentists play an important role in maintaining radiation exposures of patients and staff **as low as reasonably achievable** (ALARA). Greater numbers of intra-oral radiographs are being requested and a wide range of other dental radiographic examinations (panoramic, cephalometric) are being performed on a routine basis with the addition of advanced imaging modalities (CBCT). Individuals who operate dental X-ray equipment must have a basic knowledge of the inherent health risks associated with radiation and must have demonstrated familiarity with basic rules of radiation safety as explained in this study guide. Licensed dentists should follow the FDA/ADA Guidelines for Prescribing Dental Radiographs.

Digital imaging with photostimulable phosphor plates or solid state image receptors (i.e., CCD or CMOS receptors) forego the need for darkroom processing of film. However, quality assurance on maintenance of the receptors, phosphor plate scanners, computers and monitors take on more importance in the management of images acquired with x-radiation. Faulty management of digital data could possibly necessitate remake exposures thus violating the ALARA principle.

Can patient exposure be reduced without reducing diagnostic quality? The answer is yes. This was proven by dentists who participated in the Dental Exposure Normalization Technique (DENT) program, developed by the Food and Drug Administration's Center for Devices and Radiological Health and State radiological health programs. The American Dental Association endorsed the DENT program to aid dental facilities in identifying and correcting exposure problems.

What are appropriate exposure levels for dental radiographs? The answer must come from dentists who must evaluate exposure levels used in their facilities and compare these exposure levels to values "generally accepted" as providing diagnostic quality images without overexposure to patients. Generally accepted values are provided in a table in Appendix I.

## Section I – Licensed Dentist and X-ray Machine Registrant Responsibilities

### A. General Responsibilities

Each licensed dentist and X-ray machine registrant must take all precautions necessary to provide reasonably adequate protection to the life, health, and safety of all individuals subject to exposure to radiation. This includes judicious prescription of radiographs for individual patients based on selection criteria noted in Section VII.

### B. Specific Responsibilities

#### 1. Registration of Dental Radiographic Equipment

Dental X-ray machines and facilities with X-ray machines must be registered with the State Department of Public Health, Radiologic Health Branch in Sacramento within 30 days of acquisition. The owner of a new dental facility must submit the Radiation Machine Registration for New Registrants form RH 2261N. Already registered facilities should use form RH 2261C. The vendor reports machine installation to the FDA and to the State but cannot register the machine on behalf of the owner.

Change of name, address, location, sale/transfer/disassembly of equipment or purchase of additional equipment must be reported to the Radiological Health Branch in Sacramento within 30 days of such change using form RH 2261C. Machine registration must be renewed every two years upon payment of the specified fee.

#### 2. Radiation Protection – General Requirements

The licensed dentist and X-ray machine registrant must:

- a. Take all precautions necessary to provide reasonably adequate protection to the health and safety of individuals who are subject to radiation exposure. The main purpose in the control of radiation exposure is to ensure that all exposures are justified in relation to their benefits; that necessary exposures are kept as low as reasonably achievable (ALARA); and that the doses received by patients and personnel are kept well below the allowable limits.
- b. Provide radiation safety rules to dental personnel including any restrictions of the operating technique required for the safe use of the particular dental X-ray equipment.
- c. Ascertain that dental personnel demonstrate competence in using the X-ray equipment and imaging software, and comply with the radiation safety rules.
- d. Assure that individuals whose job requires use of X-rays should be provided individual or personnel monitoring devices. Monitoring devices must be provided if the anticipated annual dose exceeds 10% of the annual occupational dose limits (10CFR20 section 20.1201(a)). Documentation of the basis for not monitoring must be provided upon inspection. Monitoring is strongly recommended for declared pregnant employees as fetal exposure limits are considerably lower. An employee (not declared pregnant) may wear a monitoring device for one year, or for one three-month period with the results extrapolated to determine an annual exposure. If the annual exposure is less than 10% of the maximum allowable dose (5 rems), then monitors need not be worn. This procedure would need to be repeated periodically and whenever changes are made that might affect radiation safety or output to insure personnel safety. An alternative to monitoring is to hire a professional health physicist to assess potential exposure.

- e. Assure that records of occupational exposure must be made regularly. Records of individual monitoring must be retained for period of employment plus 30 years, per Cal/OSHA requirements (8 CCR §3204). Area monitoring records and health physicist reports should be kept for as long as facility is open.
- f. Assure that dental personnel do not stand in the path of the useful beam and must remain behind a protective shield or stand at least six feet away from the patient and between 90° - 135° to the direction of the primary beam during an exposure.
- g. Make or cause to be made such surveys and/or tests, including quality control (QC) tests, as are reasonable and necessary for the protection of life, health or property or are required by law or regulation.
- h. Report to the Radiologic Health Branch any dental personnel x-radiation overexposure in excess of the allowable occupational dose limits (see Section I.F.1 of this guide).
- i. Provide information to occupationally exposed individuals regarding health protection issues associated with exposure to radiation, precautions or procedures to minimize exposure, and the purpose and function of protective devices employed. These instructions should be given both verbally and in writing.

### C. Enforcement of Regulatory Prohibitions

1. Dental personnel during patient exposure may **not** do any of the following:
  - Hold the patient
  - Hold the image receptor, i.e., film, phosphor plate (PSP), CCD, or CMOS, in the patient's mouth
  - Hold X-ray tube housing, unless a valid exemption is in place and on file at the dental facility. Current exemptions may be found on the Radiologic Health Branch Web site at [cdph.ca.gov/RHB](http://cdph.ca.gov/RHB). An exemption for hand-held X-ray units was issued in March 2013.
  - Hold the aiming cylinder (also known as PID or pointer cone)
  - Stand in the path of the useful X-ray beam
  - Stand closer than six feet from the patient being radiographed
2. Dental personnel must not expose any individual to the useful beam for training or demonstration purposes without a valid X-ray prescription from a licensed dentist or a medical doctor stating a diagnostic need for the exposure.

### D. Compliance with Posting and Recordkeeping Requirements

1. Conspicuously post a current copy of the Department of Public Health Form RH-2364 (Notice to Employees) in a sufficient number of places to permit individuals working in an X-ray room to observe a copy on the way to or from the room.
2. In areas or rooms where X-ray equipment is used, post a sign (that may include the radiation symbol) stating: **CAUTION X-RAYS**
3. Provide annual report of occupational exposure to all individuals who are being monitored if requested.
4. Post or make available California Radiation Control Regulations or the excerpts of the regulations pertaining to dental practice. The excerpts are included as an appendix of this publication.
5. Post or make available safety instructions, restriction of the operating technique required for safe operation of the particular X-ray apparatus, and current copy of operating and emergency procedures.

## E. Dental Personnel Training and Competency Evaluation

1. Establish that dental X-ray equipment and imaging software is operated only by individuals adequately instructed in safe operating procedures and who are competent in the safe use of the particular dental X-ray equipment and knowledgeable use of the software.
2. Verify that dental personnel have demonstrated familiarity with basic radiation safety rules as listed in Section 1.C., III and IV.
3. Maintain documentation of training and of evaluation of competent use of the X-ray equipment and imaging software.

## F. Compliance with Occupational Exposure Requirements

1. Maximum permissible dose equivalent (MPD).

The essential goal of radiation safety is to prevent injury from exposure to ionizing radiation. For this reason, regulations have been established with the following annual occupational dose equivalent limits for adults who make radiographic exposures during the course of their work:

- Whole body (total effective dose equivalent) – 5 rem or 0.05Sv
- Skin and extremities (shallow-dose equivalent) – 50 rem or 0.5 Sv
- Lens of the eye (eye dose equivalent) – 15 rem or 0.15 Sv

The regulations distinguish the following:

- Occupational dose equivalent limits for adults (persons **over** 18 years of age)
- Occupational dose equivalent limits for persons **under** 18 years of age (may receive 10 percent of the adult occupational dose limits)
- Dose equivalent limits for general population
- Radiation dose to an embryo/fetus (prenatal radiation exposure)

**Exception:** Radiation dose received for the operator's own personal medical or dental diagnosis or medical therapy is not considered to be occupational exposure. If the dental hygienist or dental assistant is a patient, then he/she must remove the personnel monitoring device before being exposed.

2. Employees who are occupationally exposed at more than one facility.

The annual exposure limit applies to all occupational doses that an individual receives during the year. If an employee is occupationally exposed to ionizing radiation at more than one facility, each employer has the responsibility to monitor the employee's total occupational exposure to be sure that those dose limits are not exceeded.

Since a dental facility has to either (1) provide personnel monitoring or (2) determine that occupationally exposed staff are not likely to exceed 10% of the annual limit, the employer should obtain from an employee who is occupationally exposed at more than one facility:

- A copy of a dosimetry report from each of the other employers (the reporting period should not exceed one year; a quarterly report is preferable); OR
- Documentation from another employer that has determined that its employees are not likely to receive greater than 10% of the annual exposure limit.

3. Radiation dose limits for individual members of the public other than patients.

Each licensed dentist shall conduct X-ray operations so that no individual member of the public will receive more than the maximum radiation dose in any unrestricted area as indicated:

- 0.1 rems (i.e., 100 millirems or 1mSv) in a year, or
- 0.002 rem (i.e., 2 millirems or 0.02mSv) in any one hour.

## Section II – Dental Radiographic Machine Requirements

### A. X-ray Tube Housing

The X-ray beam is generated within a vacuum tube containing a cathode with a tungsten filament, and an anode “target,” usually made of copper and tungsten. The X-ray tube itself is enclosed in a metal housing, with a window (port) through which the useful or primary X-ray beam passes.

The X-ray tube housing must be of a diagnostic type. A “diagnostic type tube housing” is the type of tube housing constructed so that leakage radiation does not exceed 100 mrem, or 1 mSv, in any one hour at a distance of 1 meter (39.37 inches) from the X-ray tube. Note that this definition acknowledges that radiation can escape the X-ray tube housing from areas other than the window (port).

### B. Collimating Device – Restricting the Size of the X-ray Beam

X-rays that extend beyond the area of the dental image receptor (i.e., film, PSP, CCD, or CMOS) serve no useful purpose and should be eliminated to the maximum extent practicable. The X-ray beam shall be restricted to a diameter of not more than 7 cm (2.75 inches) in diameter at the surface of the skin. This size of the X-ray beam is sufficient to allow for reasonable alignment errors. It is highly desirable to add a rectangular collimator that limits the X-ray beam to a size just larger than that of the dental image receptor used. This can be accomplished by either adding a rectangular collimator adapter to the aiming cylinder, replacing the aiming cylinder with a rectangular collimator model, or by incorporating a rectangular collimator into the film holding device.

Restriction of the X-ray beam size reduces the total area of exposure and helps avoid exposure of sensitive areas, such as the lens of the eye, or the thyroid gland that are outside the area being examined for dental purposes. Clinically, reduction of the X-ray beam diameter improves the diagnostic quality of the image by lessening the amount of image degradation (fog) caused by scatter radiation.

### C. X-ray Beam Filtration

The primary X-ray beam is made up of X-rays of different energies. Only the X-rays with higher energies can penetrate the tissue of the patient’s face and react with the image receptor area (i.e., film, PSP, CCD, CMOS). Low-energy X-rays that have no effect on image production and are absorbed by the tissues, can cause tissue damage. A filter functions by absorbing preferentially more of the low-energy (long wavelength) X-rays before they reach the patient, while allowing more of the high-energy (short wavelength) X-rays to pass through.

Some X-ray tubes within the X-ray tube head are surrounded by oil (except the “window” through which the useful or primary X-ray beam passes) for electrical insulation and to keep the X-ray tube from overheating. X-ray beam filtration is accomplished by placing a filter (usually aluminum) in the path of the useful or primary beam to absorb some of the low-energy X-rays before they reach the patient. The total filtration of an X-ray beam includes inherent filtration and the added filtration (discussed above). Inherent filtration, which is a permanent part of the X-ray tube,



includes the X-ray tube housing, the oil and the glass envelope (window) through which the primary or useful X-ray beam passes. The amount of inherent filtration produced by most diagnostic X-ray tubes usually ranges from 0.5 to over 2.0 mm aluminum-equivalent. Added filtration includes sheets of metal (usually aluminum) placed in the direct path of the X-ray beam between the port and the patient. Added filtration can be changed or modified, as required. Proper filtration for the dental X-ray unit is provided by the manufacturer and need not be modified in most cases.

**The regulations specify the minimum total filtration as shown below:**

<b>Tube Operating Potential (kV)</b>	<b>Minimum Total Filter (inherent plus added) (millimeters of aluminum or aluminum-equivalent)</b>
Below 50	0.5
50 to 70	1.5
71 and above	2.5

Diagnostic X-ray tubes use aluminum or an aluminum-equivalent as the filter material. (“Aluminum-equivalent” is defined as a substance equivalent to aluminum in its ability to absorb preferentially less penetrating radiation.)

**D. Exposure Cord**

The exposure switch must be permanently fixed in a safe shielded location or the exposure cord on a remote hand switch must be long enough to permit the operator to make exposures while positioned at least six feet from the patient. This six-foot distance must also be between 90°-135° to the direction of the primary X-ray beam.

**E. Exposure Timer**

The X-ray machine must have a device to terminate the exposure after a preset time or exposure. This is usually in the form of a “dead-man” type exposure switch. This type of switch requires constant pressure from the operator in order for the machine to function.

**F. X-ray Tube Head and Flexible Arm Assembly**

The flexible extension arm allows the X-ray tube head to be adjusted to various positions required for dental radiography. The mechanical support of the X-ray tube head and cone shall maintain the exposure position without drift or vibration.

**G. Portable X-ray Units**

1. The portable dental X-ray system being used must have FDA approval and must be used in a manner consistent with that approval.
2. The unit must have a manufacturer-provided backscatter shield that is not less than 0.25 mm lead equivalent. The shield must be permanently affixed in place at all times. The X-ray system may not be used if this component becomes broken or dislodged.

**H. Cone Beam Computed Tomography (CBCT) Units**

Maintain these units following manufacturer’s recommendations. The units also should be tested by knowledgeable technicians on a periodic basis if not already part of the manufacturer’s recommendations.

## Section III – Patient Protection

- A. Dental personnel are responsible for requiring that all individuals unnecessary to the dental radiographic examination leave the X-ray room prior to making an exposure.
- B. Anyone who is in the X-ray room at the time of exposure must be behind a protective barrier. If someone must also be in the room to assist or maintain patient safety, then this individual must wear a protective apron. The apron should be preferably 0.5 mm of lead or lead-equivalent but not less than 0.25 mm of lead or lead-equivalent thickness. Mobile protective barriers or shields should be available for dental personnel protection and should be used as indicated.
- C. A specially designed lead-impregnated thyroid collar can be used to protect the thyroid gland from excessive and/or unnecessary radiation during intraoral X-ray exposures. It is also highly recommended for panoramic, skull and CBCT exposures if the Velcro straps can be secured and kept out of the way of the primary beam or it does not cover an area of primary interest (e.g., if cervical vertebrae need to be included in an extra-oral image.)
- D. Lead-impregnated leather or vinyl aprons must be used to cover the reproductive organs of all patients, including pregnant patients, who undergo dental X-ray examinations. The ability of the apron material to stop X-rays is measured in “lead-equivalent” thickness, that is equivalent to the same thickness of solid lead. Thus, 0.25 mm of lead-equivalent is equal to 0.25 mm of solid lead. Protective aprons are available which are constructed of a material of 0.5 mm of lead-equivalent and thus provide greater protection to the gonads. The lead-equivalent thickness is stated on a label on the hem of the apron. The American College of Obstetricians and Gynecologists recommends (August 2013) that dental practices reassure patients that prevention, diagnosis, and treatment of oral conditions, including dental X-rays (with shielding of the abdomen and thyroid) and local anesthesia (lidocaine with or without epinephrine), are safe during pregnancy.
- E. Aprons should be evaluated periodically (at least yearly) for tears and cracks. Seriously compromised aprons may have lead sheeting that is bunched up. This can be detected by feeling the lower portion of the apron.
- F. A more detailed evaluation can be accomplished with medical radiographic equipment by X-raying the apron using a large image receptor and making a routine exposure (recommended exposure factors: 85 kVp, 10 mAs, 40-inch focal-film distance) or under fluoroscopy.
- G. Proper storage of protective aprons prolongs their life and effectiveness. Aprons should be properly hung because creases eventually become cracks which allow radiation to penetrate.
- H. Protective aprons are primarily designed to protect the wearer from scatter radiation. They do not totally protect against the primary X-ray beam to provide enough protection. This is the reason why small beam (rectangular) collimation is preferred. The reduction in exposure resulting from placing 0.25 mm lead-equivalent apron material in a primary X-ray beam of 100 kVp would only be 60% as compared to 0.50 mm lead-equivalent apron that will attenuate the beam by 85%.

## Section IV – Responsibilities of Dental Personnel Operating X-ray Equipment

Dental personnel who perform dental radiography are responsible for adhering to all of the following radiation safety procedures for the protection of the patient and for their own protection.

### A. Protect Patient from Unnecessary Radiation Exposure

Use appropriate protective devices, such as protective aprons, to cover patient's reproductive organs and a protective lead collar to protect patient's thyroid gland during exposure. Rectangular collimation of the X-ray beam is highly recommended as a means of decreasing the radiation dose to the patient.

For procedures with CCD and CMOS receptors, prepare the computer and imaging software prior to intraoral receptor placement. This helps reduce technique errors and the need for technique related retakes. Taking the X-ray before the computer is prepared may expose the patient to unnecessary radiation.

