State of Maryland

REGULATORY GUIDELINES FOR DENTAL RADIATION MACHINES

REFERENCE - CODE OF MARYLAND REGULATIONS 26.12.01.01

October 2009

RADIOLOGICAL HEALTH PROGRAM
AIR AND RADIATION MANAGEMENT ADMINISTRATION
MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard
BALTIMORE, MARYLAND 21230

Section A.2 Definitions. As used in these regulations, these terms have the definitions set forth below. Additional definitions used only in a certain part will be found in that part.

"Absorbed dose" [See "Dose"]

"Act" means the Annotated Code of Maryland, Environmental Article, Title 8 "Radiation".

"Adult" means an individual 18 or more years of age.

"Agency" means the Maryland Department of Environment, Radiological Health Program.

"Annually" means either (1) at intervals not to exceed 1 year or (2) once per year, at about the same time per year (plus or minus 1 month).

"As low as reasonably achievable (ALARA)" means making every reasonable effort to maintain exposures to radiation as far below the dose limits in these regulations as is practical, consistent with the purpose for which the licensed or registered 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 or registered sources of radiation in the public interest.

The definitions are self-explanatory.

“Background radiation” means radiation from cosmic sources; naturally occurring radioactive materials, including radon, except as a decay product of source or special nuclear material, and including global fallout as it exists in the environment from the testing of nuclear explosive devices or 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 sources of radiation from radioactive materials or radiation producing machines regulated by the Agency.

“Calendar quarter” means not less than 12 consecutive weeks nor more than 14 consecutive weeks. The first calendar quarter of each year shall begin in January and subsequent calendar quarters shall be so arranged such that no day is included in more than one calendar quarter and no day in any one year is omitted from inclusion within a calendar quarter. No licensee or registrant shall change the method observed by him of determining calendar quarters for purposes of these regulations except at the beginning of a calendar year.

“Calibration” means the determination of (1) the response or reading of an instrument relative to a series of known radiation values over the range of the instrument, or (2) the strength of a source of radiation relative to a standard.

“CFR” means Code of Federal Regulations.

“Collective dose” means the sum of the individual doses

received in a given period of time by a specified population from exposure to a specified source of radiation.

“COMAR” means Code of Maryland Regulations

“Committed dose equivalent” [See “Dose”]

“Committed effective dose equivalent” [See “Dose”]

“Deep Dose equivalent” [See “Dose”]

“Dose” is a generic term that means absorbed dose, committed dose equivalent, committed effective dose equivalent, deep dose equivalent, dose equivalent, effective dose equivalent, external dose, eye dose equivalent, shallow dose equivalent, total effective dose equivalent, or total organ dose equivalent. For purposes of these regulations, “radiation dose” is an equivalent term.

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

(2) “Committed dose equivalent”($H_{T,50}$) means the dose equivalent to organs or tissues of reference (T) that will be received from an intake of radioactive material by an individual during the 50-year period following the intake.

(3) “Committed effective dose equivalent” ($H_{E,50}$) is the sum of the products of the weighting factors applicable to each of the body organs or tissues that are irradiated and the

committed dose equivalent to each of these organs or tissues ($H_{E,50} = \sum w_T H_{T,50}$).

(4) "Deep dose equivalent" (H_d), which applies to external whole body exposure, means the dose equivalent at a tissue depth of 1 centimeter (1000 mg/cm^2).

(5) "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 sievert (Sv) and rem.

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

(7) "External dose" means that portion of the dose equivalent received from any source of radiation outside the body.

(8) "Lens dose equivalent (LDE)" applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter (300 mg/cm^2).

(9) "Shallow dose equivalent" (H_S), which applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter (7mg/cm^2).

(10) "Total effective dose equivalent " (TEDE) means the

sum of the deep dose equivalent for external exposures and the committed effective dose equivalent for internal exposures.

(11) "Total organ dose equivalent" (TODE) means the sum of the deep dose equivalent and the committed dose equivalent to the organ receiving the highest dose as described in D.1107(a)(vi) of these regulations.

"Dose equivalent" [See "Dose"]

"Dose Limits" means the permissible upper bounds of radiation doses established in accordance with these regulations. For purposes of these regulations, "limits" is an equivalent term.

"Effective dose equivalent" [See "Dose"]

"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.

"Exposure" means the quotient of dQ by dm where "dQ" is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass "dm" are completely stopped in air. The special unit of exposure is the roentgen (R). See A.13 "United of Exposure and Dose" for SI equivalent.

"Exposure rate" means the exposure per unit of time, such as

roentgen per minute and milliroentgen per hour.

“External dose” [See “Dose”]

“Extremity” means hand, elbow, arm below the elbow, foot, knee, and leg below the knee.

“Eye dose equivalent” [See “Dose”]

“Facility” means the location at which one or more sources of radiation are installed or located within one building, vehicle, or under one roof and are under the same administrative control.

“Gray” (Gy) means the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

“Healing Arts” means a system of rules or methods of performing particular actions including the systematic application of knowledge or skill in effecting a desired result acquired by experience, study, or observation relating to the science of medical diagnosis, treatment, or surgery.

“Human Use” means the internal or external administration of radiation or radioactive material to human beings.

“Individual” means any human being.

“Individual monitoring” means the assessment of:

(1) Dose equivalent (a) by the use of individual monitoring devices or (b) by the use of survey data; or

(2) Committed effective dose equivalent (a) by bioassay or (b) by determination of the time-weighted air concentrations to which an individual has been exposed, that is, DAC-hours.

"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, thermoluminescent dosimeters (TLDs), pocket ionization chambers, and personal ("lapel") air sampling devices.

"Inspection" means an official examination or observation including but not limited to, tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements, and conditions of the Agency.

"Licensee" means any person who is licensed by the Agency in accordance with these regulations.

"Limits" [See "Dose Limits"]

"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.

"Monitoring" means the measurement of radiation, radioactive material concentrations, surface area activities or quantities of radioactive material and the use of the results of these measurements to evaluate potential exposures and doses. For

purposes of these regulations, “radiation monitoring” and “radiation protection monitoring” are equivalent terms.

“Occupational dose” means the dose received by an individual in the course of employment in which the individual’s assigned duties involved exposure to sources of radiation, whether in the possession of the licensee, registrant, or other person. This includes exposure to radiation from registered and unregistered radiation machines or exposure to radioactive material from licensed and unlicensed sources of radiation. Occupational dose does not include dose received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released in accordance with Sec. G.25, from voluntary participation in medical research programs, or as a member of the public.

“Person” means an individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind and any partnership, firm, association, corporation, or other entity. “Person” includes any public or municipal corporation and any agency, bureau, department, or instrumentality of state or local government and, to the extent authorized by federal law, federal government.

G.25 – refer to COMAR 26.12.01.01

“Personnel monitoring equipment” [See “Individual monitoring devices”]

“Public Dose” means the dose received by a member of the public from exposure to radiation and/or to radioactive material released by a licensee or registrant, or to any other source of

radiation under the control of the licensee or registrant. 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 in accordance with Sec. G.25, or dose from voluntary participation in medical research programs.

"Rad" means the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg/gram or 0.01 joule/kilogram (0.01 gray).