### B. Use Fast Image Receptors

Without sacrificing diagnostic quality, patient exposure may be reduced by more than 50 percent by changing to a faster film speed or to a digital image receptor.

According to the FDA, "The facts that E- and F-speed film products offer significant exposure reduction compared with D-speed film, cost approximately the same and offer comparable clinical benefits strongly support a change of practice for those facilities that continue to use slow-speed film products that contribute to patients' exposures which are greater than necessary." [fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/UCM329746.pdf](https://www.fda.gov/downloads/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-Rays/UCM329746.pdf)

#### Speed Ratings of Commonly Used Dental Films

Film Brand	Speed Group*
Kodak Ultra Speed	D
AGFA-Dentus, Flow	D
Kodak Intraoral	E
AGFA-Dentus	E/F
Kodak Insight, Flow	F
Indirect Digital Image Receptors - PSP	n/a
Direct Digital Image Receptors – CCD, CMOS	n/a

\*American National Standards Institute

### C. Plan Dental Radiographic Procedures Carefully and Avoid Unnecessary Retakes

Every examination that must be repeated results in excess patient radiation exposure. Retakes represent one of the greatest causes of excessive radiation exposure in dental radiography. Obtaining a quality dental radiographic image is a complex process demanding careful attention to many details.

1. Five of the most important factors relating to the production of quality radiographs are:
  - Patient positioning and instruction
  - Alignment of the X-ray beam and the film, or sensor, with the area to be radiographed
  - Use of rectangular collimating device
  - Selection of proper exposure factors (kV, mA, time, distance)
  - Proper film or digital image processing
2. As much as practical, the long axis of the body part being radiographed should be perpendicular to the main X-ray beam (called central ray or CR) and parallel to the image receptor (paralleling technique).
3. Use proper immobilization methods to assure that the patient does not move during exposure. Receptor holding instruments with beam alignment devices should be used instead of the patient retaining the image receptor with fingers.
4. Use an exposure time that is as short as possible to minimize the radiation dose and motion artifact during exposure.
5. Ensure that the focal spot-to-film distance (FFD) is correct. Modern machines have recessed tubes with FFD ranging from 8 to 12 inches. Research has shown 8-inch (20 cm) FFD produces adequate images with minimum absorbed dose to the patient.
6. All patient exposures procedures must be documented in the patient's record and the images should be properly labeled.
7. The diagnostic information obtained from the radiographic images also should be recorded in a notation or formal report in the patient's record.

#### **D. Using Proper Kilovoltage (kV)**

Kilovoltage determines the penetrating ability (quality) of the X-ray beam. To a lesser extent it also determines the quantity of X-rays in the X-ray beam. When a high kV is used in a film system, there will be more shades of gray (i.e., low contrast) than when low kV is used. Most of the newer dental X-ray units have fixed milliamperage (mA) and/or fixed kilovoltage (kV). Thus, in such instances the variable factors are: exposure time, target-to-receptor distance and the speed of the image receptor.

#### **E. Milliamperage (mA) and Time Setting**

Milliamperage-seconds (mAs) determines the amount (quantity) of x-radiation being produced. The mAs factor is calculated by multiplying the milliamperage (mA) x time (in seconds) = mAs (milliamperage-seconds).

A common practice is to set the mA at the highest setting available on the particular dental X-ray machine and then establish the proper timer settings. This technique results in the use of shorter time settings, which are helpful in avoiding patient motion artifacts on the radiograph.

#### **F. Protecting the Operator from Unnecessary Radiation Exposure**

1. Individuals who are occupationally exposed to radiation are not permitted to hold patients or to hold image receptors during exposure; nor shall any individual be regularly used for this service.

2. During the exposure, dental personnel who perform dental radiography should stand behind a protective barrier. In situations where dental personnel cannot stand behind a protective barrier, they must stand at least 6 feet away from the patient and the X-ray tube, not in the path of the primary beam but preferably behind a fixed or mobile barrier such as a lead-shielded wall or movable leaded Plexiglass shield. [17CCR 30311(b)(2)]
3. Increase the distance between the patient (the source of scatter radiation) and the X-ray operator to over 6 feet. The intensity of the primary X-ray beam, scatter radiation and leakage from the X-ray tube diminishes rapidly as the distance between the dental X-ray operator and the source of radiation (or the patient) increases.  
The degree of beam intensity reduction is related exponentially to the second power of the changes in the distance. If a dental X-ray operator can increase his or her distance from the radiation source by a factor of 2, his or her exposure would be reduced to  $\frac{1}{4}$  of the original amount.
4. Hand-held dental radiographic machines must have the backscatter shield provided by the manufacturer, which provides not less than 0.25 mm lead equivalent, permanently affixed in place at all times. The X-ray machine may not be used if this component becomes broken or dislodged. The operator may wear a lead apron for additional protection however, this measure is not required.

## Section V – Dental Radiographic Quality Assurance (QA) and Quality Control (QC)

Quality assurance (QA) program should include the X-ray and ancillary imaging equipment, education of dental personnel to perform quality control (QC), and preventive maintenance procedures. To complete the daily QC at the beginning of the work day does not take more than five to ten minutes of dental personnel time.

The primary cost saving of a QA program is related to the decreased need for repeat studies. The cost savings include reduction in:

- Downtime of equipment
- Dental personnel time
- Cost of equipment service

### Film

The state Department of Public Health in 2012 adopted regulations for quality assurance for X-ray film processing. The regulations implement legislation that was intended to apply to all types of radiographic equipment. The department, in its supporting documents for the regulations, stated that it hoped to develop regulations for digital equipment in the future “when standards have been established, accepted, or published by a nationally recognized radiation protection organization.”

Quality assurance (QA) equipment for dental film processing includes:

- Thermometer (dial, digital or electronic but no alcohol or mercury because these may break and contaminate processing solutions).
- Step wedge (or a sensitometer and densitometer). An aluminum step wedge, acquired from an X-ray accessories supplier or provided by a service representative.

A typical protocol for using a step wedge for checking processing solutions is as follows:

1. Expose 15 to 20 films with a step wedge using identical exposure factors (same time, kV and mA for a molar projection) and focal film distance.
2. Process one film in a recently cleaned processor with fresh chemicals. This film will be used as a standard for comparison.
3. Place the remaining films in a cool, dry place, protected from any radiation sources.
4. Process one of these remaining exposed test films daily and compare with the standard film.
5. If differences are noted between the test film and standard film, these can be attributed to faulty processing conditions (usually exhausted chemistry), film fog, or inconsistent exposure.
6. Each time solutions are changed, evaluation of the processing system should be done.

The standard film can also be used on a monthly basis as a comparison to detect changes in the exposure factors of an X-ray unit, if changes in density or contrast are noted.

When using intra-oral film for dental radiography, the following shall be done:

1. A reference film meeting the interpreting dentists' criteria for image density, contrast, sharpness and overall quality is selected for use in daily comparisons of dental radiographs.
2. For each day dental radiographs are processed, clinical radiographs are compared to the selected reference film for density, contrast, sharpness, and overall image quality.
3. Corrective action is taken when observable changes occur in clinical radiographic image density, contrast, sharpness and overall quality.
4. Records of the corrective actions taken, and the effectiveness of those corrective actions, are maintained for a minimum of one year from the date the corrective action was taken.

**Appendix III of this guide includes information on dental film processing.**

## **Digital**

Quality assurance for digital receptors are necessary just as conventional films. Since the phosphor plates and digital sensors are used repetitively, greater care in cleaning and handling is necessary. There should be periodic examination for digital receptors (whether PSP or direct sensors ) for scratching, bend marks, wear and tear or if the same artifacts appear on the images. Worn imaging plates (PSPs) with scratch marks or artifacts which detracts from image quality must be discarded and replaced with new ones. Wire connections for direct digital sensors should be examined and inspected. Any further performance testing should be done in accordance with the manufacturer.

Use of a step-wedge with digital receptors (sensors or phosphor plates) can also be part of a daily routine to confirm that computer imaging software is working properly prior to any patient exposure.

## Section VI – Equipment QA Requirements (General Provisions)

All equipment used for producing quality, diagnostic radiographs should be checked periodically to insure optimum performance. Due to the sensitive nature of the tests and the cost of the testing equipment, a qualified service representative for the type of dental X-ray unit needing evaluation should be contacted to perform the necessary tests. Periodic testing should include X-ray output, half value layer, mA and kV calibration, timer accuracy, and collimation and beam alignment.

Tube head stability should be checked at least monthly. Extend the arm of the X-ray unit fully, release the unit and observe for drift or vibration. Move the head to multiple locations and angulations and repeat the procedure. If any drift is noted, adjust the unit according to the manufacturer's instructions or have the service performed by a qualified technician.



## Section VII – Guidelines for Prescribing Dental Radiographs

The joint FDA-ADA guidelines (2012) are designed to ensure continuous radiographic surveillance for caries, alveolar bone loss associated with periodontal disease, periapical disease and other latent pathology. The use of patient selection criteria insures that each patient exposure will have maximum diagnostic benefit. Patient selection criteria are descriptions of clinical conditions derived from patient signs, symptoms and history that identify patients who are likely to benefit from a particular radiographic examination. These guidelines were developed by a panel of general dentists and specialists sponsored by the FDA and were the result of a review of the many studies available on the incidence and progression rates of caries, periodontal disease, growth and development assessment and latent pathology. The guidelines were first developed in 1987 and have been revised in 2004 and 2012.

The guidelines categorize patients first by type of visit (new or recall), then by dental status (child with primary or transitional dentition, adolescent, or adult dentulous or edentulous). Lastly the patient's risk category for caries, periodontal disease or growth and development assessment is considered. Use of these guidelines should promote the appropriate use of X-rays, by reducing overutilization and excessive radiation, and minimizing underutilization of imaging with potential inadequate diagnosis.

The full guidelines document, Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure, is available on the FDA Web site, [fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-rays/ucm116504.htm](http://fda.gov/Radiation-EmittingProducts/RadiationEmittingProductsandProcedures/MedicalImaging/MedicalX-rays/ucm116504.htm).

Cone beam CT imaging should be considered for cases in which intraoral or panoramic imaging are inadequate for proper diagnosis and/or treatment. The following position statements serve as guidelines for CBCT use in dentistry:

- The use of cone-beam computed tomography in dentistry: An advisory statement; American Dental Association, JADA August 2012, [jada.ada.org/issue/S0002-8177\(14\)X6067-8](http://jada.ada.org/issue/S0002-8177(14)X6067-8)
- Use of cone beam computed tomography in endodontics 2015 update; A joint position statement of the American Association of Endodontists and the American Academy of Oral and Maxillofacial Radiology [aae.org/specialty/wp-content/uploads/sites/2/2017/06/conebeamstatement.pdf](http://aae.org/specialty/wp-content/uploads/sites/2/2017/06/conebeamstatement.pdf)
- Position statement of the American Academy of Oral and Maxillofacial Radiology on selection criteria for the use of radiology in dental implantology with emphasis on cone beam computed tomography, June 2012, [ncbi.nlm.nih.gov/pubmed/22668710](http://ncbi.nlm.nih.gov/pubmed/22668710)
- Clinical recommendations regarding use of cone beam computed tomography in orthodontics. Position statement by the American Academy of Oral and Maxillofacial Radiology. In Oral Surg Oral Med Oral Pathol Oral Radiol 2013; 116:238-257, [oooojournal.net/article/S2212-4403%2813%2900280-0/](http://oooojournal.net/article/S2212-4403%2813%2900280-0/).

Cone beam CT images performed by or under the supervision of a licensed dentist may be performed only for dental diagnosis or treatment and may not be performed for any other purposes.

Excerpt from FDA/ADA Dental Radiographic Examinations: Recommendations for Patient Selection and Limiting Radiation Exposure (2012) [ada.org/~media/ADA/Member%20Center/Files/Dental\\_Radiographic\\_Examinations\\_2012.pdf](http://ada.org/~media/ADA/Member%20Center/Files/Dental_Radiographic_Examinations_2012.pdf)

**Recommendations for Prescribing Dental Radiographs**

These recommendations are subject to clinical judgment and may not apply to every patient. They are to be used by dentists only after reviewing the patient’s health history and completing a clinical examination. Even though radiation exposure from dental radiographs is low, once a decision to obtain radiographs is made it is the dentist’s responsibility to follow the ALARA Principle (As Low as Reasonably Achievable) to minimize the patient’s exposure.

**Table 1**

Type of Encounter	Patient Age and Dental Developmental Stage				
	Child with Primary Dentition (prior to eruption of first permanent tooth)	Child with Transitional Dentition (after eruption of first permanent tooth)	Adolescent with Permanent Dentition (prior to eruption of third molars)	Adult, Dentate or Partially Edentulous	Adult, Edentulous
<b>New Patient*</b> being evaluated for oral diseases	Individualized radiographic exam consisting of selected periapical/occlusal views and/or posterior bitewings if proximal surfaces cannot be visualized or probed. Patients without evidence of disease and with open proximal contacts may not require a radiographic exam at this time.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images.	Individualized radiographic exam consisting of posterior bitewings with panoramic exam or posterior bitewings and selected periapical images. A full mouth intraoral radiographic exam is preferred when the patient has clinical evidence of generalized oral disease or a history of extensive dental treatment.		Individualized radiographic exam, based on clinical signs and symptoms.
<b>Recall Patient*</b> with clinical caries or at increased risk for caries**	Posterior bitewing exam at 6-12 month intervals if proximal surfaces cannot be examined visually or with a probe			Posterior bitewing exam at 6-18 month intervals	Not applicable
<b>Recall Patient*</b> with no clinical caries or at increased risk for caries**	Posterior bitewing exam at 12-24 month intervals if proximal surfaces cannot be examined visually or with a probe		Posterior bitewing exam at 18-36 month intervals	Posterior bitewing exam at 24-36 month intervals	Not applicable

**Table 1** (con't.)

Type of Encounter	Patient Age and Dental Development Stage				
	Child with Primary Dentition (prior to eruption of first permanent tooth)	Child with Transitional Dentition (after eruption of first permanent tooth)	Adolescent with Permanent Dentition (prior to eruption of third molars)	Adult, Dentate or Partially Edentulous	Adult, Edentulous
<b>Recall Patient*</b> with periodontal disease	Clinical judgment as to the need for and type of radiographic images for the evaluation of periodontal disease. Imaging may consist of, but is not limited to, selected bitewing and/or periapical images of areas where periodontal disease (other than nonspecific gingivitis) can be demonstrated clinically.				Not applicable
<b>Patient (New and Recall)</b> for monitoring of dentofacial growth and development, and/or assessment of dental/skeletal relationships	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development or assessment of dental and skeletal relationships		Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of dentofacial growth and development, or assessment of dental and skeletal relationships. Panoramic or periapical exam to assess developing third molars	Usually not indicated for monitoring of growth and development. Clinical judgment as to the need for and type of radiographic image for evaluation of dental and skeletal relationships.	
<b>Patient</b> with other circumstances including, but not limited to, proposed or existing implants, other dental and craniofacial pathoses, restorative/endodontic needs, treated periodontal disease and caries remineralization	Clinical judgment as to need for and type of radiographic images for evaluation and/or monitoring of these conditions				

\*Clinical situations for which radiographs may be indicated include, but are not limited to:

**A. Positive Historical Findings**

1. Previous periodontal or endodontic treatment
2. History of pain or trauma
3. Familial history of dental anomalies
4. Postoperative evaluation of healing
5. Remineralization monitoring
6. Presence of implants, previous implant-related pathosis or evaluation for implant placement

**B. Positive Clinical Signs/Symptoms**

1. Clinical evidence of periodontal disease
2. Large or deep restorations
3. Deep carious lesions
4. Malposed or clinically impacted teeth
5. Swelling
6. Evidence of dental/facial trauma
7. Mobility of teeth
8. Sinus tract (“fistula”)
9. Clinically suspected sinus pathosis
10. Growth abnormalities
11. Oral involvement in known or suspected systemic disease
12. Positive neurologic findings in the head and neck
13. Evidence of foreign objects
14. Pain and/or dysfunction of the temporomandibular joint
15. Facial asymmetry
16. Abutment teeth for fixed or removable partial prosthesis
17. Unexplained bleeding
18. Unexplained sensitivity of teeth
19. Unusual eruption, spacing or migration of teeth
20. Unusual tooth morphology, calcification or color
21. Unexplained absence of teeth
22. Clinical tooth erosion
23. Peri-implantitis

\*\*Factors increasing risk for caries may be assessed using the ADA Caries Risk Assessment forms (0-6 years of age and over 6 years of age)

[ada.org/~media/ADA/Member%20Center/Files/topics\\_caries\\_under6.pdf?la=en](http://ada.org/~media/ADA/Member%20Center/Files/topics_caries_under6.pdf?la=en)

[ada.org/~media/ADA/Science%20and%20Research/Files/topic\\_caries\\_over6.pdf?la=en](http://ada.org/~media/ADA/Science%20and%20Research/Files/topic_caries_over6.pdf?la=en)

## Section VIII – Occupationally Exposed Women of Childbearing Age

California Radiation Control Regulations state that each licensed dentist must instruct occupationally exposed individuals (dental hygienists and dental assistants) in the health protection problems associated with radiation. A special situation arises with occupationally exposed young women. The precautions should be taken to limit exposure to young women, especially if they could be pregnant. X-ray exposure to the abdomen of such workers would involve radiation dose to the embryo or fetus in the event that they are pregnant.

Licensed dentists are responsible for the following:

- Following Nuclear Regulatory Commission Regulation requirements (10 CFR Part 20) incorporated in California Regulations by reference) at Title 17, Section 30253.
- Providing individual or personal monitoring devices to occupationally exposed individuals if they are likely to receive 10% of the annual limits in 10CFR20 section 20.1201(a).
- Providing individual or personal monitoring devices to occupationally exposed declared pregnant individuals if they are likely to receive during the entire pregnancy a deep dose equivalent in excess of 0.1 rem (1 mSv).
- Providing the employee with reasons for the requirements. (See below)
- Explaining the available options for protecting the embryo/fetus. (See below)

### A. Dose to an embryo/fetus

#### 1. Definitions:

**Declared pregnant woman** means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date (month) of conception.

**Deep-dose equivalent**, which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (100 mg/cm<sup>2</sup>).

**Embryo/fetus** means the developing human organism from conception until the time of birth.

#### 2. Regulatory provisions (10CFR20):

- a. The licensed dentist shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv).
- b. The licensed dentist shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.
- c. The dose to any embryo/fetus shall be taken as the deep-dose equivalent to the declared pregnant woman.
- d. If the dose to an embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensed dentist, the dentist shall be deemed to be in compliance with paragraph (a) of this section if the additional dose to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

### B. Reasons for requirements

Some studies have shown that there is an increased risk of leukemia and other cancers in children if the expectant mother was exposed to a significant amount of radiation. Women employees must be aware of possible risks so they can take appropriate steps to protect their offspring.

It is strongly suggested that the instruction be given both orally and in writing. Also each woman employee should be given an opportunity to ask questions, and each woman employee should be asked to acknowledge in writing that the instruction has been received. Further, it would be prudent to keep records of such acknowledgment indefinitely.

The following facts should be given to the woman employee:

- The first three months of pregnancy are the most important as the embryo-fetus is most sensitive to radiation at this time.
- In most cases of occupational exposure, the actual dose received by the embryo-fetus is less than the dose received by the mother, because some of the dose is absorbed by the mother's body.
- At the present occupational dose equivalent limits, the risk to the unborn baby is considered to be small, but experts disagree on the exact amount of risk.
- There is no need for women to be concerned about sterility or loss of ability to bear children from occupational exposure.
- Once a pregnancy becomes known, radiation dose of the embryo-fetus shall be no greater than 0.5 rem (5mSv) for the entire pregnancy. Special circumstances apply if the pregnant worker has already exceeded this dose prior to declaring her pregnancy (See Section VIII A.2.d of this document).

**C. Available options for protecting embryo/fetus**

- Temporary assignment to tasks which involve less risk of being exposed to radiation
- Use of protective apron (full size, half-size, wrap-around, or any other protective clothing appropriate to the situation) while actually exposing patients
- Abiding by the regulatory prohibitions
- Use of monitoring devices such as a film badge worn at the abdomen
- Staying out of the X-ray room and behind the protective barrier during exposure

## Section IX – Dental Radiation Protection – Protective Barriers

A discussion on protective barriers is found in the National Council on Radiation Protection and Measurements (NCRP) Report No. 145, Radiation Protection in Dentistry (2003).

### A. General

The objective of dental radiography is to obtain diagnostic quality dental radiographs with minimum exposure to the patient, dental personnel and the public. Efforts toward these objectives include:

- Use of the fast film (F-speed) or digital image receptors
- Maintenance and adherence to proper film processing
- Assurance of adequate and proper X-ray tube filtration, kV, mA and time accuracy through regular maintenance and calibration by a qualified service technician
- Operator protection (standing behind a protective barrier during exposure)

### B. Barriers

Conventional building materials in walls, partitions, floor and ceiling **may** provide adequate shielding from x-radiation; however, there may be situations where lead shielding would be required due to workload, office design or other circumstances. The Radiologic Health Branch recommends that the shielding design for your particular situation be developed by a qualified expert, an individual knowledgeable in evaluating dental radiation protection requirements. A list of individuals and/or companies who perform such services is available from the Radiologic Health Branch:

Department of Public Health  
Radiologic Health Branch  
P.O. Box 997414, MS 7610  
Sacramento, CA 95899-7414  
[cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx](http://cdph.ca.gov/Programs/CEH/DRSEM/Pages/RHB.aspx)

Generally, a wall made of two layers of 5/8" offset gypsum board can be assumed to provide the minimum protection from scatter radiation if the following conditions are met:

1. Areas occupied by patients are protected by this wall or a wall of equivalent attenuating material, and there is at least a 6 feet distance between the dental X-ray chairs.
2. Dental personnel should be careful not to aim the primary beam toward areas adjacent the X-ray room.
3. The use of dental X-ray equipment does not exceed the following operating parameters:
  - 60 seconds/week of actual beam "on-time" at 90 kVp, or
  - 100 seconds/week of actual beam "on-time" at 65 kVp

*NOTE: If your X-ray facility is located in one of the following counties, you must contact that county's Radiation Control Office prior to construction or remodeling of your X-ray operatory.*

Los Angeles County: (213) 351-7391

San Diego County: (619) 694-2169

## Section X – Glossary of Terms Pertaining to Dental Radiography

**Absorbed Dose:** See Dose.

**Absorption** (differential, rare earth screen, specific rate of, visible light): The transfer of energy from an X-ray beam to the atoms or molecules of the matter through which it passes. The process whereby radiation is stopped and reduced in intensity as it passes through matter. Lead, which is denser than most materials, is one of the best absorber of X-rays.

**Added Filter:** See Filter.

**Aiming Cylinder:** A round/circular metal tube/shield attached to the X-ray tube housing or placed in front of the X-ray tube to limit the size of the X-ray beam to a predetermined size and shape.

**ALARA:** An acronym for As Low As Reasonably Achievable, economic and social factors being taken into consideration. Relates to radiation dose to the patients, the public, and occupationally exposed individuals.

**Aluminum Equivalent:** The thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

**Anode:** A positive electrode, also referred to as a target, toward which electrons are accelerated from the cathode. The target is usually composed of tungsten.

**Artifact:** Any density or mark on a radiograph caused by something not belonging to the part being X-rayed.

**Attenuation:** The process by which an X-ray beam is reduced in intensity by absorption or scattering when passing through material.

**Barrier, Protective:** Barrier of attenuating materials used to reduce radiation exposure.

**Barrier, Primary:** Barrier sufficient to attenuate the useful beam to the required degree.

**Barrier, Secondary:** Barrier sufficient to attenuate scatter (i.e., stray) radiation to the required degree.

**Beam:** A unidirectional flow of electromagnetic radiation.

**Primary Radiation or X-ray Beam:** That part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing. Also called "useful beam."

**Bone marrow:** A soft tissue which constitutes the central filling of many bones and serves to produce blood cells, including erythrocytes, leukocytes, thrombocytes, etc. Bone marrow is especially sensitive to X-rays.

**Cataract:** a clouding of crystalline lens of the eye which obstructs the passage of light.

**Cathode:** A negative electrode; electrode in the X-ray tube from which electrons are emitted. It consists of one or two tungsten filaments and a focusing cup.

**Centigray:** 0.01 Gray (Gy). 1 cGy equals 1 rad.

**Central Ray** (Central Beam): Refers to the X-rays in the center of the useful or primary beam.

**Characteristic Curve:** A type of input-output curve used to express the change in density with the change in radiation dose (exposure) of photographic or X-ray film. The slope of the straight line portion of this curve is called "gamma."

**Charge-Coupled Device (CCD):** Direct digital image receptor (sensory that forms images on a silicon crystal pixel matrix which automatically transfers data to a computer.

**Chromosome:** Important macromolecules found in the nucleus of all body cells. Chromosomes contain the genes of heredity-determining units.

**Chronic Exposure:** Irradiation which is spread out over a period of years. Those who are occupationally exposed to radiation can suffer from chronic exposure.

**Collimator:** A device for restricting/confining/limiting a beam of radiation within an assigned solid angle.



**Complementary Metal Oxide Semiconductor (CMOS):** Direct digital image receptor (sensor) that forms images on silicon-based semiconductors. This method of reading pixel charges is different from CCD technology, but the data is also automatically transferred to a computer.

**Compton Scatter Radiation:** The incident radiation has sufficient energy to dislodge a bound electron, but attacks a loosely bound electron, dislodges the electron and the remaining radiation energy proceeds in a different direction as scatter radiation. Compton scatter radiation is the main process responsible for the radiation dose the patient receives during a radiographic procedure.

**Cone:** A round/circular metal tube/shield attached to the X-ray tube housing or placed in front of the X-ray tube to limit the size of the X-ray beam to a predetermined size and shape.

**Cone Beam Computerized Tomography (CBCT):** Imaging method that utilizes a cone shaped beam centered on a two-dimensional X-ray sensor to scan a rotational arc of up to 360 degrees around the patient's head. Raw digital data of a volume of tissue can be reformatted to produce two-dimensional or three dimensional images of any selected plane within the tissue volume that was scanned.

**Contrast:** In radiology, contrast is defined as the difference in density between light and dark areas on the processed film.

**Control Chart:** A chart used to record and control the performance of a radiographic processor as a function of time.

**Dead-Man Switch:** A switch so constructed that a circuit-closing contact can be maintained only by continuous pressure by the X-ray operator on the switch.

**Densitometer:** An instrument used to measure film density which is the degree of blackening of film by measuring the ratio of the light intensity incident on the film to the light intensity transmitted by the film. (The densitometer is a device designed to measure the optical density of an exposed and processed film. It can measure the density of the individual steps on films exposed in a sensitometer, and is commonly used for daily processor quality control.)

**Density:** Film blackening (the amount of light transmitted through the film).

**Detail (definition):** In radiography, detail refers to the sharpness of structure lines or contour lines on the processed film.

**Developer:** The chemical solution (alkaline) used in film processing that makes the latent image visible.

**Developer Replenishment:** Developer replenishment is used to maintain the proper alkalinity, chemical activity, and level of solution in the developer tank.

**Diagnostic Type Tube Housing:** Means any X-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed 100 millirads in one hour when the tube is operated at any of its specified ratings.

**Diaphragm:** A plate, usually lead, with a central aperture so placed as to restrict the useful X-ray beam. See Collimator.

**DICOM (Digital Imaging and Communication in Medicine):** The international standard format for electronic communication of digital images.

**Digital Detectors:** Image receptors that form images from collections of pixels; charge-coupled devices (CCD), complementary metal oxide semiconductors (CMOS) or photostimulable phosphor plates (PSP).

**Distortion:** Unequal magnification of different portions of body area being X-rayed.

**Dose:** A general term denoting the quantity/amount of radiation or energy absorbed per unit mass. For special purposes it must be appropriately qualified as follows:

**Absorbed Dose:** The amount of energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad (1 rad equals 100 ergs per gram, see Rad, and the Gray). The SI unit of absorbed dose is the Gray (Gy). 1 Gy = 1 joule/kg. There are 100 rads per Gy.

**Deep-dose equivalent:** The dose equivalent at a tissue depth of 1 cm (100 mg/cm<sup>2</sup>).

**Dose Equivalent:** Means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The unit of dose equivalent are the rem and the Sievert (Sv). 1 rem = 0.01 Sv

**Dose rate:** Absorbed dose (or dose equivalent) delivered per unit of time.

**Dosimeter:** An instrument to detect and measure accumulated radiation dose (exposure).

**Personnel Dosimetry:** The use of instruments and associated procedures (including calibration and quality assurance) to ascertain the radiation dose absorbed by personnel.

**Personnel Dosimeters:** Devices designed to be worn or carried by an individual for the purpose of determining the dose equivalent received [for example: film badge, pocket chamber, pocket dosimeter, ring badges, thermoluminescent (TLD) badges, etc.].

**Emulsion:** The sensitive layer of photographic or X-ray film containing a silver compound (i.e., silver-halide crystals) in a layer of gelatin.

**Exposure or Irradiation Time:** The time interval in a radiological examination within which X-rays are incident upon the body part under examination.

**Film Badge:** a personnel monitoring device (i.e., dosimeter) which measures radiation exposure and is used for personnel monitoring.

**Film Speed:** A relative exposure number needed to produce a density of 1.0 above gross fog – used for screen type, dental and medical X-ray films.

**Filter/Filtration:** Means material placed in the primary or useful X-ray beam to absorb preferentially the less penetrating radiations. The use of appropriate filtration prevents the patient from receiving unnecessary radiation dose.

**Added Filter:** Sheets of metal (usually aluminum or its equivalent) which are placed in the direct path of the X-ray beam.

**Inherent Filter:** The X-ray tube and its housing such as the glass envelope (window) through which the X-ray beam passes.

**Total Filtration:** The sum of the inherent and added filters.

**Fixer:** A chemical solution (acidic) which removes the unexposed and underdeveloped silver halide crystals from the film so it will not discolor or darken with age or exposure to light. Fixer solution also hardens the gelatin containing the black metallic silver so film may be dried and resist damage from abrasions.

**Fixer Retention:** The inadequate removal of fixer from the film by the water in the wash tank of the processor. Retained fixer causes eventual brown discoloration of the radiograph.

**Focal Spot:** A small area on the target of the anode toward which the electrons from the focusing cup of the cathode are directed. X-radiation originates at the focal spot.

**Effective Focal Spot:** The apparent size of the radiation source when viewed from the central axis of the useful beam.

**Fog or Fogging:** A cloudy appearance of the finished radiograph caused by several factors such as old or contaminated processing solutions, exposure to chemical fumes, faulty darkroom safelight, or scatter radiation.

**Geometric Unsharpness:** Unsharpness of the recording image due to the combined optical effect of finite size of the radiation source and geometric separation of the anatomic area of interest from the image receptor and the collimator.

**Gonad Shielding:** Devices used during radiographic procedures to protect the reproductive organs from exposure to the useful X-ray beam.

**Gray (Gy):** The SI unit of absorbed dose equal to an energy deposition of 1 joule/kg = 10,000 ergs/gm (1 Gy = 100 rads).

**H & D Curve:** See Characteristic Curve

**Half-Value Layer (HVL):** The thickness of a specified substance/material (usually aluminum, copper – for X-ray beam quality, or lead – for shielding purposes) which, when introduced into the path of a given beam of radiation reduces the exposure rate by one-half.

**Health Physics:** The science of protecting human beings from injury by radiation, and promoting better health through beneficial applications of radiation. (Also called Radiological Health).

**Individual:** Any human being.

**Installation:** The location where one or more reportable sources of radiation are possessed (located).

**Intensifying Screens:** Devices which increase the brightness of the image produced by the action of X-rays upon a phosphor.

**Inverse Square Law:** The intensity of the radiation is inversely proportional to the square of the distance from the source.

**Ion:** An atom or molecule which has one or more of its surrounding electrons separated from it and therefore carries a positive electric charge, or a free electron carrying a negative electrical charge.

**Ion/Ionization Chamber:** An X-ray measuring device in which gas is ionized in proportion to the quantity of X-ray energy passing through the chamber.

**Ionization:** The process whereby one or more electrons is removed from a neutral atom by the action of radiation (the conversion of atoms to ions).

**Kilovolt:** A unit of electrical potential difference equal to 1,000 volts.

**Kilovolt Peak (kV):** A unit of maximum or crest value of electrical potential difference between the anode and cathode of an X-ray tube. Kilovolt peak (kV) determines the penetrating ability of X-rays and refers to the “quality” of X-rays.

**Latitude:** The property of an X-ray film to have a great number of units of density produced within certain log-relative exposure numbers; longer latitude films have lower contrasts.

**Lead Equivalent:** The thickness of lead affording the same attenuation, under specified conditions, as the material in question.

**Leakage Radiation:** Means all radiation coming from within the X-ray tube housing except the useful beam.

**Leukemia:** A blood disease which is characterized by overproduction of white blood cells. It may result from overexposure of the bone marrow to radiation.

**Magnification:** The ratio of image size to object size. The image may be larger than, smaller than, or equal to the object; so magnification can be greater than, equal to, or less than 1.

**Milliamperere (mA):** The electron current (measured in milliamperes) flowing across the X-ray tube from the cathode to the anode. Milliamperere (mA) multiplied by the time during which the beam strikes an object (measured in seconds) is milliamperere-seconds (mAs) and is a measure of the “quantity” of X-rays.

**Millirad (mrad):** A division of the rad, equal to one one-thousandth of a rad. See Rad.

**Millirem (mrem):** A division of the rem, equal to one one-thousandth of a rem. See Rem.

**Mutation:** A transformation of the gene which may be induced by radiation and may alter characteristics of the offspring.

**Occupational Dose:** Means the dose received by an individual in the course of employment. Exception: Radiation dose received for the operator’s own personal medical or dental diagnosis or therapy.

**Operator’s Station:** the area where the control panel for the operation of an X-ray machine is located. The operator’s station at the control shall be behind a protective barrier either in a separate room, in a protective booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

**Phantom:** An object used to simulate the absorption and scatter characteristics of the patient’s body for radiation measurement purposes.

**Phosphor Plates:** See photostimulable phosphor plates (PSP).

**Photoelectric Absorption:** An interaction between an X-ray photon and an inner shell electron in which the photon surrenders all of its kinetic energy to the electron and ceases to exist. The atom responds by ejecting the electron from the inner shell. Photo electric absorption is one of the processes responsible for the dose of radiation the patient receives during a radiographic procedure.

**Photon:** A quantity of energy emitted in the form of electromagnetic radiation. X-rays are examples of photons.

**Photostimulable Phosphor Plates:** Digital receptors similar in size and shape to film that absorb and store energy from X-rays and then release this energy when stimulated by other light of appropriate wavelength to form a digital image that is transferred to a computer after this processing step.