"Radiation" means alpha particles, beta particles, gamma rays, x- rays, neutrons, high-speed electrons, high-speed protons, and other particles capable of producing ions. For purposes of these regulations, ionizing radiation is an equivalent term. Radiation, as used in these regulations, does not include non-ionizing radiation, such as radiowaves or microwaves, visible, infrared, or ultraviolet light.

"Radiation area" means any area, accessible to individuals, in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 mSv (0.005 rem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates.

"Radiation machine" means any assemblage of components capable of producing radiation except those devices with radioactive material as the only source of radiation. This assemblage may include, as determined by the Agency:

(1) Not more than one control panel;
(2) The necessary supporting structures; and
(3) Any additional components or auxiliary equipment that function with the assemblage to produce the result desired by using the machine.

"Registrant" means any person who is registered with the Agency or is legally obligated to register with the Agency pursuant to these regulations and Act.

"Registration" means registration with the Agency in accordance with the regulations adopted by the Agency.

"Rem" means the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rem is equal to the absorbed dose in rad multiplied by the quality factor (1 rem = 0.01 sievert).

"Restricted area" means an area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. A restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.

"Roentgen" means the special unit of exposure. One roentgen (R) equals 2.58 X 10^{-4} coulombs/kilogram of air (see "Exposure").

"Shallow Dose Equivalent" [See "Dose"]

"SI" means the abbreviation for the International System of Units.

"Sievert" means the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

"Survey" means an evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of sources of radiation. When appropriate, such evaluation includes, but is not limited to, tests, physical examinations, and measurements of levels of radiation or concentrations of radioactive material present.

"Test" means the process of verifying compliance with an applicable regulation.

"These regulations" mean all parts of COMAR 26.12 "Radiation Management".

"Total effective dose equivalent" [See "Dose"]

"Total organ dose equivalent" [See "Dose"]

"Unrestricted area" means any area, access to which is not limited by the licensee or registrant.

"Week" means 7 consecutive days starting on Sunday.

"Whole Body" means, for purposes of external exposure, head,

trunk including male gonads, arms above the elbow, or legs above the knee.

"Worker" means an individual engaged in work under a license or registration issued by the Agency and controlled by a licensee or registrant, but does not include the licensee or registrant.

"Year" means the period of time beginning in January used to determine compliance with the provisions of these regulations. The licensee or registrant may change the starting date of the year used to determine compliance by the licensee or registrant provided that the change is made at the beginning of the year and that no day is omitted or duplicated in consecutive years.

Under certain conditions, the Agency may exempt an x-ray machine or use of an x-ray machine from these regulations.

Section A.3 Exemptions

(a) General Provision. The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety or property.

Refer to Appendix A (located at the end of the document)
All records must be kept at the location of radiation machine. (Example: Radiation Machine Facility Registration form (RX1), personnel monitoring records, notice to employee posting, and log of processing solutions changes).

Section A.4 Records.

(b) Each person responsible for a radiation machine facility shall maintain such records as required by these regulations at the facility where the radiation machine is located or stored.

All service reports such as installation reports and disassembly reports must be available.

(c) Each licensee or registrant shall maintain records showing the receipt, inventory, transfer, and disposal of all

The Agency may conduct an inspection of your office at any reasonable time. Inspections do not have to be pre-announced if a

sources of radiation.

violation is suspected or determined to exist.

Section A.5 Inspections.

(a) Each licensee and registrant shall afford the Agency at all reasonable times opportunity to inspect sources of radiation, the premises and facilities wherein such sources of radiation are used or stored.

(b) Each licensee and registrant shall make available, upon inspection by the Agency, records maintained pursuant to these regulations.

The Agency may perform certain tests to the radiation machine and to the automatic processor or manual tank to ensure the optimum performance.

Section A.6 Tests.

Each licensee and registrant shall perform upon instructions from the Agency, or shall permit the Agency to perform, such reasonable tests as the Agency deems appropriate or necessary including, but not limited to, tests of:

(a) sources of radiation;
(b) facilities wherein sources of radiation are used or stored;
(c) radiation detection and monitoring instruments; and
(d) other equipment and devices used in connection with utilization or storage of licensed or registered sources of radiation.

The Agency may add requirements if necessary to protect public health, safety, and the environment.

Section A.7 Additional Requirements.

The Agency may, by rule, regulation, order, license amendment or registrant condition, impose such requirements

upon any licensee/registrant above and beyond those established in these regulations as it deems appropriate or necessary to minimize danger to public health and safety or property.

The Agency may issue injunctions or orders.

Section A.8 Violations.

An injunction or other court order may be obtained prohibiting any violation of any provision of the Act or any regulation or order issued thereunder. Any person who willfully violates any provision of the Act or any regulation or order issued thereunder may be guilty of a misdemeanor and, upon conviction, may be punished by fine or imprisonment or both, as provided by law.

The agency may impound your x-ray machine for violating these regulations.

Section A.9 Impounding.

Sources of radiation shall be subject to impounding pursuant to the Act.

B.6 – refer to COMAR 26.12.01.01.
COMAR 26.12.02 – refers to radiation machines that undergo the certification process.
Have your radiation machine disabled by a registered service company.

Section A.10 Prohibited Uses.

(c) No person shall posses or store a radiation machine which does not meet the requirements of these regulations or COMAR 26.12.02 unless such radiation machine has been internally rendered inoperable, in a manner approved by the Department, by a service provider registered under COMAR 26.12.01.01B.6.

The Office of the Attorney General, MDE, must make official interpretations of these regulations.

Section A.11 Interpretations.

Except as specifically authorized by the Agency in writing, no interpretation of these regulations by an officer or employee of the Agency will be recognized to be binding upon the Agency.

Mail correspondence to:
Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard
Baltimore, MD 21230
Phone number: (410) 537-3300 or
call 1-800-633-6101

Section A.12 Communications.

All communications and reports concerning these regulations, and applications filed thereunder, should be addressed to the Maryland Department of the Environment, Radiological Health Program, 1800 Washington Boulevard, Baltimore, Maryland 21230.

Section A.13 Units of Exposure and Dose.

(a) As used in these regulations, the unit of Exposure is the coulomb per kilogram (C/kg). One roentgen is equal to 2.58×10^{-4} coulomb per kilogram of air.

(b) As used in these regulations, the units of dose are:

Gray (Gy) is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 joule per kilogram (100 rad).

Rad is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 erg per gram or 0.01 joule per kilogram (0.01 Gy).

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

Sievert is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sievert is equal to the absorbed dose in gray multiplied by the quality factor (1 Sv = 100 rem).

Section A.15 False Statements, Representations and Certifications.

No person shall:

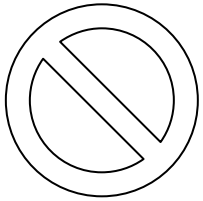
(a) make a false statement, representation, or certification in any application, record, report, plan or other document regarding radiation levels, tests performed, radiation safety conditions, practices or notices, or

(b) falsify, tamper with or render inaccurate any monitoring device or method for data collection if the data collected by that device or method is required by these regulations, or by any license or registration condition.

Section A.17 Public Posting of the Notices of Violation

(a) A notice of violation issued by the Agency to a registered or licensed facility shall be conspicuously posted at the facility for public review within two (2) working days after receipt.

Giving the agency false information is forbidden.



(b) A notice of violation shall remain posted for a minimum of 30 working days or until action correcting the violation has been completed and this correction has been verified by the Agency.