**Pointer Cone:** A means used to indicate the direction of the useful beam and to establish the minimum source-surface distance. It may be a cylinder or a cone and must be open ended.

**Quality:** A term used to describe the penetrating power of X-rays and is related to the energies of the photons in the useful or primary X-ray beam.

**Quality Assurance (QA):** Quality Assurance (QA) is a management tool that includes policies and procedures designed to optimize the performance of facility personnel and equipment. QA includes all of the following:

- Quality control (QC)
- Administration
- Education of personnel
- Preventive maintenance methods

**Quality Control:** Quality Control refers to routine performance and interpretation of test equipment function and to corrective action needed and taken.

**Quantity:** A term used to describe the number of photons in an X-ray beam.

**Rad:** The rad is the unit of absorbed dose. One rad is the dose corresponding to the absorption of 100 ergs per gram. (A special unit of absorbed dose and the specific energy imparted. One rad is 0.01 joules per kilogram of any material. The Gray (Gy) is the SI unit of absorbed dose.)

**Radiograph:** A film or other recording produced by the action of X-rays transmitted through the patient.

**Radiography:** Utilizing ionizing radiation, this technique involves making shadow images on photographic emulsions. The image is the result of differences in attenuation of the radiation as it passes through the object in its path.

**Rem:** The rem is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 Sievert).

**Repeats/Retakes:** Additional radiographs taken because of technical or mechanical error. These lead to increased radiation exposure for the patient and the radiation worker and should be avoided.

**Resolution:** The process or capability of distinguishing closely adjacent optical images.

**Resolving Power:** This term refers to the ability to distinguish separate images of line pairs (lines and spaces) per millimeter.

**Scattered Radiation:** means radiation that, during passage through matter, has been deviated in direction. It usually has also been modified by a decrease in energy.

**Secondary or Stray Radiation:** means radiation not serving any useful purpose. It includes leakage and scattered radiation.

**Sensitometer:** An instrument used to expose film to precisely controlled steps of increasing light intensity.

**Sensitometry:** The act, the art, or the science of measuring sensitivity, as of photographic material or X-ray film.

**Sensors:** See digital detectors.

**Shield/Shielding:** Material which is interposed between a radiation source and an irradiated site for the purpose of minimizing the radiation hazard (used to prevent or reduce the passage of radiation). Shielding is usually made of lead which is dense and absorbs radiation easily. Shielding is often used to protect the reproductive organs, testes or ovaries, from the X-ray beam during an examination.

**Sievert (Sv):** The SI unit of dose equivalent equal to the product of a dose of one Gray, the quality factor, and any other applicable modifying factors. (1Sv = 100 rem).

**Somatic:** Pertaining to the body tissue other than reproductive cells.

**Source-to-Image Distance (SID):** The distance measured along the central ray from the center of the front surface of the source (X-ray focal spot) to the surface of the image detector.

**Source-to-Skin Distance (SSD):** The distance measured along the central ray from the center of the front surface of the source (X-ray focal spot) to the surface of the irradiated object or patient.

**Speed Factor:** With intensifying screens, the speed factor is defined as the ratio of the radiation dose (exposure required without screens to the radiation dose (exposure) required with screens to get the same degree of blackening of X-ray films.

**Step Wedge (Penetrometer):** A device made up of different density filters shaped in a step-like form where each step or filter differs in density by the square root of 2.

**Supervision:** Supervision means responsibility for, and control of, quality, radiation safety, and technical aspects of all X-ray examinations and procedures.

**Survey:** Means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of sources of radiation.

**Target:** Material at which electrons from the cathode in an X-ray tube are aimed in order to produce X-rays. See Anode.

**Target-Film Distance:** The distance from the X-ray tube target (anode) to the film measured in inches or centimeters.

**Target-Skin Distance:** The distance from the X-ray tube target (anode) to the skin of the patient where the X-ray beam enters the body.

**Thermoluminescence:** The property of certain inorganic crystals to emit light when heated following exposure to ionizing radiation. The quantity of light is related to the total absorbed dose.

**Thermoluminescent Dosimetry (TLD):** A dose measurement system utilizing certain inorganic crystals, such as lithium fluoride (LiF). Energy is accumulated by radiation induced dislocation of electrons. Upon heating the TLD material, the dislocated electrons return to their original locations releasing the stored energy in the form of light. The quantity of emitted light is proportional to the absorbed radiation.

**Useful Beam:** Means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing.

**X-rays:** Penetrating electromagnetic radiation whose wavelengths are shorter than those of visible light. For radiographic purposes, X-rays are usually produced by bombarding a metallic target with fast electrons in a vacuum.

**X-ray Generator:** A device which supplies electrical power to the X-ray tube. It does not, as the name implies, actually generate X-rays.

**X-ray Personnel:** The following individuals are legally allowed to use diagnostic X-rays on human beings:

- Licensed dentists
- Individuals (dental hygienists and dental assistants) who have successfully completed a radiation safety course approved by the Dental Board of California

## APPENDIX I

# Excerpts from the California Radiation Control Regulations Pertaining to Dentistry

## Radiologic Health Branch

The Radiologic Health Branch, within the California Department of Public Health, is responsible for administering the rules and regulations developed pursuant to the Radiologic Technology Act and the Radiation Control laws (California Health and Safety Code

§106925 – 107175, and §114650-0115273). The California Health and Safety Code may be accessed online at [leginfo.ca.gov](http://leginfo.ca.gov).

- A. California Radiation Control Regulations.  
Regulations relating to radiation control are found in § 30100-30570 of Title 17, California Code of Regulations (CCR). 17 CCR may be accessed online at [ccr.oal.ca.gov/linkedslice/default.asp?SP=CCR-1000&Action=Welcome](http://ccr.oal.ca.gov/linkedslice/default.asp?SP=CCR-1000&Action=Welcome)
- B. Title 10 Code of Federal Regulations Part 20 (10 CFR 20)  
Regulations of the Nuclear Regulatory Commission, Standards for Protection Against Radiation, are incorporated by reference in 17 CCR §30253. 10 CFR 20 may be accessed online at [gpo.gov/fdsys/pkg/CFR-2008-title10-vol1/content-detail.html](http://gpo.gov/fdsys/pkg/CFR-2008-title10-vol1/content-detail.html)

### Dental Intra-Oral X-ray Machine Assessment Program (DIQUAD®)

In March, 2009, RHB contracted with a commercial vendor – DIQUAD®, LLC, to screen dental offices via a mail out self-testing program. The program utilizes a small device which is able to assess radiation dose and image quality for both film and digital intraoral imaging systems. This program complements the bureau's on-site radiation safety inspections, and fulfills specific regulatory requirements. As with the on-site safety inspection, the cost of this service has been covered by X-ray machine registration fees. Participation in this program is mandatory as it is a vital component of the inspection program. The surveys must be completed and returned together with the test device according to the instructions provided by DIQUAD®.

## Dental Board of California

### Authorization to take Radiographs in a Dental Practice

The following California-licensed professionals may take radiographs in a dental practice:

- Dentist
- RDH/RDHAP
- RDA/RDAEF who completed an approved California dental assisting educational program after January 1, 1985

These individuals must successfully complete a Dental Board-approved radiation safety course prior to taking radiographs in a dental practice:

- RDA/RDAEF who did NOT complete an approved California dental assisting educational program after January 1, 1985
- Unlicensed dental assistant

A list of Dental Board-approved radiation safety courses is available on the board's web site, [dbc.ca.gov/applicants/rda/course\\_rs.pdf](http://dbc.ca.gov/applicants/rda/course_rs.pdf).

# 17 CCR Chapter 5. Subchapter 4 Radiation

## Group 1.5 Registration of Sources of Radiation

### Article 1. Registration Procedure

#### 30100. Definitions

As used in subchapter 4:

- (a) "Act" means the "Radiation Control Law," Health and Safety Code, Division 104, Part 9, chapter 8, sections 114960 et seq.
- (b) "Agreement State" means any state with which the United States Atomic Energy Commission or Nuclear Regulatory Commission has entered into an effective agreement under section 274b of the Atomic Energy Act of 1954, Title 42, United States Code, section 2021(b) (formerly section 274(b)).
- (c) "Decommission" means to remove safely from service and reduce residual radioactivity to a level that permits release of the property for unrestricted use and termination of the license.
- (d) "Department" means the California Department of Public Health.
- (e) "Depleted uranium" means the source material uranium in which the isotope uranium-235 is less than 0.711 weight percent of the total uranium present. Depleted uranium does not include special nuclear material.
- (f) "Hazardous radioactive material," as used in section 33000 of the California Vehicle Code and 114820(d) of the Health and Safety Code means any "highway route controlled quantity" of radioactive material as such material is defined in title 49, Code of Federal Regulations, section 173.403.
- (g) "Human use" means the internal or external administration of radiation or radioactive materials to human beings.
- (h) "Installation" means the location where one or more reportable sources of radiation are possessed.
- (i) "License," except where otherwise specified, means a license issued pursuant to group 2, Licensing of Radioactive Material.
- (j) "Other official agency specifically designated by the Department" means an agency with which the Department has entered into an agreement pursuant to section 114990 of the Health and Safety Code.
- (k) "Person" means any individual, corporation, partnership, limited liability company, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other state or political subdivision or agency 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.
- (l) "Personnel monitoring equipment" means devices designed to be worn or carried by an individual for the purpose of measuring the dose received by that individual (e.g., film badges, pocket chambers, pocket dosimeters, film rings, etc.).
- (m) "Possess" means to receive, possess, use, transfer or dispose of radioactive material pursuant to this regulation.
- (n) "Possessing a reportable source of radiation" means having physical possession of, or otherwise having control of, a reportable source of radiation in the State of California.
- (o) "Radiation" (ionizing radiation) means gamma rays and X-rays; alpha and beta particles, high-speed electrons, neutrons, protons, and other nuclear particles; but not sound or radio waves, or visible, infrared, or ultraviolet light.
- (p) "Radiation machine" means any device capable of producing radiation when the associated control devices are operated, but excluding devices which produce radiation only by the use of radioactive material.



- (q) "Radioactive material" means any material which emits radiation spontaneously.
- (r) "Registrant" means any person who is registering or who has registered with the Department pursuant to group 1.5, Registration of Sources of Radiation.
- (s) "Reportable sources of radiation" means either of the following:
- (1) Radiation machines, when installed in such manner as to be capable of producing radiation.
  - (2) Radioactive material contained in devices possessed pursuant to a general license under provisions of sections 30192.1 and 30192.6.
- (t) "Research and development" means theoretical analysis, exploration, experimentation or the extension of investigative findings and scientific or technical theories into practical application for experimental or demonstration purposes, including the experimental production and testing of models, prototype devices, materials and processes; but shall not include human use.
- (u) "Sealed source" means any radioactive material that is permanently encapsulated in such manner that the radioactive material will not be released under the most severe conditions likely to be encountered by the source.
- (v) "Source of radiation" means a discrete or separate quantity of radioactive material or a single radiation machine.
- (w) "Special nuclear material" means:
- (1) Plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, and any other material which the Department declares by rule to be special nuclear material after the United States Nuclear Regulatory Commission, or any successor thereto, has determined the material to be such, but does not include source material; or
  - (2) Any material artificially enriched by any of the foregoing, but does not include source material.
- (x) "Specific license" means a license or the equivalent document issued to a named person by the Department or by the Nuclear Regulatory Commission or by any other Agreement State.
- (y) "This regulation" means: California Code of Regulations, Title 17, Division 1, Chapter 5, Subchapter 4.
- (z) "User" means any person who is licensed to possess radioactive material or who has registered as possessing a reportable source of radiation pursuant to groups 1.5 and 2 of this subchapter, or who otherwise possesses a source of radiation which is subject to such licensure or registration.
- (aa) "Worker" means any individual engaged in activities subject to this regulation and controlled by a user, but does not include the user.

#### **30104. Exemptions**

- (a) The Department may, upon application by any user, or upon its own initiative, grant such exemptions from the requirements of this regulation as it determines are authorized by law and will not result in undue hazard to health, life or property. Applications for exemptions shall specify why such exemption is necessary.
- (b) Before granting an exemption, the Department shall determine that there is reasonable and adequate assurance that:
- (1) the doses to any individual in any controlled area will not exceed those specified in Section 30265;
  - (2) the dose to the whole body of any individual in an uncontrolled area will not exceed 0.5 rem in a year;
  - (3) The deposition of radioactive material in the body of any individual will not likely result in a greater risk to the individual than would be expected from the dose specified in Section 30104 (b)(1) or (2), as appropriate, based on guidance from such bodies as the International Commission on Radiological Protection, and the National Council on Radiation Protection and Measurements; and
  - (4) there is no significant hazard to life or property.

**30105. Deliberate Misconduct**

(a) A user, applicant for a license or registration, employee of a user or applicant, or any contractor (including a supplier or consultant), subcontractor, employee of a contractor or subcontractor of any user or applicant for a license or registration, who knowingly provides to any user, applicant, contractor, or subcontractor, any components, equipment, materials, or other goods or services that relate to a user's or applicant's activities subject to this regulation, shall not:

(1) Engage in deliberate misconduct, as defined in subsection (c), that causes or would have caused, if not detected, a user or applicant to be in violation of any rule, regulation, or order; or any term, condition, or limitation of any license issued by the Department; or

(2) Deliberately submit to the Department, a user, an applicant, or a user's or applicant's contractor or subcontractor, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the Department.

(b) A person who violates subsection (a) shall be subject to enforcement action in accordance with the Act.

(c) For the purposes of subsection (a), deliberate misconduct by a person means an intentional act or omission that the person knows:

(1) Would cause a user or applicant to be in violation of any rule, regulation, or order, or any term, condition, or limitation, or any license or registration issued by the Department; or

(2) Constitutes a violation of a requirement, procedure, instruction, contract, purchase order, or policy of a user, applicant, contractor, or subcontractor.

**30108. Registration Requirement**

Every person possessing a reportable source of radiation shall register with the Department in accordance with the provisions of this Group.

**30110. Initial Registration.**

(a) Every person not already registered who acquires a reportable source of radiation shall register with and pay the fee as specified in Section 30145 to the Department within 30 days of the date of acquisition.

(b) Every person who intends to acquire a radiation machine capable of operating at a potential in excess of 500 kVp shall notify the Department at least 60 days prior to his/her possession of the machine or at least 60 days prior to the commencement of construction or reconstruction of the room which will house the machine, whichever occurs first. This equipment shall not be used to treat patients until written approval of provisions for radiation safety has been obtained by the user from the Department.

(c) Every person who registers or renews a registration shall complete a separate registration form furnished by the Department for each separate installation.

**30111. Renewal of Registration.**

Every person already registered pursuant to 30110 shall renew such registration annually and pay the fee as specified in Section 30145 to the Department on or before the registration renewal date.

**30115. Report of Change.**

Except for persons subject to section 30108.1, the registrant shall report in writing to the Department, within 30 days, any change in: registrant's name, registrant's address, location of the installation, or receipt, sale, transfer, disposal, or discontinuance of use of any reportable source of radiation.

**30118. Vendor Obligation.**

(a) Any manufacturer, distributor, retailer, agent, or any other person who sells, leases, transfers or lends a radiation machine to any person who may be required to register such machine shall notify the Department on a form approved by the Department no later than 30 days after the end of each calendar quarter of:

(1) The names and addresses of persons who have received such machines.

(2) The manufacturer and model of each such machine.

(3) The date of transfer of each radiation machine.

(4) Other related information as may be required by the Department.

(b) The vendor shall inform the receiver of each machine of the registration requirements of Section 30108 of these regulations

## Article 4. Fees

### 30145. Registration Fees.

(a) Each radiation machine that is a reportable source of radiation as defined in section 30100(f), is classified as one of the following:

(1) "High priority radiation machine," a radiation machine, which has high potential for exposing humans by means of heavy use, high radiation exposure, specialized use for radiosensitive areas of the human body, or misadjustment or malfunction of radiation safety features. A high priority radiation machine is further defined as one of the following machine types, or a machine that is used by any of the following categories of users:

- (A) Orthopedist.
- (B) Radiologist or roentgenologist.
- (C) Chiropractor.
- (D) Hospital.
- (E) Medical clinic.
- (F) Portable X-ray service (human use).
- (G) Fluoroscope used on humans.
- (H) Chest photofluorography (minifilm unit).
- (I) Non-human use particle accelerator with maximum energy capable of equaling or exceeding 10 MeV.
- (J) Non-human use radiation machine used in field radiography, as defined in Section 30336(c).

(2) "Medium priority radiation machine," a radiation machine not covered by subsections (a)(1), (a)(3) or (a)(4).

(3) "Dental priority radiation machine," a radiation machine used exclusively in dental radiography of human beings.

(4) "Special priority radiation machine," a radiation machine used for mammography.

(b) When a radiation machine is equipped with two or more tubes that can be used separately, each tube shall be considered as a single radiation machine.

(c) For registration or renewal of registration as a general licensee pursuant to section 30192.1, the fee shall be \$70.00 for each device in possession, except that persons possessing such devices under a specific license shall be exempt from this fee.

(d) Except as provided in subsection (e), initial registration shall be valid for a period of one year.

(e) The initial registration period for a reportable source of radiation being registered by a person who has a reportable source of radiation already registered with the Department shall be coterminous with the existing registration.

(f) Any fees collected for a radiation machine or a device for any registration period shall be transferred to any replacement radiation machine or device for the remainder of the registration period.

(g) For initial registration or renewal of registration, the fees shall be \$214.00 annually for each high priority radiation machine, \$172.00 annually for each medium priority radiation machine, \$79.00 annually for each dental priority radiation machine and, except as provided in section 30145.1, \$475.00 annually for each special priority radiation machine. Where the initial registration period is less than one year pursuant to subsection (e), the initial registration fee shall be prorated, based on the priority classification and number of full months in the initial registration period in accordance with the following formula:

$$\text{Initial Registration Fee} = A \times [B / (12 \text{ Months})]$$

Where:

A = Annual fee as specified above, dollars per year

B = Number of full months remaining in coterminous period

(h) The total registration fee paid by a registrant for high priority, medium priority, special priority, and dental priority radiation machines, which are at the same installation, shall not exceed \$6,000.00 per year.

(i) A late fee of 25% of the annual fee shall be charged for any registration fee which is 30 days past due.

(j) Fees required by this section shall be nonrefundable.

## Group 3. Standards for Protection Against Radiation

### Article 1. General

#### 30252. Scope and Purpose.

(a) Group 3 regulations apply to all persons who possess sources of radiation, except as exempt from the licensing and registration requirements or otherwise specifically exempted by the provisions of Group 1 and Group 2 of this subchapter.

(b) The limits in Group 3 do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs.

#### 30253. Standards for Protection Against Radiation.

(a) The regulations governing standards for protection against radiation in title 10, Code of Federal Regulations, part 20, (10 CFR 20) sections 20.1001 through 20.2402 and Appendices A through G, (January 1, 2008) are hereby incorporated by reference with the following exceptions:

(1) Title 10, Code of Federal Regulations, sections 20.1001, 20.1002, 20.1006, 20.1007, 20.1008, 20.1009, 20.1401, 20.1402, 20.1403, 20.1404, 20.1405, 20.1406, 20.1905(g), 20.2106(d), 20.2203(c), 20.2206, 20.2302, 20.2401, and 20.2402, and Appendix D are not incorporated by reference.

(2) Any references to the United States Nuclear Regulatory Commission (NRC) or any component thereof shall be deemed to be a reference to the California Department of Public Health.

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(4) The definition of the term "License" in 10 CFR 20, section 20.1003 is replaced by the definition of the term "License" as defined in section 30100 of this regulation.

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(6) The definition of the term "Licensee" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "User" as set forth in section 30100 of this regulation.

(7) The definition of the term "Person" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Person" as set forth in section 114985(c) of the Health and Safety Code.

(8) The definition of the term "Radiation (ionizing radiation)" as defined in 10 CFR 20, section 20.1003 is replaced by the definition of the term "Ionizing radiation" as set forth in section 114985(b) of the Health and Safety Code.

\*\*\*

(b) The terms defined in 10 CFR 20, section 20.1003, as incorporated by reference, shall apply to this regulation, except that:

(1) The term "Act" as defined in 10 CFR 20, section 20.1003 is limited to the textual material incorporated by reference in subsection (a) above. The meaning of the term "Act" elsewhere in this regulation, is as defined in section 30100 of this regulation.

(2) The term "Department" as defined in 10 CFR 20, section 20.1003 is limited to the provisions incorporated by reference in subsection (a). The meaning of the term "Department" elsewhere in this regulation, is as defined in section 30100 of this regulation.

## Article 2. Notices, Instructions, And Reports To Workers; Inspections And Investigations

### 30254. Inspection

(a) Each user shall afford to the Department or other official agency specifically designated by the Department, at all reasonable times, opportunity to inspect materials, machines, activities, facilities, premises, and records pursuant to these regulations.

(b) During an inspection, inspectors may consult privately with workers as specified below. The user may accompany inspectors during other phases of an inspection.

(1) Inspectors may consult privately with workers concerning matters of occupational radiation protection and other matters related to applicable provisions of Department regulations and licenses to the extent the inspectors deem necessary for the conduct of an effective and thorough inspection.

(2) During the course of an inspection any worker may bring privately to the attention of the inspectors, either orally or in writing, any past or present condition which he has reason to believe may have contributed to or caused any violation of the Radiation Control Law, these regulations, or license condition, or any unnecessary exposure of an individual to radiation from licensed radioactive material or a registered radiation machine under the user's control. Any such notice in writing shall comply with the requirements of subsection (h) hereof.

(3) The provision of paragraph (b)(2) of this section shall not be interpreted as authorization to disregard instructions pursuant to Section 30255(b)(1).

(c) If, at the time of inspection, an individual has been authorized by the workers to represent them during inspections, the user shall notify the inspectors of such authorization and shall give the workers' representative an opportunity to accompany the inspectors during the inspection of physical working conditions.

(d) Each worker's representative shall be routinely engaged in work under control of the user and shall have received instructions as specified in Section 30280(b)(1).

(e) Different representatives of users and workers may accompany the inspectors during different phases of an inspection if there is no resulting interference with the conduct of the inspection. However, only one workers' representative at a time may accompany the inspectors.

(f) With the approval of the user and the workers' representative, an individual who is not routinely engaged in work under control of the user, for example, a consultant to the user or to the workers' representative, shall be afforded the opportunity to accompany inspectors during the inspection of physical working conditions.

(g) Notwithstanding the other provisions of this section, inspectors are authorized to refuse to permit accompaniment by an individual who deliberately interferes with a fair and orderly inspection. With regard to any area containing proprietary information, the workers' representative for that area shall be an individual previously authorized by the user to enter that area.

(h) Any worker or representative of workers who believes that a violation of the Radiation Control Law, these regulations or license conditions exists, or has occurred in work under a license or registration with regard to radiological working conditions in which the worker is engaged, may request an inspection by giving notice of the alleged violation to the Department or other official agency specifically designated by the Department. Any such notice shall be in writing, shall set forth the specific grounds for the notice, and shall be signed by the worker or representative of the workers. A copy shall be provided to the user by the Department no later than at the time of inspection except that, upon the request of the worker giving such notice, his name and the name of individuals referred to therein shall not appear in such copy or on any record published, released, or made available by the Department except for good cause shown.

(i) If, upon receipt of such notice, the Chief, Radiologic Health Branch, of the Department, determines that the complaint meets the requirements set forth in subsection (h) hereof, and that there are reasonable grounds to believe that the alleged violation exists or has occurred, he shall cause an inspection to be made as soon as practicable, to determine if such alleged violation exists or has occurred. Inspections pursuant to this section need not be limited to matters referred to in the complaint.

(j) No user shall discharge or in any manner discriminate against any worker because such worker has filed any complaint or instituted or caused to be instituted any proceeding under these regulations or has testified or is about to testify in any such proceeding or because of the exercise by such worker on behalf of himself or others of any option afforded by this section.

(k) If the Chief, Radiologic Health Branch, of the Department, determines with respect to a complaint under subsection (h) hereof that an inspection is not warranted because there are no reasonable grounds to believe that a violation exists or has occurred, the complainant shall be notified in writing of such determination. The complainant may obtain review of such determination by submitting a written statement of position to the Director of the Department, who will provide the user with a copy of such statement by certified mail, excluding, at the request of the complainant, the name of the complainant. The user may submit an opposing written statement of position with the Director of the Department who will provide the complainant with a copy of such statement by certified mail. Upon the request of the complainant, the Director of the Department, or his designee, may hold an informal conference in which the complainant and the user may orally present their views. An informal conference may also be held at the request of the user, but disclosure of the identity of the complainant will be made only following receipt of written authorization from the complainant. After considering all written or oral views presented, the Director of the Department shall affirm, modify, or reverse the determination of the Chief, Radiologic Health Branch, of the Department, and furnish the complainant and the user a written notification of his decision and the reason therefor.

(l) If the Department determines that an inspection is not warranted because the requirements of subsection (h) hereof have not been met, it shall notify the complainant in writing of such determination. Such determination shall be without prejudice to the filing of a new complaint meeting the requirements of subsection (h) hereof.

### **30255. Notices, Instructions, and Reports to Personnel.**

(a) This section establishes requirements for notices, instructions, and reports by users to individuals engaged in work under a license or registration and options available to such individuals in connection with Department inspections of licensees or registrants to ascertain compliance with the provisions of the Radiation Control Law and regulations, orders, and licenses issued thereunder regarding radiological working conditions. The requirements in this section apply to all persons who receive, possess, use, own or transfer material licensed by or registered with the Department.

(b) Each user shall:

(1) Inform all individuals working in or frequenting any portion of a controlled area of the storage, transfer, or use of radioactive materials or of radiation in such portions of the controlled area; instruct such individuals in the health protection problems associated with exposure to such radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed; instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations and license conditions for the protection of personnel from exposures to radiation or radioactive materials occurring in such areas; instruct such individuals of their responsibility to report promptly to the licensee or registrant any condition which may lead to or cause a violation of department regulations or license conditions or unnecessary exposure to radiation or radioactive material, and of the inspection provisions of Section 30254; instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation or radioactive materials; and advise such individuals as to the radiation exposure reports which they may request pursuant to this section. The extent of these instructions shall be commensurate with potential radiological health protection problems in the controlled area.

(2) Conspicuously post a current copy of this regulation, a copy of applicable licenses for radioactive material, and a copy of operating and emergency procedures applicable to work with sources of radiation. If posting of documents specified in this paragraph is not practicable the user may post a notice which describes the document and states where it may be examined.

(3) Conspicuously post a current copy of Department Form RH-2364 (Notice to Employees) in a sufficient number of places to permit individuals working in or frequenting any portion of a controlled area to observe a copy on the way to or from such area.

(4) Conspicuously post any notice of violation involving radiological working conditions or any order issued pursuant to the Radiation Control Law and any required response from the user. Department documents posted pursuant to this paragraph shall be posted within two working days after receipt of the documents from the Department; the user's response, if any, shall be posted within two working days after dispatch by the user. Such documents shall remain posted for a minimum of five working days or until action correcting the violation has been completed, whichever is later.

(5) Assure that documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in work under the license or registration to observe them on the way to or from any particular work location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered.

(6) Provide reports to any individual of their radiation exposure data and the results of any measurements, analyses, and calculations of radioactive material deposited or retained in the body of that individual as specified in this section. The information reported shall include data and results obtained pursuant to Department regulations, orders, or license conditions, as shown in records maintained by the user pursuant to Department regulations. Each notification and report shall: be in writing; include appropriate identifying data such as the name of the user, the name of the individual, the individual's Social Security number; include the individual's exposure information; and contain the following statement:

"This report is furnished to you under the provisions of the California State Department of Public Health Regulations: Standards for Protection Against Radiation. You should preserve this report for future reference."

These reports shall be provided as follows:

(A) Each user shall advise each worker annually of the worker's dose as shown in records maintained by the user pursuant to title 10, Code of Federal Regulations, part 20, (10 CFR 20), section 20.2106 as incorporated by reference in section 30253. The user shall provide an annual report to each monitored individual pursuant to section 20.1502, incorporated by reference in section 30253, of the dose received in that monitoring year if:

1. The individual's occupational dose exceeds 100 mrem total effective dose equivalent or 100 mrem to any individual organ or tissue; or
2. The individual requests his or her annual dose report.

(B) At the request of a worker formerly engaged in work controlled by the user, the user shall furnish to the worker a report of the worker's exposure to radiation or radioactive material as shown in records maintained by the user pursuant to 10 CFR 20, section 20.2106 that has been incorporated by reference in section 30253, for each year the worker was required to be monitored pursuant to section 20.1502 and for each year the worker was required to be monitored under the monitoring requirements in effect prior to March 3, 1994. Such report shall be furnished within 30 days from the time the request is made, or within 30 days after the exposure of the individual has been determined by the user, whichever is later. This report shall cover the period of time that the worker's activities involved exposure to radiation from radioactive material licensed by, or radiation machines registered with, the Department and shall include the dates and locations of work under the license or registration in which the worker participated during this period.

(C) When a user is required pursuant to 10 CFR 20, sections 20.2202, 20.2203, or 20.2204, as incorporated by reference in section 30253, to report to the Department any exposure of an individual to radiation or radioactive material, the user shall also provide the individual a report on his exposure data included therein. Such reports shall be transmitted at a time not later than the transmittal to the Department.

(D) At the request of a worker who is terminating employment with the user that involved exposure to radiation or radioactive materials, during the current calendar quarter or the current year, each user shall provide at termination to each worker, or to the worker's designee, a written report regarding the radiation dose received by that worker from operations of the user during the current year or fraction thereof. If the most recent individual monitoring results are not available at that time, a written estimate of the dose must be provided together with a clear indication that this is an estimate.

### **30275. Surveys and Tests**

(a) Each user shall make or cause to be made such surveys as are necessary for compliance with all provisions of this regulation.

(b) Upon instruction from the Department or other official agency specifically designated by the Department, each user shall perform or cause to have performed, and shall permit the Department or said agency to perform, such reasonable tests as the Department or said agency deems necessary for the protection of life, health, or property, including, but not limited to, tests of:

- (1) Sources of radiation.
- (2) Facilities wherein sources of radiation are used or stored.
- (3) Radiation detection and monitoring instruments.

(4) Other equipment and devices used in connection with utilization or storage of sources of radiation.

(c) Each sealed source other than sources listed below, shall be tested for contamination prior to initial use and for leakage at least every six months:

(1) Hydrogen-3 or krypton-85 sources.

(2) Sealed sources containing licensed radioactive material in gaseous form.

(3) Source material.

(4) Sources containing radioactive material with a half life of 30 days or less.

(5) Sources of beta- and/or gamma-emitting radioactive material with an activity of 100 microcuries or less.

(6) Sources of alpha and/or neutron-emitting radioactive material with an activity of 10 microcuries or less.

In the absence of a certificate from a transferor indicating that a test has been made prior to the transfer, the sealed source shall not be put into use until tested. If there is reason to suspect that a source might have been damaged, it shall be tested for leakage before further use. Contamination and leak tests shall be capable of determining the presence of 0.005 microcuries of removable contamination. When any contamination or leak test reveals the presence of 0.005 microcuries or more of removable contamination the user shall immediately withdraw the source from use and shall cause it to be decontaminated and repaired or to be disposed of in accordance with applicable provisions of Group 2 of this subchapter. Two copies of a report shall be filed, within 5 days of the test, with the Department or other official agency specifically designated by the Department, describing the source involved, the test results, and the corrective action taken.

(d) The test sample shall be taken from the surface of the source, or source holder, or from the surface of the device in which the source is stored or mounted and on which one might expect contamination to accumulate. Where sealed sources are permanently mounted in devices or equipment, alternate tests for contamination and leakage may be approved by the Department.

(e) Tests for contamination and leakage, decontamination, and repair of sealed sources shall be performed only by persons specifically authorized by the Department to do so in accordance with provisions of Group 2 of this subchapter.

(f) Records of leak tests shall be maintained as specified in United States, title 10, Code of Federal Regulations, part 20, subpart L as incorporated by reference in section 30253..

### **30295. Records**

(a) Each user shall keep records showing the receipt, transfer, and disposal of each source of radiation which is subject to licensure or registration pursuant to groups 1.5 and 2 of this subchapter as follows:

(1) The user shall retain each record of receipt of a source of radiation as long as the source of radiation is possessed and for three years following transfer or disposal of the source of radiation.

(2) The user who transferred the source of radiation shall retain each record of transfer for three years after each transfer unless a specific requirement in another part of the regulations in this subchapter dictates otherwise.

(3) The user who disposed of the radioactive material shall retain each record of disposal of the radioactive material until the Department terminates each license that authorizes disposal of the radioactive material.

(b) The user shall retain each record that is required by the regulations in this subchapter or by license condition for the period specified by the appropriate regulation or license condition. If a retention period is not otherwise specified by regulation or license condition, the record shall be retained until the Department terminates each license that authorizes the activity that is subject to the recordkeeping requirement.

(c) Records which shall be maintained pursuant to this subchapter may be the original or a reproduced copy or microform if such reproduced copy or microform is duly authenticated by authorized personnel and the microform is capable of producing a clear and legible copy after storage for the period specified by department regulations. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, shall include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.



(d) If there is a conflict between the Department's regulations in this subchapter, license condition, or other written Department approval or authorization pertaining to the retention period for the same type of record, the retention period specified in the regulations in this subchapter for such records shall apply unless the Department, pursuant to 30104, has granted a specific exemption from the record retention requirements specified in the regulations in this subchapter.

(e) Prior to license termination, each licensee authorized to possess radioactive material with a half-life greater than 120 days, in an unsealed form, shall, if requested by the Department, forward the following records to the Department:

(1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and

(2) Records required by Title 10, Code of Federal Regulations section 20.2103(b)(4), incorporated by reference in section 30253.

(f) If licensed activities are transferred or assigned in accordance with section 30194(c), each licensee authorized to possess radioactive material, with a half-life greater than 120 days, in an unsealed form, shall transfer the following records to the new licensee and the new licensee will be responsible for maintaining these records until the license is terminated:

(1) Records of disposal of licensed material made under Title 10, Code of Federal Regulations, sections 20.2002, 20.2003, 20.2004, 20.2005, incorporated by reference in section 30253; and

(2) Records required by Title 10, Code of Federal Regulations, section 20.2103(b)(4), incorporated by reference in section 30243.

(g) Prior to license termination, each licensee shall, if requested by the Department, forward the records required by section 30256(a) to the Department.

## Article 4. Special Requirements For The Use Of X-ray In The Healing Arts

### 30305. General Provisions.

(a)

(1) This article pertains to use of X-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine. The provisions of this article are in addition to, and not in substitution for, other applicable provisions of this regulation and of Group 1 of this subchapter.