The definitions are self-explanatory.

Section B.2 Definitions.

"Facility" means the location at which one or more devices or sources are installed and/or located within one building, vehicle, or under one roof and are under the same administrative control.

These regulations do not apply to certain electronic equipment such as televisions.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable by a person registered under Sec. B.6 of this Part.

If you notified the agency in writing and provide documentation such as a removal report from a registered service provider that all of your x-ray machines are in storage, these regulations do not apply to you. But, if you have a service provider energize an x-ray machine in storage, the rules apply.

Section B.3 Exemptions.

(a) Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration and notification requirements of this Part, provided that the dose equivalent rate averaged over an area of 10 square centimeters does not exceed 5 μSv (0.5 millirem) per hour at 5 centimeters from any accessible surface of such equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

(b) Radiation machines while in transit or storage incident thereto are exempt from the requirements of this Part.

(c) Domestic television receivers are exempt from the requirements of this Part.

Section B.5 Registration of Radiation Machine Facilities.

Each person owning or operating a radiation machine facility shall:

(a) Apply for registration of such facility with the Agency prior to the following, whichever is earliest:

(i) The completion of the installation of a radiation machine in the facility;
(ii) The receipt of a radiation machine by a facility, if installation is not required by a service provider as described in Section B.6;
(iii) The relocation of a radiation machine to a new facility location; or
(iv) The purchase of the facility or radiation machine in the facility.

(b) Complete application forms for registration furnished by the Agency that contain all the information required by the forms and accompanying instructions;

(c) Designate on the application form an individual to be

Send the Radiation Machine Facility Registration Form (RX1), payment transmittal form, installation reports, and the annual fee **before** the radiation machine is completely installed.

You must name an individual who is responsible for the radiation machine.

Refer to www.mde.state.md.us
http://www.mde.state.md.us/Programs/AirPrograms/Radiological_Health/xray_applications/index.asp

Visit our website at www.mde.state.md.us to obtain registration forms.

1. You will see the word “Air” on the bottom of screen
2. Click on Choose Program
3. Click on Radiological Health
4. Click on X-ray Application Forms and Guidance
5. Download the RX1, Payment Transmittal Form, and Instructions for Registering New Facilities

responsible for radiation protection.

(d) Include full payment of all fees in the application for registration, as specified in COMAR 26.12.03 for the type(s) of radiation machines(s).

Section B.7 Issuance of Notice of Registration.

(a) Upon a determination that an applicant meets the requirements of the regulations, the agency shall issue a notice of registration. For a radiation machine facility, this will be issued in the form of a certificate of registration, which shall be posted by the facility as required in J.11.

A certificate of registration will be issued if the application is complete, meets all the requirements, and the fee is paid.

(b) The Agency may incorporate in the notice of registration at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, transfer, or servicing of radiation machines as it deems appropriate or necessary.

The agency may add conditions to your registration if necessary to protect occupational and public health. The Agency will notify you of any conditions it deems necessary.

Section B.8 Expiration of Notice of Registration.

Except as provided by B.9(b), each notice of registration shall expire at the end of the specified day in the month and year stated therein.

The certificate of registration expires every two years on the last day of the month the facility was registered.

Section B.9 Renewal of Notice of Registration.

(a) Application for renewal of registration shall be filed in accordance with B.5 or B.6.

(b) If a registrant has filed a complete application, not less than 14 days prior to the expiration of the existing notice of registration, including payment of all fees and submission of required inspections or certifications with all violations corrected, the existing notice of registration shall not expire until the application status has been determined by the Agency.

B.6 refer to COMAR 26.12.01.01.
The Agency will send you a Radiation Machine Registration Form (RX1) and an invoice a month prior to reregistering. You must complete the Radiation Machine Registration Form (RX1) and submit fees in order for your registration to be renewed.

Section B.10 Report of Changes.

The registrant shall notify the Agency in writing before making any change which would render the information contained in the application for registration and/or the notice of registration no longer accurate. This includes, but is not limited to, requests for registration cancellation, changes of location and ownership, or changes to radiation machines or tubes.

Refer to Appendix B (located at the end of the document)
If you decide to relocate, or ownership has changed, or terminate your registration the following must be done:
- You must inform the agency in writing and submit appropriate documentation such as:
  - submit installation reports
  - submit disassembly reports
  - submit bill of sale that shows ownership has changed
  - pay any outstanding fees
  - submit an RX1
  - submit registration fees

Section B.11 Approval Not Implied.

No person, in any advertisement, shall refer to the fact that he or his facility is registered with the Agency pursuant to the provisions of B.5 or B.6, and no person shall state or imply that any activity under such registration has been approved by the Agency.

You cannot advertise you are registered.
B.6 refer to COMAR 26.12.01.01.

Section B.13 Out-of-State Radiation Machines.

(a) Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring

This applies only to dental machines brought in to Maryland from out-of-state for temporary use.

such machine into the State shall give written notice to the Agency at least 3 working days before such machine is to be used in the State.

An out-of-state radiation machine must be registered and inspected. All regulations apply to this radiation machine.

The notice shall include:

(i) The type of radiation machine;
(ii) The nature, duration, and scope of use;
(iii) The exact location(s) where the radiation machine is to be used; and
(iv) The State of Maryland facility registration number, the State machine number and the date last certified.

(b) If, for a specific case, the three-day period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

(c) The person referred to in B.13(a) shall:
(i) Comply with all applicable regulations of the Agency;
(ii) Supply the Agency with such other information as the Agency may reasonably request; and
(iii) Not operate within the State on a temporary basis in excess of 180 calendar days per year.

Section D.3 Definitions. As Used in Part D.

The definitions are self-explanatory.

"Declared pregnant woman" means a woman who has voluntarily informed her employer, 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.

"Dosimetry processor" means a person that processes and evaluates individual monitoring devices in order to determine the radiation dose delivered to the monitoring devices.

"Nonstochastic effect" means a health effect, 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. For purposes of these regulations, "deterministic effect" is an equivalent term.

"Quarter" means a period of time equal to one-fourth of the year observed by the licensee, approximately 13 consecutive weeks, providing that the beginning of the first quarter in a year coincides with the starting date of the year and that no day is omitted or duplicated in consecutive quarters.

"Stochastic effect" means a health effect that occurs 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. For purpose of these regulations, "probabilistic effect" is an equivalent term.

Section D.101 Radiation Protection Programs.

(a) In addition to complying with all other provisions of these regulations, a licensee or registrant shall use to the extent practical procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to the members of the general public as low as is

You must maintain radiation exposures as low as reasonably achievable (ALARA).

reasonably achievable (ALARA).

Section D.201 Occupational Dose Limits for Adults.

(a) The licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures pursuant to D.206, to the following dose limits:

D.206 – refer to COMAR 2.12.01.01.

(i) An annual limit, which is the more limiting of:

There are annual radiation dose limits for workers, pregnant women, and the public.

(1) The total effective dose equivalent being equal to 0.05 Sv (5 rem); or

5,000 millirem for workers
500 millirem in 9 months for pregnant women
100 millirem to the general public

(2) 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 0.5 Sv (50 rem).

(ii) 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:

15,000 millirem for the lens of the eye

(1) A lens dose equivalent of 0.15 Sv (15 rem), and

50,000 millirem for the skin and extremity

(2) A shallow dose equivalent of 50 rem (/5Sv) to the skin of the whole body or to the skin of any extremity.

D.206e.i and ii – refer to COMAR 26.12.01.01.

(b) Doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, shall be subtracted from the limits for

planned special exposures that the individual may receive during the current year and during the individual's lifetime. See D.206e.i and ii.

(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. Such dose shall be determined as follows:

(i) 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; or

(ii) The dose equivalent as computed by formula or methodology specifically approved the Agency.

(f) The licensee or registrant 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 D.205e.

<u>Section D.207 Occupational Dose Limits for Minors</u>.

The annual occupational dose limits for minors are 10 percent of the annual occupational dose limits specified for

The Agency interprets the dose received by the collar badge to represent the dose received by the individual assigned to the badge.

Other methods for calculating dose are pre-approved by the Agency on a case by case basis.

D.205e refer to COMAR 26.12.01.01.

Annual dose is 500 millirem for any individual under 18 years old

adult workers in D.201.

Section D.208 Dose to an Embryo/Fetus.

a. The licensee or registrant shall ensure that the dose equivalent to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem). See D.1107 for record keeping requirements.

b. The licensee or registrant 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 D.208a.

c. The dose equivalent to an embryo/fetus is the sum of:
   (i) The deep dose equivalent to the declared pregnant woman; and
   (ii) 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 or registrant, the licensee or registrant 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.

For 9 months the dose is 500 millirem for a pregnant women. Should not exceed more than 50 millirem per month.

Facilities must insure and /or demonstrate that dose from the radiation machines will not expose the general public to more than

Section D.301 Dose Limits for Individual Members of the Public.

a. Each licensee or registrant shall conduct operations so that:

i. The total effective dose equivalent to individual members of the public from the licensed or registered operation does not exceed 0.1 rem (1mSv) in a year, exclusive of the dose contribution from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under G.75, from voluntary participation in medical research programs, and from the licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with D.1003, and

ii. The dose in any unrestricted area from external sources exclusive of the dose contributions from patients administered radioactive material and released in accordance with Sec G.75, does not exceed 0.002 rem (0.02 mSv) in any one hour.

b. The Agency may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee may release in effluents in order to restrict the collective dose.

c. If the licensee or registrant permits members of the public to have access to restricted areas, the limits for members of the public continue to apply to those individuals.

100 millirem per year.
G. 25 and D.1003 – refer to COMAR 26.12.01.01.

Facilities must also insure and/or demonstrate that dose from the radiation machines will not expose the general public to more than 2 millirem per hour.

You must send your personnel monitoring back to the accredited film badge supplier for a dose reading.

Section D.501 General.

c. All personnel dosimeters, except for direct and indirect reading pocket ionization chambers and those dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that are used by licensees and registrants to comply with D.201, with other applicable provisions of these regulations, or with conditions specified in a license or registration shall be processed and evaluated by a dosimetry processor:

i. Holding current personnel dosimetry accreditation from the National Voluntary Laboratory Accreditation Program (NVLAP) of the National Institute of Standards and Technology; and

An investigation by the Agency will be initiated to determine the root cause.

ii. 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.

Personnel monitoring is required for all dental facilities in order to exhibit that it is not possible to exceed 10 percent of the legal limits.

d. Exposure of a personnel monitoring device to deceptively indicate a dose delivered to an individual is prohibited

If badges are turned in monthly – monitor for 6 months consecutively.

Section D.502 Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

If badges are turned in quarterly – monitor for 1 year consecutively.

Each licensee or registrant shall monitor exposures from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Part D. As a minimum:

a. Each licensee or registrant shall monitor occupational exposure to radiation from the licensed and unlicensed radiation sources under the control of the licensee or registered and unregistered radiation machines under the control of the registrant and shall supply and require the use of individual monitoring devices by:

i. Adults who potentially may receive, in 1 year, from sources external to the body, a dose in excess of 10 percent of the limits in D.201a.;

ii. Minors who potentially may 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 .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);

iii. Declared pregnant women likely who potentially may receive during the entire pregnancy from radiation sources external to the body a deep dose equivalent in excess of 0.1 rem (1 mSv); and

iv. Individuals entering a high or very high radiation

area.

Section D.901 Caution Signs.

a. Standard Radiation Symbol. Unless otherwise authorized by the Agency, the symbol prescribed by D.901 shall use the colors magenta, or purple, or black on yellow background. The symbol prescribed is the three-bladed design as follows:

Radiation Symbol

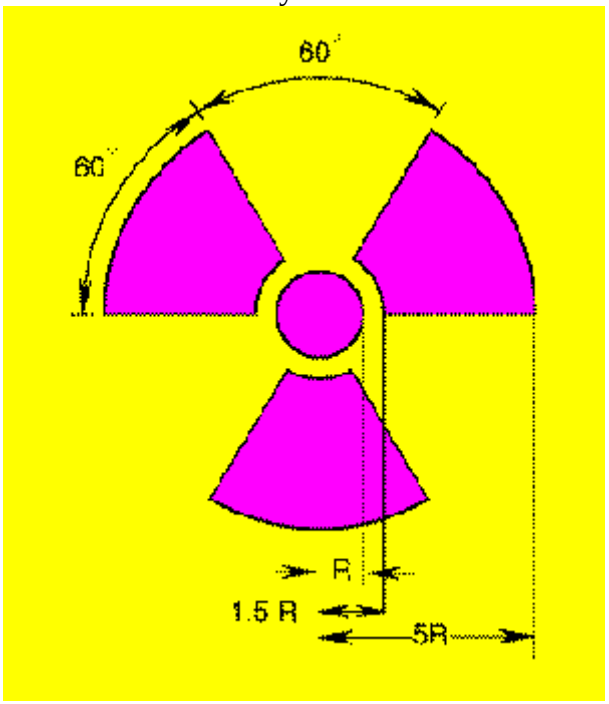
i. Cross-hatched area is to be magenta, or purple, or black, and

ii. The background is to be yellow.

b. Exception to Color Requirement for Standard Radiation Symbol. Notwithstanding the requirements of D.901a., licensees or registrants are authorized to label sources, source holders, or device components containing sources of radiation that are subjected to high temperatures, with conspicuously etched or stamped radiation caution symbols and without a color requirement.

c. Additional Information on Signs and Labels. In addition to the contents of signs and labels prescribed in Part D, the licensee or registrant shall provide, on or near the required signs and labels, additional information as appropriate to make

This is the radiation symbol:



Exception to using only magenta and yellow are allowed.

You may use more posting than required.

You must maintain all dosimetry badge reports supplied by the film

individuals aware of potential radiation exposures and to minimize the exposures.

badge supplier at the facility at all times for review as proof of minimal radiation exposure.

Section D.902 Posting Requirements.

a. Posting of Radiation Areas. The licensee or registrant shall post each radiation area with a conspicuous sign or signs bearing the radiation symbol and the words "CAUTION, RADIATION AREA."

Section D.1107 Records of Individual Monitoring Results.

a. Recordkeeping Requirement. Each licensee or registrant shall maintain records of doses received by all individuals for whom monitoring was required pursuant to D.502, and records of doses received during planned special exposures, accidents, and emergency conditions. Assessments of dose equivalent and records made using units in effect before October 9, 1995 need not be changed. These records shall include, when applicable:

All records must be kept until the Agency notifies the facility that the registration has been cancelled.

i. The deep dose equivalent to the whole body, lens dose equivalent, shallow dose equivalent to the skin, and shallow dose equivalent to the extremities;

d. The licensee or registrant shall maintain the records of dose to an embryo/fetus with the records of dose to the declared pregnant woman. The declaration of pregnancy, including the estimated date of conception, shall also be kept on file, but may be maintained separately from the dose records.