(2) Any existing machine or installation need not be replaced or substantially modified to conform to the requirements of this regulation provided that the user demonstrates to the Department's satisfaction achievement of equivalent protection through other means.

(3) No person shall make, sell, lease, transfer, lend, or install X-ray or fluoroscopic equipment or the supplies used in connection with such equipment unless such supplies and equipment, when properly placed in operation or properly used, will meet the requirements of this regulation. This includes responsibility for the delivery of cones or collimators, filters, adequate timers and fluoroscopic shutters (where applicable).

(4) For X-ray equipment manufactured after July 31, 1974, the user shall provide sufficient maintenance to keep the equipment in compliance with all applicable radiation protection sections of the Code of Federal Regulations, Title 21, Chapter 1, Subchapter J, Part 1020, Sections 1020.30, 1020.31, and 1020.32.

(5) Each installation shall be provided with such primary barriers and/or secondary barriers as are necessary to ensure compliance with title 10, Code of Federal Regulations, part 20, (10 CFR 20) subparts C and D incorporated by reference in section 30253. Special requirements are contained in title 24, California Code of Regulations, Part 2, Chapter 31C, sections 3101C through 3104C.

(b) Use.

(1) The user shall assure that all X-ray equipment under his jurisdiction is operated only by persons adequately instructed in safe operating procedures and competent in safe use of the equipment.

(2) The user shall provide safety rules to each individual operating X-ray equipment under his control, including any restrictions of the operating technique required for the safe operation of the particular X-ray apparatus, and require that the operator demonstrate familiarity with these rules.

(3) No user shall operate or permit the operation of X-ray equipment unless the equipment and installation meet the applicable requirements of these regulations and are appropriate for the procedures to be performed.

(4) Deliberate exposure of an individual to the useful beam for training or demonstration purposes shall not be permitted unless there is also a medical or dental indication for the exposure and the exposure is prescribed by a physician or dentist.

(c) Areas or rooms that contain permanently installed X-ray machines as the only source of radiation shall be posted with a sign or signs: **CAUTION**

**X-RAY**

in lieu of other signs required by the United States, title 10, Code of Federal Regulations, part 20, section 20.1902 as incorporated by reference in section 30253.

(d) High radiation areas caused by radiographic and fluoroscopic machines used solely in the healing arts and which are in compliance with the access control and signal requirements of title 24, California Code of Regulations, Part 2, Chapter 31C, sections 3101C through 3104C shall be exempt from the access control and signal requirements of 10 CFR 20, section 20.1601 as incorporated by reference in section 30253.

### **30305.1. Quality Assurance General Provisions.**

(a) Each user subject to this article, as specified in section 30305(a)(1), who performs radiography shall assure that:

(1) Radiographic films are stored, handled, and processed in accordance with manufacturers' recommendations. Expired film may not be used for clinical purposes.

(2) Intensifying screens, grids, viewers, film processing equipment, chemicals, and solutions are stored, used, and maintained in accordance with manufacturers' recommendations.

(3) For each X-ray machine, a technique chart is provided which establishes for each view commonly performed:

(A) Patient size versus selectable exposure factors;

(B) Source-to-Image distance (if not fixed)

(C) Grid data;

(D) Film/Screen combination; and

(E) Patient shielding (if appropriate).

### **30306. Definitions.**

(a) "Automatic exposure control" means a device which automatically controls one or more technique factors in order to obtain at a preselected location(s) a required quantity of radiation.

(b) "Cineradiography" means the making of a motion picture record of the successive images appearing on a fluorescent screen.

(c) "Contact therapy" means irradiation of accessible lesions usually employing a very short source-skin distance and potentials of 40-50 KV.

(d) "Dead-man switch" means a switch so constructed that a circuit-closing contact can only be maintained by continuous pressure by the operator.

(e) "Diagnostic-type tube housing" means an X-ray tube housing so constructed that the leakage radiation measured at a distance of 1 meter from the source cannot exceed 100 milliroentgens in 1 hour when the tube is operated at its maximum continuous rate of current for the maximum rated tube potential.

(f) "Filter" means material placed in the useful beam to absorb preferentially the less penetrating radiations.

(g) "Interlock" means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

- (h) "Leakage radiation" means all radiation coming from within the tube housing except the useful beam.
- (i) "Protective barrier" means a barrier of attenuating materials used to reduce radiation exposure.
- (j) "Primary protective barrier" means a barrier sufficient to attenuate the useful beam to the required degree.
- (k) "Scattered radiation" means radiation that, during passage through matter, has been deviated in direction.
- (l) "Secondary protective barrier" means a barrier sufficient to attenuate stray radiation to the required degree.
- (m) "Shutter" means a device, generally of lead, fixed to an X-ray tube housing to intercept the useful beam.
- (n) "Stray radiation" means radiation not serving any useful purpose. It includes leakage and scattered radiation.
- (o) "Therapeutic-type tube housing" means,
  - (1) For X-ray therapy equipment not capable of operating at 500 kVp or above, an X-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the source does not exceed 1 roentgen in an hour when the tube is operated at its maximum rated continuous current for the maximum rated tube potential.
  - (2) For X-ray therapy equipment capable of operating at 500 kVp or above, an X-ray tube housing so constructed that the leakage radiation at a distance of 1 meter from the source does not exceed either 1 roentgen in an hour or 0.1 percent of the useful beam dose rate at 1 meter from the source, whichever is greater, when the machine is operated at its maximum rated continuous current for the maximum rated accelerating potential.
  - (3) In either case, small areas of reduced protection are acceptable provided the average reading over any 100 square centimeters area at 1 meter distance from the source does not exceed the values given above.
- (p) "Useful beam" means that part of the radiation which passes through the window, aperture, cone, or other collimating device of the tube housing. (T17-30306-T24).

### **30311. Dental Radiographic Installations.**

- (a) Equipment.
  - (1) The tube housing shall be of diagnostic type.
  - (2) Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing.
    - (A) For intra-oral radiography the useful beam shall be restricted to a diameter of not more than 7 cm (2.75 inches) at the surface of the skin.
  - (3) For intra-oral film exposures a cone or spacer frame shall provide a target-to-skin distance of not less than 18 cm (7 inches) with apparatus operating above 50 kVp or 10 cm (4 inches) with apparatus operating at 50 kVp or below.
  - (4) The total filtration permanently in the useful beam shall be equivalent to at least 0.5 millimeters of aluminum for equipment operating below 50 kVp, equivalent to at least 1.5 millimeters of aluminum for equipment operating from 50 kVp through 70 kVp, and equivalent to at least 2.5 millimeters of aluminum for equipment operating above 70 kVp.
  - (5) A device shall be provided to terminate the exposure after a pre-set time or exposure.
  - (6) The exposure control switch shall be of the dead-man type. If a recycling timer is employed it shall not be possible to make a repeat exposure without release of the exposure switch to reset the timer.
  - (7) Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.
  - (8) Mechanical support of the tube head and cone shall maintain the exposure position without drift or vibration.
  - (9) Panoramic installations. This part applies to those installations which consist of a tube head with a collimator providing a narrow useful beam and an extra oral film carrier which are interlocked in their motion about the patient.
    - (A) All provisions of Section 30311 (a) apply except 30311 (a)(2)(A), 30311 (a)(3), 30311 (a)(10).
  - (10) Cephalometric installations.

(A) All provisions of Section 30311 (a) apply except 30311 (a)(2)(A), 30311 (a)(3), and 30311 (a)(9).

(B) The radiographic field shall be restricted to the area of the image receptor.

(11) The X-ray control panel shall include means for indicating X-ray tube voltage (kVp), tube current (mA), and exposure duration. The tube voltage and current shall be indicated by meters or by control settings. A milliammeter, a light or other device shall give clear and distinct visual or audible indication to the operator when X-rays are being produced.

(b) Operating Procedures.

(1) No individual occupationally exposed to radiation shall be permitted to hold patients or films during exposure, nor shall any individual be regularly used for this service.

(2) During each exposure, the operator shall stand at least 6 feet from the patient or behind a protective barrier.

(3) Only the patient shall be in the useful beam.

(4) Neither the tube housing nor the position indicating device (cone, cylinder) shall be hand-held during exposure.

(5) Fluoroscopy shall not be used in dental examinations.

(6) Each patient undergoing dental radiography shall be draped with a protective apron of not less than 0.25 millimeter lead-equivalent to cover the gonadal area.

(7) For intra-oral and cephalometric radiography the X-ray beam and the film shall be aligned very carefully with the area to be radiographed.

(8) Only persons required for the radiographic procedure shall be in the radiographic room during exposures.

### 30311.1. Quality Assurance for Dental Radiography.

(a) Each user subject to this article, as specified in section 30305(a)(1), using intra-oral film for dental radiography of human beings shall assure all of the following:

(1) A reference film meeting the interpreting dentists' criteria for image density, contrast, sharpness and overall quality is selected for use in daily comparisons of dental radiographs.

(2) For each day dental radiographs are processed, clinical radiographs are compared to the selected reference film for density, contrast, sharpness, and overall image quality.

(3) Corrective action is taken when observable changes occur in clinical radiographic image density, contrast, sharpness and overall quality.

(4) Records of the corrective actions taken, and the effectiveness of those corrective actions, are maintained for a minimum of one year from the date the corrective action was taken.

(5) Corrective action, as directed by the Department, is taken if the entrance exposure to an adult patient for a routine intraoral bitewing exam is found by the Department to be outside the ranges specified in the following table.

Tube Potential <sup>1</sup> (kVp) <sup>2</sup>	"D" Speed Film (mR) <sup>3</sup>	"E or F" Speed Film (mR) <sup>3</sup>
50	425-575	220-320
55	350-500	190-270
60	310-440	165-230
65	270-400	140-200
70	240-350	120-170
75	170-260	100-140
80	150-230	90-120
85	130-200	80-105
90	120-180	70-90
95	110-160	60-80
100	100-140	50-70

<sup>1</sup>Linear extrapolation or interpolation shall be used for an X-ray tube potential (kVp) not listed in the table.

<sup>2</sup>The kVp shall be measured to determine the correct exposure limit to be applied.

<sup>3</sup>Exposures values are specified as free-in-air exposures without backscatter.

# Excerpts From Code Of Federal Regulations, Nuclear Regulatory Commission, 10 CFR 20

(Incorporated by reference in 17 CCR §30253)

## Subpart A – General Provisions

### 20.1003 Definitions\*.

\*Only definitions relevant to dental practice are included in this document.

As used in this part:

*Absorbed dose* means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the gray (Gy).

*ALARA* (acronym for “as low as is reasonably achievable”) means making every reasonable effort to maintain exposures to radiation as far below the dose limits in this part as is practical consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

*Background radiation* means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. “Background radiation” does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.

*Declared pregnant woman* means a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception. The declaration remains in effect until the declared pregnant woman withdraws the declaration in writing or is no longer pregnant.

*Deep-dose equivalent* ( $H_d$ ), which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm (1000 mg/cm<sup>2</sup>).

*Dose equivalent* ( $H_T$ ) means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv).

*Dosimetry processor* means an individual or organization that processes and evaluates individual monitoring equipment in order to determine the radiation dose delivered to the equipment.

*Effective dose equivalent* ( $H_E$ ) is the sum of the products of the dose equivalent to the organ or tissue ( $H_T$ ) and the weighting factors ( $w_T$ ) applicable to each of the body organs or tissues that are irradiated ( $H_E = \sum w_T H_T$ ).

*Embryo/fetus* means the developing human organism from conception until the time of birth.

*Exposure* means being exposed to ionizing radiation or to radioactive material.

*Individual* means any human being.

*Individual monitoring* means—(1) The assessment of dose equivalent by the use of devices designed to be worn by an individual;(2) The assessment of committed effective dose equivalent by bioassay (see Bioassay) or by determination of the time-weighted air concentrations to which an individual has been exposed, i.e., DAC-hours; or(3) The assessment of dose equivalent by the use of survey data.

*Individual monitoring devices* (individual monitoring equipment) means devices designed to be worn by a single individual for the assessment of dose equivalent such as film badges, thermoluminescence dosimeters (TLDs), pocket ionization chambers, and personal (“lapel”) air sampling devices.

Member of the public means any individual except when that individual is receiving an occupational dose.

*Minor* means an individual less than 18 years of age.

*Nonstochastic effect* means health effects, the severity of which varies with the dose and for which a threshold is believed to exist. Radiation-induced cataract formation is an example of a nonstochastic effect (also called a deterministic effect). NRC means the Nuclear Regulatory Commission or its duly authorized representatives.

*Occupational dose* means the dose received by an individual in the course of employment in which the individual’s assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, or as a member of the public.

*Public dose* means the dose received by a member of the public from exposure to radiation or to radioactive material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, or from voluntary participation in medical research programs.

*Stochastic effects* means health effects that occur randomly and for which the probability of the effect occurring, rather than its severity, is assumed to be a linear function of dose without threshold. Hereditary effects and cancer incidence are examples of stochastic effects.

## Subpart B – Radiation Protection Programs

### 20.1101 Radiation protection programs.

(a) Each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of this part. (See § 20.2102 for recordkeeping requirements relating to these programs.)

(b) The licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA).

(c) The licensee shall periodically (at least annually) review the radiation protection program content and implementation.

(d) To implement the ALARA requirements of § 20.1101 (b), and notwithstanding the requirements in § 20.1301 of this part, a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its daughters, shall be established by licensees other than those subject to § 50.34a, such that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent in excess of 10 mrem (0.1 mSv) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the exceedance as provided in § 20.2203 and promptly take appropriate corrective action to ensure against recurrence.

## Subpart C – Occupational Dose Limits

### 20.1201 Occupational dose limits for adults.

(a) The licensee shall control the occupational dose to individual adults, except for planned special exposures under § 20.1206, to the following dose limits.

(1) An annual limit, which is the more limiting of—(i) The total effective dose equivalent being equal to 5 rems (0.05 Sv); or(ii) The sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye being equal to 50 rems (0.5 Sv).

(2) The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities, which are:(i) A lens dose equivalent of 15 rems (0.15 Sv), and(ii) A shallow-dose equivalent of 50 rem (0.5 Sv) to the skin of the whole body or to the skin of any extremity.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, must be subtracted from the limits for planned special exposures that the individual may receive during the current year (see § 20.1206(e)(1)) and during the individual's lifetime (see § 20.1206(e)(2)).

(c) The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens-dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are unavailable.

(d) Derived air concentration (DAC) and annual limit on intake (ALI) values are presented in table 1 of appendix B to part 20 and may be used to determine the individual's dose (see § 20.2106) and to demonstrate compliance with the occupational dose limits.

(e) In addition to the annual dose limits, the licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity (see footnote 3 of appendix B to part 20). (f) The licensee shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person (see § 20.2104(e)).

### **20.1207 Occupational dose limits for minors.**

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adult workers in § 20.1201.

### **20.1208 Dose equivalent to an embryo/fetus.**

(a) The licensee shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). (For recordkeeping requirements, see § 20.2106.)

(b) The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section.

(c) The dose equivalent to the embryo/fetus is the sum of—

(1) The deep-dose equivalent to the declared pregnant woman; and

(2) The dose equivalent to the embryo/fetus resulting from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

(d) If the dose equivalent to the embryo/fetus is found to have exceeded 0.5 rem (5 mSv), or is within 0.05 rem (0.5 mSv) of this dose, by the time the woman declares the pregnancy to the licensee, the licensee shall be deemed to be in compliance with paragraph (a) of this section if the additional dose equivalent to the embryo/fetus does not exceed 0.05 rem (0.5 mSv) during the remainder of the pregnancy.

## **Subpart D – Radiation Dose Limits for Individual Members of the Public**

### **20.1301 Dose limits for individual members of the public.**

(a) Each licensee shall conduct operations so that -

(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any administration the individual has received, from exposure to individuals administered radioactive material and released under § 35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in accordance with § 20.2003, and

(2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with § 35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.

(b) If the licensee permits members of the public to have access to controlled areas, the limits for members of the public continue to apply to those individuals.

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**20.1302 Compliance with dose limits for individual members of the public.**

(a) The licensee shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in § 20.1301.

**Subpart F – Surveys and Monitoring****20.1501 General.**

(a) Each licensee shall make or cause to be made, surveys that—

- (1) May be necessary for the licensee to comply with the regulations in this part; and
- (2) Are reasonable under the circumstances to evaluate—
  - (i) The magnitude and extent of radiation levels; and
  - (ii) Concentrations or quantities of radioactive material; and
  - (iii) The potential radiological hazards.

(b) The licensee shall ensure that instruments and equipment used for quantitative radiation measurements (e.g., dose rate and effluent monitoring) are calibrated periodically for the radiation measured.

(c) All personnel dosimeters (except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to the extremities) that require processing to determine the radiation dose and that are used by licensees to comply with § 20.1201, with other applicable provisions of this chapter, or with conditions specified in a license must be processed and evaluated by a dosimetry processor—

- (1) Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and
- (2) Approved in this accreditation process for the type of radiation or radiations included in the NVLAP program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

**20.1502 Conditions requiring individual monitoring of external and internal occupational dose.**

Each licensee shall monitor exposures to radiation and radioactive material at levels sufficient to demonstrate compliance with the occupational dose limits of this part. As a minimum—

(a) Each licensee shall monitor occupational exposure to radiation from licensed and unlicensed radiation sources under the control of the licensee and shall supply and require the use of individual monitoring devices by—

- (1) Adults likely to receive, in 1 year from sources external to the body, a dose in excess of 10 percent of the limits in § 20.1201(a),
- (2) Minors likely to receive, in 1 year, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv), a lens dose equivalent in excess of 0.15 rem (1.5 mSv), or a shallow dose equivalent to the skin or to the extremities in excess of 0.5 rem (5 mSv);
- (3) Declared pregnant women likely to receive during the entire pregnancy, from radiation sources external to the body, a deep dose equivalent in excess of 0.1 rem (1 mSv);<sup>2</sup> and
- (4) Individuals entering a high or very high radiation area.