If your x-ray machine is lost or stolen, you must notify the Agency immediately by telephone (410-631-3300) and notify the Agency within 24 hours in writing.

e. The licensee or registrant shall retain each required form

Within 30 days from your telephone call, send the agency a written

or record until the Agency terminates each pertinent license or registration requiring the record, or for such time as the Agency shall determine.

Section D.1201 Reports of Stolen, Lost, or Missing Licensed or Registered Sources of Radiation.

a. Immediate Report. Each licensee or registrant shall report by telephone immediately and in writing within 24 hours to the Agency the theft or loss of any source of radiation immediately after such occurrence becomes known.

b. Following Report. Each licensee or registrant required to make a report pursuant to D.1201a. shall, within 30 days after making the telephone report, make a written report to the Agency setting forth the following information:

i. A description of the licensed or registered source of radiation involved, including for radioactive material, the kind, quantity, and chemical and physical form; and, for radiation machine, the manufacturer, model and serial number, type and maximum energy of radiation emitted; and

ii. A description of the circumstances under which the loss or theft occurred; and

iii. A statement of disposition, or probable disposition, of the licensed or registered source of radiation involved; and

report that includes these details:
- manufacturer's name, model, serial number
- how the machine was lost or stolen
- what happened to the machine
- what you have done to prevent it from happening again

iv. Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

v. Actions that have been taken, or will be taken, to recover the source of radiation; and

vi. Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed or registered sources of radiation.

The definitions are self-explanatory.

c. Subsequent to filing the written report required in D.1201(b), the licensee or registrant shall also report additional substantive information on the loss or theft within 30 days after the licensee or registrant learns of such information.

d. The licensee or registrant shall prepare any report filed with the Agency pursuant to D.1201 so that names of individuals who may have received exposure to radiation are stated in a separate and detachable portion of the report.

Section F.2 Definitions. As used in this part, the following definitions apply:

"Added Filtration" means any filtration which is in addition to the inherent filtration.

"Aluminum equivalent" means the thickness of type 1100 aluminum alloy[1]/affording the same attenuation, under specified

conditions, as the material in question.
[1/] The nominal chemical composition of type 1100 aluminum alloy is 99.00 percent minimum aluminum, 0.12 percent copper.

“Assembler” means any person engaged in the business of assembling, replacing, or installing one or more components into an x-ray system or subsystem. The term includes the owner of an x-ray system or his or her employee or agent who assembles components into an x-ray system that is subsequently used to provide professional or commercial services

“Barrier” (See “Protective barrier”).

“Beam axis” means a line from the source through the centers of the x-ray fields.

“Beam-limiting device” means a device which provides a means to restrict the dimensions of the x-ray field.

“Cephalometric device” means a device intended for the radiographic visualization and measurement of the dimensions of the human head.

“Certified components” means components of x-ray systems which are subject to regulations promulgated under Public Law 90-602, the Radiation Control for Health and Safety Act of 1968.

“Certified system” means any x-ray system which has one or more certified component(s).

"Coefficient of variation" or "C" means the ratio of the standard deviation to the mean value of a population of observations. It is estimated using the following equation:

$$C = \frac{s}{\bar{x}} = \frac{1}{\bar{x}}\left[\sum_{i=1}^{n}\frac{(x_i - \bar{x})^2}{n-1}\right]^{1/2}$$

"Control panel" means that part of the x-ray control upon which are mounted the switches, knobs, pushbuttons, and other hardware necessary for manually setting the technique factors.

"Cooling curve" means the graphical relationship between heat units stored and cooling time.

"Diagnostic source assembly" means the tube housing assembly with a beam-limiting device attached.

"Diagnostic x-ray system" means an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

"Entrance exposure rate" means the exposure per unit time at the point where the center of the useful beam enters the patient.

"Equipment" (See "X-ray equipment")

"Field emission equipment" means equipment which uses an x-ray tube in which electron emission from the cathode is due solely to the action of an electric field.

“Filter” means material placed in the useful beam to absorb preferentially selected radiations.

“Focal spot” means the area projected on the anode of the x-ray tube by the electrons accelerated from the cathode and from which the useful beam originates.

“Gonad shield” means a protective barrier for the testes or ovaries.

“Half-value layer” means the thickness of specified material which attenuates the beam of radiation to an extent such that the exposure rate is reduced to one-half of its original value. In this definition, the contribution of all scattered radiation, other than any which might be present initially in the beam concerned, is deemed to be excluded.

“Heat unit” means a unit of energy equal to the product of the peak kilovoltage, milliamperes, and seconds, i.e., kVp x mA x second.

“HVL” (See “Half-value layer”)

“Image receptor” means any device, such as a fluorescent screen or radiographic film, which transforms incident x-ray photons either into a visible image or into another form which can be made into a visible image by further transformations.

“Inherent filtration” means the filtration of the useful beam provided by the permanently installed components of the tube housing assembly.

“Kilovolts peak” (See “Peak tube potential”).

“kV” means kilovolts.

“kVp” (See “Peak tube potential”)

“Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

“Leakage radiation” means radiation emanating from the diagnostic or therapeutic source assembly except for:

(1) the useful beam, and
(2) radiation produced when the exposure switch or timer is not activated.

“mA” means milliampere.

“mAs” means milliampere second.

“Mobile x-ray equipment” (See “X-ray equipment”).

“Patient” means an individual subjected to healing arts examination, diagnosis, or treatment.

“Peak tube potential” means the maximum value of the potential difference across the x-ray tube during an exposure.

“PID” (See Position indicating device”).

"Position indicating device" means a device on dental x-ray equipment used to indicate the beam position and to establish a definite source-surface (skin) distance. It may or may not incorporate or serve as a beam-limiting device.

"Protective apron" means an apron made of radiation absorbing materials used to reduce radiation exposure.

"Protective barrier" means a barrier of radiation absorbing material(s) used to reduce radiation exposure. The types of protective barriers are as follows:

(1) "Primary protective barrier" means the material, excluding filters, placed in the useful beam, for protection purposes, to reduce the radiation exposure.

(2) "Secondary protective barrier" means a barrier sufficient to attenuate the stray radiation to the required degree.

"Qualified expert" means an individual who has demonstrated to the satisfaction of the Agency that such individual possesses the knowledge and training to measure ionizing radiation, to evaluate safety techniques, and to advise regarding radiation protection needs.

"Radiograph" means an image receptor on which the image is created directly or indirectly by an x-ray pattern and results in a permanent record.

“Radiographic imaging system” means any system whereby a permanent or semi-permanent image is recorded on an image receptor by the action of ionizing radiation.

“Rating” means the operating limits as specified by the component manufacturer.

“Recording” means producing a permanent form of an image resulting from x-ray photons.

“Scattered radiation” means radiation that, during passage through matter, has been deviated in direction (See “Direct scattered radiation”).

“Secondary protective barrier” (See “Protective barrier”).

“SID” (see “Source-image receptor distance”).

“Source” means the focal spot of the x-ray tube.