<sup>2</sup> All of the occupational doses in § 20.1201 continue to be applicable to the declared pregnant worker as long as the embryo/fetus dose limit is not exceeded.

**Subpart L – Records****20.2101 General provisions.**

(a) Each licensee shall use the units: curie, rad, rem, including multiples and subdivisions, and shall clearly indicate the units of all quantities on records required by this part.



(b) In the records required by this part, the licensee may record quantities in SI units in parentheses following each of the units specified in paragraph (a) of this section. However, all quantities must be recorded as stated in paragraph (a) of this section.

(c) Notwithstanding the requirements of paragraph (a) of this section, when recording information on shipment manifests, as required in § 20.2006(b), information must be recorded in the International System of Units (SI) or in SI and units as specified in paragraph (a) of this section.

(d) The licensee shall make a clear distinction among the quantities entered on the records required by this part (e.g., total effective dose equivalent, shallow-dose equivalent, lens dose equivalent, deep-dose equivalent, committed effective dose equivalent).

### **20.2102 Records of radiation protection programs.**

(a) Each licensee shall maintain records of the radiation protection program, including:

- (1) The provisions of the program; and
- (2) Audits and other reviews of program content and implementation.

(b) The licensee shall retain the records required by paragraph (a)(1) of this section until the Commission terminates each pertinent license requiring the record. The licensee shall retain the records required by paragraph (a)(2) of this section for 3 years after the record is made.

### **20.2106 Records of individual monitoring results.**

(a) Recordkeeping requirement. Each licensee shall maintain records of doses received by all individuals for whom monitoring was required pursuant to § 20.1502, and records of doses received during planned special exposures, accidents, and emergency conditions. These records<sup>5</sup> must include, when applicable—

- (1) The deep-dose equivalent to the whole body, lens dose equivalent, shallow-dose equivalent to the skin, and shallow-dose equivalent to the extremities;
- (2) The estimated intake of radionuclides (see § 20.1202);
- (3) The committed effective dose equivalent assigned to the intake of radionuclides;
- (4) The specific information used to assess the committed effective dose equivalent pursuant to § 20.1204(a) and (c), and when required by § 20.1502;
- (5) The total effective dose equivalent when required by § 20.1202; and
- (6) The total of the deep-dose equivalent and the committed dose to the organ receiving the highest total dose.

(b) *Recordkeeping frequency.* The licensee shall make entries of the records specified in paragraph (a) of this section at least annually.

(c) *Recordkeeping format.* The licensee shall maintain the records specified in paragraph (a) of this section on NRC Form 5, in accordance with the instructions for NRC Form 5, or in clear and legible records containing all the information required by NRC Form 5.

(d) *Privacy protection.* The records required under this section should be protected from public disclosure because of their personal privacy nature. These records are protected by most State privacy laws and, when transferred to the NRC, are protected by the Privacy Act of 1974, Public Law 93-579, 5 U.S.C. 552a, and the Commission's regulations in 10 CFR part 9.

(e) The licensee shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy shall also be kept on file, but may be maintained separately from the dose records.

(f) The licensee shall retain the required form or record until the Commission terminates each pertinent license requiring this record. This includes records required under the standards for protection against radiation in effect prior to January 1, 1994.

<sup>5</sup> Assessments of dose equivalent and records made using units in effect before the licensee's adoption of this part need not be changed.

### **20.2107 Records of dose to individual members of the public.**

(a) Each licensee shall maintain records sufficient to demonstrate compliance with the dose limit for individual members of the public (see § 20.1301).

(b) The licensee shall retain the records required by paragraph (a) of this section until the Commission terminates each pertinent license requiring the record.

## Subpart M – Reports

### 20.2203 Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the constraints or limits.

(a) Reportable events. In addition to the notification required by § 20.2202, each licensee shall submit a written report within 30 days after learning of any of the following occurrences:

- (1) Any incident for which notification is required by § 20.2202; or
- (2) Doses in excess of any of the following:
  - (i) The occupational dose limits for adults in § 20.1201; or
  - (ii) The occupational dose limits for a minor in § 20.1207; or
  - (iii) The limits for an embryo/fetus of a declared pregnant woman in § 20.1208; or
  - (iv) The limits for an individual member of the public in § 20.1301; or
  - (v) Any applicable limit in the license; or
  - (vi) The ALARA constraints for air emissions established under § 20.1101(d); or
- (3) Levels of radiation or concentrations of radioactive material in—
  - (i) A restricted area in excess of any applicable limit in the license; or
  - (ii) An unrestricted area in excess of 10 times any applicable limit set forth in this part or in the license (whether or not involving exposure of any individual in excess of the limits in § 20.1301); or
- (4) For licensees subject to the provisions of EPA's generally applicable environmental radiation standards in 40 CFR part 190, levels of radiation or releases of radioactive material in excess of those standards, or of license conditions related to those standards.

(b) Contents of reports.

- (1) Each report required by paragraph (a) of this section must describe the extent of exposure of individuals to radiation and radioactive material, including, as appropriate:
  - (i) Estimates of each individual's dose; and
  - (ii) The levels of radiation and concentrations of radioactive material involved; and
  - (iii) The cause of the elevated exposures, dose rates, or concentrations; and
  - (iv) Corrective steps taken or planned to ensure against a recurrence, including the schedule for achieving conformance with applicable limits, ALARA constraints, generally applicable environmental standards, and associated license conditions.
- (2) Each report filed pursuant to paragraph (a) of this section must include for each occupationally overexposed 1 individual: the name, Social Security account number, and date of birth. The report must be prepared so that this information is stated in a separate and detachable part of the report and must be clearly labeled "Privacy Act Information: Not for Public Disclosure."

Footnote(s): 1 With respect to the limit for the embryo/fetus (§ 20.1208), the identifiers should be those of the declared pregnant woman.

For holders of an operating license or a combined license for a nuclear power plant, the occurrences included in paragraph (a) of this section must be reported in accordance with the procedures described in §§ 50.73(b), (c), (d), (e), and (g) of this chapter, and must include the information required by paragraph (b) of this section. Occurrences reported in accordance with § 50.73 of this chapter need not be reported by a duplicate report under paragraph (a) of this section. (d) All licensees, other than those holding an operating license or a combined license for a nuclear power plant, who make reports under paragraph (a) of this section shall submit the report in writing either by mail addressed to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland; or, where practicable, by electronic submission, for example, Electronic Information Exchange, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site [atnrc.gov/site-help/e-submittals.html](http://atnrc.gov/site-help/e-submittals.html), by calling (301) 415-0439, by e-mail to [EIE@nrc.gov](mailto:EIE@nrc.gov), or by writing the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. A copy should be sent to the appropriate NRC Regional Office listed in appendix D to this part.

## APPENDIX II

# The Dental Monitor Display and Image Quality Considerations

## Introduction

There are three components to a digital imaging system: the X-ray generator, the sensor (image acquisition component) and the monitor (image display component). The latter has replaced the film/viewbox combination which was the primary image display component for film-based imaging.

There are no published requirements that regulate the use of computer monitors for dental imaging for the various licensed treatment facilities within the state of California. Although this makes the choice of a monitor less exacting, dentists are still obligated to stay abreast of the variety and types of monitors available.

### CRT vs. LCD

Although the bulky CRT (cathode ray tube) monitors may still be present in many dental facilities, they are out of date. Their displays flicker and have a slower response time. These features may be disruptive and lead to eye fatigue. Although the LCD (liquid crystal display) monitor is a more expensive unit, its smaller size and convenience have become more popular, ultimately replacing the CRT commercially.

### Commercial vs Medical Grade Monitors

The main quality features of concern with respect to commercial grade LCD monitors are the display format and the aspect ratio. The VGA (Visual Graphics Array), XGA (eXtended Graphics Array) and related types of monitors were very popular at one time. However, their pixel display formats of either 640 x 480 or 800 x 600, and their related aspect ratios of 4:3, are below the expectations for medical imaging. These monitors may still be useful in dental offices for various clerical tasks, dental charting, and record keeping within patient management software, but they are inferior for diagnosing disease from acquired radiographic images.

Commercially available HD (High-Definition) monitors with display formats of 1920 x 1080 and aspect ratios of 16:9 are now the more desirable technical specifications for medical imaging. When multiplying the horizontal pixel units by the vertical pixel units, one can determine the total number of pixels in the display. The 1920 horizontal pixels/row on the display multiplied by the 1080 vertical pixels/column on the display (hence 1920 x 1080) equates to a 2 MP (megapixel) display, i.e. there are ~two megapixels formulating the monitor display. Due to the widespread availability of these monitors commercially, they should be standard even if not necessarily mandated for use in dental imaging.

The higher quality medical grade monitors are mandated by regulatory agencies for medical imaging applications (Andriole KP, et al. 2013). The medical grade monitors have enhancements and are more expensive. The enhancements are higher monitor display formats and upgraded electronic circuitry. The higher monitor display formats are anywhere from 2 MP to as high as 5 MP. The upgraded circuitry requirement for a medical-grade monitor is the addition of multiple internal closed loop electronic circuits that routinely calibrate and maintain stable peak luminance and contrast levels on the display. Such monitors are not mandated for dental imaging. In the absence of this self-calibrating feature, commercial grade (i.e., standard desktop) monitors require frequent manual calibration as the optimal display luminance and contrast levels afforded in medical grade monitors are not always assured in the display patterns of commercial grade monitors.

It has been reported that the standard commercial grade monitor is inadequate for diagnostic radiology (Gutierrez D et al., 2005). Many oral and maxillofacial radiologists would subjectively agree that medical grade monitors are better for their routine work. However, it was recently reported that there was no difference between conventional and medical monitor displays in detecting vertical root fractures (Tofangchiha M et al., 2013). Clearly, more research studies are necessary to support a need for medical grade monitors when evaluating diagnostic tasks in dentistry.

### **Practical Guidelines for Dental Imaging Monitor Usage**

The contrast demands and spatial resolution for dental caries detection are similar to those for mammography. A high display luminance (i.e. brightness) with reduced ambient lighting has demonstrated optimal viewing-decision making time intervals for mammography (Krupinski E, et al., 1999). Hence, the brighter the background lighting, the higher the screen luminance necessary for perception of gray scales. But gray scale perception is adversely affected by bright luminance. The brighter luminance contributes to eye fatigue and potential misdiagnosis. Hence, when viewing radiographic images, the visual perception of black and white visual displays is enhanced in a quiet, darkened room. In many instances, masking the screen to eliminate light interference and to reduce screen glare, is extremely beneficial. It has been demonstrated that masking will improve dental caries detection (Kutcher MJ et al., 2006). These comments are significant since most dental clinic monitors are positioned in operatories within dental clinics. The background lighting in these areas is 25 to 100 times brighter than the recommended levels of reduced background ambient lighting necessary to diagnose radiographic images (Samei E et al., 2005).



Caries detection (Goo JM et al, 2004) and dental imaging in general (Haak R et al. 2002) are best with reduced ambient lighting. Enhanced monitor contrast and brightness settings also improve the diagnostic accuracy of imaging simulated dental caries (Nair MK et al., 2001).

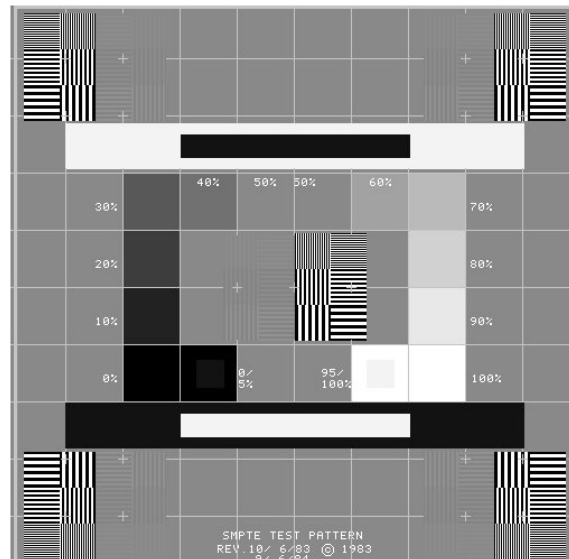
Despite these recommendations, the dental clinician has the liberty to select the monitor of their choice.

### **Suggested non-mandated procedures for evaluating image quality on a monitor**

Having reviewed the basic guidelines for monitor calibration and use, the following recommendations used in other disciplines would be beneficial in dental facilities.

1. In the absence of any strict dental monitor guidelines, there is still one simple and yet intuitive practice to maximize equipment performance. Following a manufacturer's usage guidelines for any specific monitor will optimize user settings for luminance, contrast, resolution, etc...
2. Once the manufacturer's settings have been made, posting a test object on the display can further establish optimal viewing settings. The Society of Motion Picture and Television Engineers i.e., SMPTE has developed many recommended visual test patterns for various imaging disciplines including photography, cinematography, petroleum ultrasonography and radiography. An example of one such recommended pattern (Gray JE, 1992) is formally known as the "SMPTE RP-133" but it has been modified to the more commonly recommended and simpler "SMPTE Medical Diagnostic Imaging Test Pattern."

Example of a hooded monitor display to shield the display from distracting glare and overhead or other extraneous lighting.



This pattern can be used to optimize contrast at the lowest and highest luminance values of the pattern. The SMPTE image phantom should not demonstrate gross artifacts in the brightness display (blurring, bleeding, etc...) or aliasing of the spatial resolution patterns (Mah P et al, 2011).

The pattern is available as a free and legally licensed download from [commons.wikimedia.org/wiki/File:SMPTE\\_RP-133.png#filelinks](https://commons.wikimedia.org/wiki/File:SMPTE_RP-133.png#filelinks).

For details on how to use the pattern for image quality, the reader is directed to Appendix II-A, How to use the SMPTE Medical Diagnostic Imaging Test Pattern.

For those more technically inclined, the American Association of Physicists in Medicine developed a detailed modification of the SMPTE, i.e., the QC test pattern (Samei E et al., 2005). Its complex algorithms are applicable for the high resolution medical grade monitors used in mammography and interventional radiographic studies.

The *Technical Standard for Electronic Practice of Medical Imaging* (Andriole KP et al. 2013) is a detailed document concerning the use of digital information in hospital and medical radiology facilities. The document was first developed in 2007 with the latest revision released in 2012. Although it may be more elaborate and overly detailed for dental facilities, it nevertheless is an excellent guideline for dental applications.

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## APPENDIX II-A

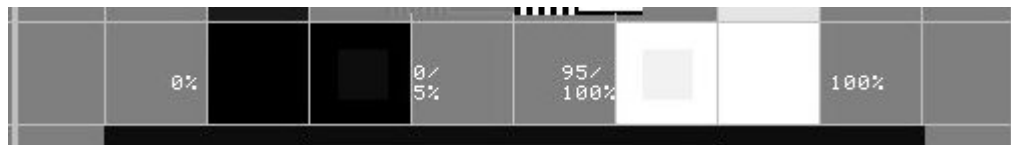
# How to use the SMPTE Medical Diagnostic Imaging Test Pattern

The following information was downloaded from [eurocjd.ed.ac.uk/smpte.htm](http://eurocjd.ed.ac.uk/smpte.htm). This link is no longer active.

### SmpTE - Monitor Calibration

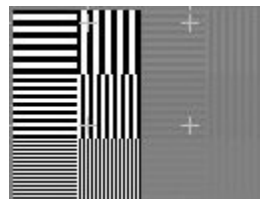
The SMPTE test pattern can be used to assess your workstation's ability to display the gray-scale images available on this webserver. The SMPTE (Society of Motion Picture and Television Engineers) test pattern should help you determine whether the contrast and brightness settings of your monitor are acceptable. Using the SMPTE test pattern, you can also check for limitations in spatial resolution and aliasing of your display.

#### Step 1 - Brightness and Contrast



- Ensure that there is a good range of gray-scale from 0% (Black) to 100% (White).
- Referencing the 0/5% and the 95/100% boxes, ensure that you can distinctly see the smaller boxes within the larger boxes.
- You may need to adjust the brightness and contrast controls on your monitor to find the optimal settings.
- Note: Most monitors cope better with the 95/100% box test than the 0/5%. You may find lowering ambient light helps.

#### Step 2 - Spatial Resolution and Aliasing



- Reference the 6 squares containing varying widths of alternating black/white horizontal and vertical lines.
- All the lines should be visually distinct, from a wide 6 pixel lines to a narrow 2 pixel lines in both the horizontal and vertical planes.

## APPENDIX III

# Film Processing

## Darkroom QA Requirements (General Provisions)

- A. Establish a consistent routine in the darkroom.
- B. No smoking, eating, or drinking is permitted in the darkroom.
- C. The darkroom should be kept free of dust.
- D. Counter tops and processor feed trays shall be cleaned daily.
- E. Hands should be gloved appropriately when working with film packets contaminated with blood or saliva. Please refer to your office infection control protocol for proper techniques to be followed in the individual office. Hands should be clean, dry and free of glove powder when handling dental films or any sensitive surface of an image recording medium.
- F. The darkroom safelight shall be equipped with a combination of an appropriate bulb and a safelight filter (15 watt bulb with a GBX 2 filter).
- G. Film and any other sensitive surface of an imaging medium should be handled carefully to prevent artifacts due to static electricity or fingerprints.
- H. When manual (i.e., hand) processing is used, stir solutions well in the morning before use. Be sure to use separate stirring paddles for the developer and the fixer to prevent cross-contamination.
- I. Cover both the developer and the fixer tanks when not in use. This helps prevent oxidation of the processing solutions. It also minimizes evaporation of the chemicals and spread of fumes to the adjacent areas.
- J. Practice good housekeeping by wiping up spilled solutions immediately, washing hangers after each use, and always using clean, dry hangers.

## Film Processing Quality Assurance

### A. Film and Chemical Storage

Dental film should be stored at temperatures less than 24°C (75°F), preferably in the range of 15° to 21°C (60° to 70°F). Open packages of dental film should be stored on edge (never flat) in an area with humidity ranging between 40 to 60 percent and in areas where they cannot be exposed to chemical fumes or radiation. If the humidity is allowed to drop below 40 percent, an increase in static marks on the film may result. If humidity rises above 60 percent, the films sometimes will become sticky and film handling becomes difficult. Processing chemicals should also be stored in an upright position. Chemicals should never be allowed to freeze.

### B. Darkroom Conditions

The darkroom should be properly illuminated with a safelight that is correctly matched with the film in order to avoid film fogging.

#### Safelight

A proper safelight provides ample lighting for an operator to work during processing, yet is safe for unprocessed films. An improper safelight will fog the films. Recommendations for safelighting include:

- Use 15 watt bulb with a GBX 2 filter.
- Place safelight at least 4 feet from working surface.

- Check for cracked or faded filter at least annually.
- Keep safelight exposure of unprocessed films as short as practical.

**Procedure for checking safelight safety:**

- Place film on work surface below the safelight.
- Place a small coin on the film.
- Turn on the safelight.
- Leave film exposed to safelight for the length of time it requires to unwrap and clip a full-mouth series (about five minutes).
- Process the film.
- Presence of coin outline indicates a defective safelight.
- Correct any deficiency by replacing either the bulb or the safelight filter, or increasing the distance between the safelight and working surface.

A similar coin test can also be done for chairside film processors.

**Checking for darkroom fog**

Adequate time (8-10 minutes) should be spent in the darkroom before testing for darkroom fog. This time permits one's eyes to adapt to the dark and to visually inspect the darkroom for light leaks. Light leaks cause fogging of films with substantial loss in film detail and contrast.

**Light leaks can be detected as follows:**

- Close and lock door.
- Turn off all lights.
- Dark adapt eyes for 8 to 10 minutes.
- Look for light leaks on the walls, floor and ceiling; specifically door jams, ceiling tiles, light fixtures, etc.
- Mark light leaks with chalk.

**Additional factors that can produce fog on a dental film:**

- Processing in old, exhausted solutions.
- Processing in poorly mixed solutions.
- Using outdated film.
- Storing unexposed film at high temperature.
- Storing unexposed film in contact with chemical fumes or radiation exposure.
- Failing to store films in a protective container.

**Manual Film Processing**

Proper processing of dental film is very important in optimizing diagnostic quality dental radiographs and in reducing the number of retakes. An X-ray film should never be overexposed in order to shorten the developing time.

Film that has been overexposed and underdeveloped tends to lose much of its diagnostic quality and results in a significant increase in exposure to patient and possibly to dental personnel.

Although manufacturer's directions vary, developing for five (5) minutes at 68°F - 70°F is the general time-temperature setting for optimal diagnostic quality films. Since the correct developing time varies with the temperature of the developing solution, measurements must be made with an accurate thermometer and timer.

### Full Film Processing Techniques

Developer: Temperature (Fahrenheit)	Minimum time (minutes)
64 – 66	7
68 – 70	5
72 – 76	4

A thermometer must be kept in the developing solution. Temperature should be checked and developing time adjusted in accordance with the temperature each time film is developed.

The temperature of developing solutions should not exceed 75°F or fall below 65°F. Developing solutions function correctly only within the above noted temperature range.

In addition dental personnel must follow these rules:

- Use solutions designed for use with dental X-ray film.
- Change solutions regularly per manufacturer's recommendations.
- Replenish solutions properly per manufacturer's recommendations.
- Avoid contaminating solutions (be sure to have separate stirring paddles for developer and fixer solutions).
- Keep films in the fixer solution for at least 10 minutes.
- Washing films in a running water bath for at least 20 minutes.
- Dry films thoroughly in a dust-free environment.

### Automatic Film Processing

When chemicals are formulated for automatic film processing, the manufacturers assume that a certain number of films of various sizes and of typical radiographic density will be processed daily. Most automatic processors require processing of at least 25-50 films daily. Please refer to the manufacturer's recommendations for your particular processor to determine if any adjustments may need to be made in the type of chemistry or replenishment rates.

The processor QC program should monitor the following:

#### 1. Processor Sensitometric (Step Wedge) Evaluation

Processor QC should be carried out at the beginning of each day, after sufficient time has elapsed for the developer temperature to reach its operating level and all systems have stabilized. A sample protocol for using a step wedge is listed in Section V.

#### 2. Tank Level Check, Clean-up Films, cleaning of Crossover Rollers

At the end of the work day the cross-over rollers should be removed, cleaned with warm water and a damp, soft cloth, and dried. The cover of the processor should be left open about 5 cm (2 inches).

#### 3. Fixer Replenishment Rate

Fixer solutions should be changed regularly, usually when developer solutions are changed. Fixer tanks and racks should be cleaned at that time. The pH or silver concentration may be monitored as an indicator of fixer activity. It should be noted that it is impossible to over-replenish fixer; however, in order to optimize the cost, the amount of fixer replenished or added should be as specified by the manufacturer.

#### 4. Fixer Flow Meter Accuracy

Check fixer replenishment rates daily using the built-in flow meter, if so equipped; otherwise use a graduated cylinder and compare to the manufacturer's recommendations. The accuracy of the flow meter should be checked semiannually.

#### 5. Washing Time

A useful tool in ensuring adequate film washing is a flow meter on the water line feeding the processor. The flow meter should be visually inspected daily to ensure adequate water flow. An in-line water filter may be necessary if water supply contains particulate matter.

#### 6. Film Fixer Retention

Too much fixer retained on the film will discolor the film over time leading to image degradation. Films should be adequately washed and finished radiographs should be stored at 21°C (70°F) and 40-60% humidity. There are tests for fixer retention in processed films. Most kits require that a few drops of the test solution be applied to one emulsion so that the resulting stain be compared with a standard sample. For archival purposes, less than 2g/cm<sup>2</sup> thiosulfate ion (fixer) should remain in the film after washing.

#### 7. Processor Transport Time

Automatic processors have more or less fixed transport speeds or times. These speeds or times can be changed internally if necessary. Even small changes in transport time can significantly affect the development time. The total developer immersion time is only 20 seconds for a 90-second processor.

The processor transport time is measured, using a stop watch, from the instant the leading edge of the film enters the entrance roller until the leading edge exits the last set of rollers in the drier section of the processor.

#### 8. Developer Temperature

The developer temperature should be maintained as recommended by the manufacturer for the specific film-developer combination being used and should not vary more than  $\pm 0.3^{\circ}\text{C}$  ( $\pm 0.5^{\circ}\text{F}$ ).

#### 9. Wash Water Temperature

An in-line thermometer should be used to monitor the wash-water temperature.

#### 10. Built-in Developer Thermometer Accuracy

The accuracy of the thermometer should be checked at least monthly against another thermometer.

#### 11. Developer Recirculation Filter

Every processor should also contain a filter in the developer recirculating system. This filter should be changed regularly as recommended by the manufacturer.

#### 12. Replenishment Rate

The replenishment rates should be those suggested by the film manufacturer as required by workload.

#### 13. Water Flow Meter Accuracy

A water-flow meter should be provided at the point where the water enters the processor. The replenishment flow meter should be calibrated when the processor is installed and the calibration should be checked quarterly.

## Mounting and Viewing Radiographs

### A. Dental Film Mounting

Dental films should be mounted on an opaque film mount with clean and dry hands to avoid scratching or smearing the film surface. For best results, thin, light cloth gloves can be worn in the performance of mounting dental films. Films should be handled by edges only. The use of a viewbox will facilitate correct mounting.

Some mounts have slots for holding each film, whereas other styles provide gummed paper to hold the radiographs. Because films may be placed in the mount in two ways, dental personnel should follow the routine established for the dental office. Films should always be placed in the mount with the embossed dot up (toward the viewer) which provides a normal right to left view of the patient's dentition.

Film mounts must be correctly labeled with patient identifier data. The minimum amount of information that must be included on the mount is the Patient's name and date of exposure.

### B. Film Viewing

Ideally, dental radiographs should always be viewed on a viewbox that is uniformly lit and that has a variable light intensity option. A magnifying glass should be available to facilitate the viewing of dental radiographs. Viewing should be done in a subdued room lighting and a template on the viewbox should be available to eliminate distracting light around the film mount.

### C. Viewbox Maintenance

The condition of the viewbox or illuminator has an effect on the perception of density and contrast of a dental radiograph. Variations or distortions can result from:

- Dirt on the Plexiglas
- Discoloration of the Plexiglas front
- Type or age of the illuminator bulb

As a bulb approaches the end of its useful life, it will begin to blacken. If this happens, the lamp should be replaced before it burns out. The entire bank of light should be replaced simultaneously and the illuminator fronts cleaned regularly as suggested by the manufacturer.

## APPENDIX IV

# Radiation Safety Program

## **Template**



## Dental Radiation Safety Program

*This template provides the basic framework of a required radiation safety program. The program must be evaluated and expanded as needed to include any other aspects of radiation safety pertinent to the scope and unique dental practices of each dentist. Italicized text provides instruction and information to assist you in completing the required written documentation.*

*Check one box and provide facility’s legal name and fictitious name, if applicable.*

Yes \_\_\_\_\_  
Facility Registrant Name and DBA

hereby adopts the California Dental Association’s (CDA) Radiation Safety in Dental Practice guidance document into our Radiation Safety Program.

No \_\_\_\_\_  
Facility Registrant Name and DBA

does not want to use the California Dental Association’s (CDA) Radiation Safety in Dental Practice guidance document into our Radiation Safety Program. We will write our own documents.

### 1. Organization and Administration

*(Insert name of individual)* \_\_\_\_\_ is responsible for the facility’s radiation program and the provisions for ensuring enforcement of radiation safety policies and procedures. This individual is licensed by the Dental Board of California and is responsible for supervising staff use of X-ray equipment. The individual’s responsibilities are outlined in Section 1 of the CDA guidance document.

Additional responsibilities related to the radiation program and not previously identified include:

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### 2. ALARA Program

*Each facility should identify and document any items or practices that it uses to reduce or control exposure to radiation, such as patient positioning aids, lead aprons or mobile shields, leaded gloves, etc.*

We will use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA). Many such practices are included throughout the CDA guidance document and in relevant portions of the regulations that are appended to the guidance document. Exceptions and additional information related to our practice are listed below.

These items do not apply to this practice:

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These are additional procedures or controls used in this practice:

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### 3. Dosimetry Program

All registrants are responsible to protect from radiation the people who enter areas near operational X-ray machines.

Each facility must evaluate whether or not personnel monitoring for occupational exposures is required. If a facility has determined that individual monitoring is not required, documentation of how that decision was reached must be available for inspection. Refer to Section I-F of "Radiation Safety in Dental Practice," the CDA guidance document and to the regulations for more information.

If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation should be instructed in the following:

- Types of individual monitoring devices used and exchange frequency.
- What control badges are for and how to use them.
- How to properly use individual monitoring devices, including consequences for intentional exposure of the device.

Whether the facility monitors individual dose or not, those who are occupationally exposed to radiation should be instructed in the following:

- How the employer will ensure that the occupational dose to any employee, and the combined occupational dose of any employee who has multiple employers, does not exceed 5 rems (0.05 mSv) per year.
- How the employee can report concurrent occupational doses at other employers.
- How the employer will ensure that if minors are employed, their occupational does not exceed 500 millirem per year.
- How and when to formally declare a pregnancy.
- How the employer will monitor the dose to the embryo/fetus and to the declared pregnant worker.

Check the applicable box

This facility is not currently monitoring personnel because we determined annual exposure to staff is less than 10 percent of the annual limit. Documentation is available for inspection.

This facility is utilizing personnel monitoring.

The type of individual monitoring device used is: \_\_\_\_\_

The devices will be exchanged at this interval :

monthly     quarterly     other: \_\_\_\_\_

Records of instruction provided on personnel monitoring devices are available for inspection.

### 4. Radiological Controls

#### Maintenance

Maintenance information may be provided in the operator's manual from the manufacturer. Also check the manufacturer's Web site.

X-ray machines are maintained as follows:

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Records of machine maintenance and maintenance requirements are available for inspection.

Name of the X-ray machine service/maintenance provider:

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Name of the processor or electronic image receptor/computer service/maintenance provider(s):

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### Posting

Areas that are required to be posted should be identified in the Radiation Protection Program, in addition to procedures for ensuring that such areas are properly posted with a sign or signs that read "CAUTION X-RAY".

Caution X-ray signs are posted at these locations:

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The individual responsible for maintaining those signs and/or labels is:

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In addition, the following documents are conspicuously posted. *(This requirement is found in the regulations, section 30255(b).)*

1. A current copy of the California Code of Regulations, title 17, incorporated sections of 10 CFR 20, and a copy of operating and emergency procedures applicable to work with sources of radiation. *(If posting of documents specified above is not practicable the user may post a notice which describes the document and states where it may be examined. Posting the CDA Radiation Safety in Dental Practice guidance document satisfies this requirement.)*
2. A current copy of department form RH-2364 (Notice to Employees) in a sufficient number of places to permit individuals working in or frequenting any portion of a restricted area to observe a copy on the way to or from such area. *This is available on the website: [cdph.ca.gov/rhb](http://cdph.ca.gov/rhb).*
3. Any notice of violation involving radiological working conditions or any order issued pursuant to the Radiation Control Law and any required response from this facility.

### Acquisition and Disposal of X-ray Machines

All X-ray machines are registered by this facility with the state. The sale, transfer, or discontinued use of any reportable source of radiation is reported to the state. *(Registration/reporting form (RH 2261C) is available on the website: [cdph.ca.gov/rhb](http://cdph.ca.gov/rhb).)*

**5. Emergency Exposure Situations**

Identify any possible emergency exposure situations and what should be done in these situations. This scenario should explain what would happen in the event of an X-ray machine malfunction such as if the machine failed to terminate the exposure.

The following actions are taken in an emergency situation when the X-ray machine fails to terminate the exposure:

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**6. Record Keeping and Reporting**

All record keeping and reporting requirements are specified in CCR, title 17 subchapter 4. (See the regulations portion of the CDA guidance document.) Document the applicable requirements and commitments to compliance. The facility must maintain all records of the radiation protection program, including annual program audits and program content review.

(Insert name of individual) \_\_\_\_\_ is responsible for maintaining all required records.

Records are maintained at this location: \_\_\_\_\_

Records and documentation are kept in the following format(s):

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Following are the procedures for record keeping with regard to additional authorized sites (applicable to mobile providers).

Not Applicable

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**7. Reports to Individuals**

The Registrant shall provide employees with a report of individual exposure. Document how you meet this requirement.

Employees are provided with a report of individual exposure in the following manner:

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**8. Training**

**Operating and Safety Procedures**

Regulations require registrants have a written operating and safety procedure manual, and to train employees on those procedures. The written manual may be the operating manual that comes with the X-ray machine if it includes safety procedures. If safety procedures are not included in the manual, they must be developed. These safety procedures must be posted on the machine or where the operator can observe them while using the machine.

All employees, both occupationally exposed and non-occupationally exposed workers, have been trained on the safety procedures and the required content below before using or working around radiation machines. We:

1. Inform all individuals working in or frequenting any portion of a controlled area of the use of radiation in such portions of the controlled area;
2. Instruct such individuals in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of Department regulations for the protection of personnel from exposures to radiation occurring in such areas;
3. Instruct such individuals of their responsibility to report promptly to the registrant any condition which may lead to or cause a violation of department regulations or unnecessary exposure to radiation, and of the inspection provisions of section 30254;
4. Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and advise such individuals as to the radiation exposure reports which they may request pursuant to section 30255.

Employees and other individuals working in the facility have received other training related to radiation safety during safety meetings, formal classroom training, continuing education, etc.

Training documentation is available for inspection.

**9. Quality Assurance Programs**

*Document quality efforts or tasks for your radiation machine(s) and processors to ensure that the machine is functioning properly and that all safety controls are in effect. [Some of these are included in the CDA guidance document and in regulation.]* **Document and attach any items not included previously. Retain all results of QA for inspection.**

Following is a description of the QA checks that are performed and the intervals at which they are performed:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

These checks are performed by:

\_\_\_\_\_

If problems are identified, the following actions are taken:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**10. Internal Audit Procedures**

We review our Radiation Protection Program on an annual basis. The review covers these items:

- That the program information is current and applicable.
- That required tests have been performed in a timely manner.
- That test results are satisfactory and corrective action taken when needed.
- That training been provided on time and as needed.
- That all of these above have been documented and kept for inspection.

Audit was performed by the individual identified below on the associated date:

Name	Title	Date
Name	Title	Date
Name	Title	Date
Name	Title	Date
Name	Title	Date