“Source-image receptor distance” means the distance from the source to the center of the input surface of the image receptor.

“SSD” means the distance between the source and the skin of the patient.

“Stationary x-ray equipment” (See “X-ray equipment”).

“Stray radiation” means the sum of leakage and scattered radiation.

“Technique factors” means the following conditions of operation:

(5) For all other equipment, peak tube potential in kV, and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs.

“Termination of irradiation” means the stopping of irradiation in a fashion which will not permit continuance of irradiation without the resetting of operating conditions at the control panel.

“Traceable to a national standard” means that a quantity or a measurement has been compared to a national standard directly or indirectly through one or more intermediate steps and that all comparisons have been documented.

“Tube” means an x-ray tube, unless otherwise specified.

“Tube housing assembly” means the tube housing with tube installed. It includes high-voltage and/or filament transformers and other appropriate elements when such are contained within the tube housing.

“Tube rating chart” means the set of curves which specify the rated limits of operating of the tube in terms of the technique factors.

“Useful beam” means the radiation emanating from the tube housing port or the radiation head and passing through the aperture of the beam limiting device when the exposure controls

are in a mode to cause the system to produce radiation.

"X-ray control" means a device which controls input power to the x-ray high-voltage generator and/or the x-ray tube. It includes equipment such as timers, phototimers, automatic brightness stabilizers, and similar devices, which control the technique factors of an x-ray exposure.

"X-ray equipment" means an x-ray system, subsystem, or component thereof. Types of x-ray equipment are as follows:

(1) "Mobile x-ray equipment" means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

(2) "Portable x-ray equipment" means x-ray equipment designed to be hand-carried.

(3) "Stationary x-ray equipment" means x-ray equipment which is installed in a fixed location, and includes x-ray equipment permanently installed in a vehicle.

"X-ray field" means that area of the intersection of the useful beam and any one of the set of planes parallel to and including the plane of the image receptor, whose perimeter is the locus of points at which the exposure rate is one-fourth of the maximum in the intersection.

"X-ray high-voltage generator" means a device which

transforms electrical energy from the potential supplied by the x-ray control to the tube operating potential. The device may also include means for transforming alternating current to direct current, filament transformers for the x-ray tube(s), high voltage switches, electrical protective devices, and other appropriate elements.

You are responsible for the operation of your radiation machine.

"X-ray subsystem" means any combination of two or more components of an x-ray system.

"X-ray system" means an assemblage of components for the controlled production of x-rays. It includes minimally an x-ray high voltage generator, an x-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the system are considered integral parts of the system.

If your radiation machine does not meet the requirements set forth in these regulations, you may not use the machine.

"X-ray tube" means any electron tube which is designed to be used primarily for the production of x rays.

The operators must be registered or licensed through the Department of Health and Mental Hygiene.

Section F.3 General Requirements.

(a) Administrative Controls.

You must have a technique chart for each x-ray machine and follow that chart. This is required for cephalometric machines and the newer panoral machines.

(1) Registrant. The registrant shall be responsible for directing the operation of the x-ray system(s) under his administrative control. The registrant or the registrant's agent shall assure that the requirements of these regulations are met in the operation of the x-ray system(s).

(i) An x-ray system which does not meet the

provisions of these regulations shall not be operated for diagnostic or therapeutic purposes.

(ii) Individuals who will be operating the x-ray systems shall be adequately instructed in the safe operating procedures and be competent in the safe use of the equipment.

(iii) A chart shall be provided in the vicinity of the diagnostic x-ray system's control panel which specifies, for all examinations performed with that system, the following information:

(a) patient's body part and anatomical size or body part thickness, or age (for pediatrics) versus technique factors to be utilized;

(b) type and size of the film or film-screen combination to be used;

(c) type and focal distance of the grid to be used, if any;

(d) source to image receptor distance to be used;

(e) type and location of placement of

Lead aprons should be used on patients to protect them from scatter

patient shielding (e.g., gonad, etc.) to be used; and

(iv) Written safety procedures shall be provided to each individual operating x-ray equipment, including any restrictions of the operating technique required for the safe operation of the particular x-ray system. The operator shall be able to demonstrate familiarity with these procedures.

(v) Except for patients who cannot be moved out of the room, only the staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. Other than the patient being examined:

(a) All individuals shall be positioned such that no part of the body will be struck by the useful beam unless protected by no less than 0.5 millimeter lead equivalent.

(b) All persons shall be protected from the direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 millimeter lead equivalent.

radiation.

Only qualified users may operate the x-ray machine.

(c) Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 millimeter lead equivalent or shall be so positioned that the nearest portion of the body is at least 2 meters from both the tube head and the nearest edge of the image receptor.

Minimum dose to the patient is achieved not only by the radiation machine working according to manufactures specification but:

(vi) Gonad shielding of not less than 0.5 millimeter lead equivalent shall be used for patients, who have not passed the reproductive age, during radiographic procedures in which the gonads are in the useful beam, except for cases in which this would interfere with the diagnostic procedure.

Ensuring that darkrooms are properly maintained.

(vii) Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision also prohibits deliberate exposure for the purpose of training, demonstration, or other non-healing-arts purposes.

The timer should be set as low as possible.

(ix) Procedures and auxiliary equipment designed

to minimize patient and personnel exposure commensurate with the needed diagnostic information shall be utilized. Such procedures and equipment shall include, but are not limited to the following:

(a) The speed of film or screen and film combinations shall be the fastest speed consistent with the diagnostic objective of the examinations;

Tests are used to determine the processing of the film and the amount of the light in the darkroom.

(b) The radiation exposure to the patient shall be the minimum exposure required to produce images of good diagnostic quality;

(c) Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation; or

(d) X-ray systems subject to F.6 shall not be utilized in procedures where the source to patient distance is less than 30 centimeters.

The manual tank must be divided into at least three sections –

developer, water, and fixer. Also a controlled temperature must be maintained in the manual tank.

(b) Processing of film.

(1) All film shall be processed in such a fashion as to achieve adequate sensitometric performance. "Adequate sensitometric performance" means:

(i) A measured processing speed of greater than or equal to 80; and

(ii) that the base plus fog of the facility's film shall not exceed 0.3 OD; as measured by the Sensitometric Technique for the Evaluation of Processing (STEP) test [1/].

A thermometer and a timer must be used for manual processing.

[1]/This test is described by Suleiman, O.H. et al. in the article "Automatic Film Processing: Analysis of 9 Years of Observations." Radiology 1992 Vol. 185, pp. 25-28.

(2) Manual Processing of Film.

(i) Where film is developed manually, a system shall be available which consists of at least one three-sectional tank made of mechanically rigid, corrosion resistant material (each section of

Follow the manufacturer's instructions for mixing chemicals.

Chemical must be changed a minimum of every 3 months and as

which shall be constructed so as to retain its solution separate from the other two) and has the overall temperature controlling capability of maintaining each solution such that the temperature of each solution will always fall within the range of 60°F to 80°F (16-27°C).

(ii) Devices shall be available which will:

(a) Give the actual temperature of the developer, plus or minus 2° F (or 1°C if SI units are used), and

(b) Give an audible or visible signal after a preset time, plus or minus 10% of the preset time.

(3) Chemical-Film Processing Control.

(i) Chemicals shall be mixed in accord with the chemical manufacturer's recommendations.

(ii) Replenishing of chemicals shall be sufficient to maintain the standards of (b)(1) above.

(iii) All processing chemicals shall be

often as required to maintain optimum processing. (This is dependent on the workload of the facility)

Keep a record of when you changed chemicals, cleaned your processor, and made any repairs to the processor.
Automatic daily replenishment of chemicals does not need to be denoted.

Your darkroom must not have any extraneous light leakage except for light from the proper safelight (for example: GBX 2 or equivalent).

completely replaced at least every 3 months.

(4) Automatic Processors and Other Closed Processing Systems. Preventative maintenance shall be performed on the unit, except for extended periods of non-use, on a frequency basis which is not less than that schedule recommended by the manufacturer. In the event that no schedule is available from the manufacturer, a maintenance schedule shall be established which will preserve good film quality.

Poor processing contributes to a low quality radiographic film so a quality assurance program must be established to obtain the highest quality of diagnostic imaging and ensures low radiation to the patients. (example: step wedge, time-temperature chart, etc)

(5) Film Fog Prevention

(i) Film processing areas and devices shall be constructed so that film being processed, handled, or stored will be exposed only to light which as passed through a proper safelight filter.

(ii) That light which remains in a film processing area or device following compliance with F.3(b)(5)(i) shall, when exposed to film in a two minute fog test, produce an increase in fog of not more than 0.05 density units.

(iii) In determining compliance with F.3(b)(5)(ii), fog measurements are

to be made at exposed film densities of 1.0 plus base plus fog.

(c) Quality Assurance.

The registrant shall be responsible for establishing and operating an effective program for radiographic imaging quality control. This program shall be designed to fulfill the following goals:

(1) That the diagnostic quality of radiographic images will be maintained at the highest level;
(2) That film processing systems will be maintained a the highest quality level;
(3) That radiographic images will be produced using the minimum radiation doses to patients; and
(4) That the above three goals will be consistently met.

The x-ray beam must be filtered. Most dental x-ray machines are manufactured with the correct filters.

(d) Machine Maintenance.

(1) A registrant shall maintain each radiation machine in accordance with the manufacturer's recommended maintenance specifications
(2) A registrant shall maintain documentation, in the form of logs, service tickets, or work orders, that the machine manufacturer's recommended maintenance schedule has

been met.

Section F.4 General Requirements for All Diagnostic X-ray Systems. In addition to other requirements of this part, all diagnostic x-ray systems shall meet the following requirements:

(a) Warning Label. The control panel containing the main power switch shall bear the warning statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

(e) Beam Quality.

(1) Half-Value Layer.

(i) The half-value layer of the useful beam for a given x-ray tube potential shall not be less than the values shown in Table I. If it is necessary to determine such half-value layer at an x-ray tube potential which is not listed in Table I, linear interpolation or extrapolation may be made.

Table I		
Design operating range (kVp)	Measured potential (kVp)	Half-value layer (mm of aluminum)
Below 50	30	0.3

If your x-ray machine has more than one tube head, the control panel and the tube head must show which tube head is being used except for non-certified equipment.

	40	0.4
	49	0.5
50 to 70	50	1.2
	60	1.3
	70	1.5
Above 70	71	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	130	3.5
	140	3.8
	150	4.1

The x-ray machine tube head shall be stable. Do not hold the tube head during the exposure.

The technique factors shall be posted prior to making an exposure.

(ii) In addition to the requirements of F.4(e)(1)(i), all intraoral dental radiographic systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent filtration permanently installed in the useful beam.

These regulations apply to panoral and cephalometric radiation machines.

(f) Multiple Tubes. Where two or more radiographic tubes are controlled by one exposure switch, the tube or tubes which have been selected shall be clearly indicated prior to initiation of the exposure. This indication shall be both on the x-ray control panel and at or near the tube housing assembly

The x-ray field must be contained within the borders of the image receptor.

which has been selected. Non-certified equipment is exempt from this requirement.

(g) Mechanical Support of Tube Head. The tube housing assembly supports shall be adjusted such that the tube housing assembly will remain stable during an exposure unless tube housing movement is a designed function of the x-ray system.

(h) Technique Indicators.

(1) The technique factors to be used during an exposure shall be indicated before the exposure begins. If automatic exposure controls are used, the technique factors which are set prior to the exposure shall be indicated.

(2) The requirement of F.4(h)(1) may be met by permanent markings on equipment having fixed technique factors. Indication of technique factors shall be visible from the operator's position except in the case of spot films made by the fluoroscopist.

Section F.6 Radiographic Systems Other Than Fluoroscopic, Dental Intraoral, Veterinarian, or Computed Tomography X-ray Systems.

(a) Beam Limitation. The useful beam shall be limited to the area of clinical interest.

(3) X-ray Systems Designed for One Image Receptor Size. Radiographic equipment designed for only one image receptor size at a fixed SID shall be provided with means to limit the field at the plane of the image receptor to dimensions no greater than those of the image receptor, and to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or shall be provided with means to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

The x-ray timer must be accurate and shall stop x-ray production at a preset time.

(5) X-ray Systems Other Than Those Described in F.6(a)(1),(2),(3), and (4).

(i) Means shall be provided to limit the x-ray field in the plane of the image receptor so that such field does not exceed each dimension of the image receptor by more than 2 percent of the SID when the axis of the x-ray beam is perpendicular to the plane of the image receptor. Podiatry units with a circular beam are exempted from the 2% limit provided the diameter of the x-ray field shall not exceed the diagonal dimension of the image receptor.

(ii) Means shall be provided to align the center of the x-ray field with the center of the image receptor to within 2 percent of the SID, or means shall

Stand at least 6 feet from the x-ray beam or behind a barrier. You must still be able to view the patient throughout the entire exposure.

be provided to both size and align the x-ray field such that the x-ray field at the plane of the image receptor does not extend beyond any edge of the image receptor.

(6) Source to Image Distance

Except for certified systems, a method shall be provided to indicate the SID to within 2 inches.

A signal audible to the operation shall be exempted if the x-ray machine is manufactured before 1978.

(b) Radiation Exposure Control Devices.

(1) Timers.

(i) Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. Such means shall provide that the resulting time interval product of current and time, number of pulses or radiation exposure is accurate to within ten percent of the true value.

(ii) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) X-ray Control.

(ii) Each x-ray control shall be located in such a way as to meet the following requirements:

The exposure from an x-ray machine must be consistent at each setting.

(a) Stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area so that the operator is required to remain in that protected area during the entire exposure; and

(c) Means shall be provided so that the operator can view the patient during the exposure.

(d) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(iii) ACCURACY. Except for certified systems, means shall be provided to terminate an exposure at a preset time interval, preset product of current and

Pertains to intraoral radiation machines.

time, or preset number of pulses. Such means shall produce a time interval, product of current and time, or number of pulses within 10 percent of the indicated preset value.

(4) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\overline{T} \geq 5 (T_{max} - T_{min})$$

(d) Exposure Reproducibility. The coefficient of variation of exposure shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when four exposures are made at identical technique factors, the value of the average exposure ($\overline{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\overline{E} \geq 5 (E_{max} - E_{min})$$

(g) Additional Requirements Applicable to Certified Systems Only. Diagnostic x-ray systems incorporating one or more certified component (s) shall be required to comply with the following additional requirement (s) which relate to that

If you use an intraoral x-ray machine, there are specific requirements for the size of the x-ray beam and the distance from the source of the x-rays to the patients skin. Most dental x-ray machines are manufactured to meet these requirements.

The x-ray timer must be accurate and shall stop x-ray production at a preset time.

certified component (s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer in accordance with the requirements of applicable Federal standards, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

Section F.7 Intraoral Dental Radiographic Systems. In addition to the provisions of F.3 and F.4, the requirements of F.7 apply to x-ray equipment and associated facilities used for dental radiography. Requirements for extraoral dental radiographic systems are covered in F.6.

(a) Source-to-Skin Distance. X-ray systems designed for use with an intraoral image receptor shall be provided with means to limit source-to-skin distance, to not less than:

(1) 18 centimeters if operable above 50 kVp, or
(2) 10 centimeters if not operable above 50 kVp.

(b) Field Limitation.

(1) Radiographic systems designed for use with an intraoral image receptor shall be provided with means to limit the x-ray beam such that:

(i) if the minimum source-to-skin distance (SSD) is 18 centimeters or more, the x-ray field, at the minimum SSD, shall be containable in a circle having a

diameter of no more than 7 centimeters; and

(ii) if the minimum SSD is less than 18 centimeters, the x-ray field, at the minimum SSD, shall be containable in a circle having a diameter of no more than 6 centimeters.

(2) An open ended, shield position indicating device shall be used.

(c) Timers. Means shall be provided to terminate the exposure at a preset time interval, preset product of current and time, a preset number of pulses, or a preset radiation exposure to the image receptor. In addition:

(1) It shall not be possible to make an exposure when the timer is set to a "zero" or "off" position if either position is provided.

(2) Reproducibility. With a timer setting of 0.5 seconds or less, the average exposure period ($\overline{T}$) shall be greater than or equal to 5 times the maximum exposure period (T_{max}) minus the minimum exposure period (T_{min}) when 4 timer tests are performed:

$$\overline{T} \geq 5(T_{max} - T_{min})$$

(3) Accuracy. Except for certified systems, means shall be provided to terminate exposure at a preset time interval, preset product of current and time, or preset number of pulses. Such means shall produce a time interval, product of

current and time, or number of pulses within ten percent of the indicated preset value.

The exposure from an x-ray machine must be consistent at each setting.

(d) X-ray Control.

(1) An x-ray control shall be incorporated into each x-ray system such than an exposure can be terminated by the operator at any time, except for exposures of one-half (1/2) second or less.

(2) Each x-ray control shall be located in such a way as to meet the following requirements:

The kilovoltage (kVp) of the x-ray machine must be accurate.

(i) stationary x-ray systems shall be required to have the x-ray control permanently mounted in a protected area, so that the operator is required to remain in that protected area during the entire exposure; and

(ii) mobile and portable x-ray systems which are:

(a) used for greater than 1 week in the same location, i.e., a room or suite, shall meet the requirements of F.7(d)(2)(i);

(b) used for greater than 1 hour and less than 1 week at the same location, i.e., a room or suite, shall meet the requirements of F.7(d)(2)(ii)(a) or be provided with a 6.5 feet (1.98 m) high protective barrier which is placed at least 6 feet (1.83 m) from the patient; or

(c) used to make an exposure(s) of a patient at the use location shall meet the requirement of F.7(d)(2)(ii)(a) or (b) or be provided with a method of x-ray control which will permit the operator to be at least 12 feet (3.66m) from the tube housing assembly during an exposure.

(3) The x-ray control shall provide visual indication observable at or from the operator's protected position whenever x-rays are produced. In addition, a signal audible to the operator shall indicate that the exposure has terminated.

(e) Exposure Reproducibility. The coefficient of variation shall not exceed 0.10 when all technique factors are held constant. This requirement shall be deemed to have been met if, when 4 exposures are made at identical technique factors, the value of the average exposure ($\bar{E}$) is greater than or equal to 5 times the maximum exposure (E_{max}) minus the minimum exposure (E_{min}):

$$\bar{E} \geq 5(E_{max} - E_{min})$$

(f) kVp Accuracy. Except for certified systems, the true value of kVp shall not be different from the indicated value by greater than ten percent.

(g) Administrative Controls.

(1) Patient and film holding devices shall be used when the techniques permit.

(2) The tube housing and the PID shall not be hand-held during an exposure
(3) The x-ray system shall be operated in such a manner that the useful beam at the patient's skin does not exceed the requirements of F.7(b)(1).
(4) Dental fluoroscopy without image intensification shall not be used.

Post the certificate of registration.

(h) Additional Requirements Applicable to Certified Systems Only. Only diagnostic x-ray systems incorporating one or more certified component(s) shall be required to comply with the following additional requirements(s) which relate to that certified component(s).

(1) Reproducibility. When the equipment is operated on an adequate power supply as specified by the manufacturer, the estimated coefficient of variation of radiation exposures shall be no greater than 0.05, for any specific combination of selected technique factors.

Post the "Notice to Employees" (Form MDE 279) in a conspicuous place.
This posting has the Agency's emergency number, employee and employer's responsibility.
This form can be obtained by calling the Agency.

(2) Linearity. When the equipment allows a choice of x-ray tube current settings and is operated on a power supply as specified by the manufacturer in accordance with the requirements of applicable federal standards, for any fixed x-ray tube potential within the range of 40 to 100 percent of the maximum rating, the average ratios of exposure to the indicated milliampere-seconds product obtained at any 2 consecutive tube current settings shall not differ by more than 0.10 times their sum:

$$|\overline{X}_1 - \overline{X}_2| \leq 0.10\,(\overline{X}_1 + \overline{X}_2),$$

where $\overline{X}_1$ and $\overline{X}_2$ are the average mR/mAs values obtained at each of 2 consecutive tube current settings.

(3) Accuracy. Deviation of technique factors from indicated values shall not exceed the limits specified for that system by its manufacturer.

(4) Timers. Termination of exposure shall cause automatic resetting of the timer to its initial setting or to "zero".

(5) Beam Quality. All certified dental x-ray systems manufactured on and after December 1, 1980, shall have a minimum half-value layer not less than 1.5 millimeters aluminum equivalent. Systems operating above 70 kVp are subject to the filtration requirements of F.4(e)(1).

Section J.11 Posting of Notices to Workers.

(a) Each licensee or registrant shall post current copies of the following documents:

(2) The license, certificate of registration, conditions or documents incorporated into the license by reference and amendments thereto.

(c) Agency MDE 279 "Notice to Employees" shall be posted by each licensee or registrant as required by these regulations.

(d) Agency documents posted pursuant to J.11(a)(4) shall be posted within two (2) working days after receipt of the documents from the Agency; the licensee's or registrant's response, if any, shall be posted within five (5) working days after dispatch from the licensee or registrant. Such documents shall remain posted for a minimum of 30 working days of until action correcting the violation has been completed and this correction has been verified by the Agency.

Appendix A: The Dental Inspection Process

General information pertaining to dental inspections:

Currently all dental facilities are inspected every three years.
The dental facilities are contacted and appointments are scheduled 30 days in advance.
It is up to the dentist's discretion whether patients should be scheduled during the time of an inspection. It seems to be more convenient for the inspector if patients are not scheduled due to the equipment and the accessibility of the room(s).
An unannounced inspection could be held if there is a complaint from an employee or the general public.
If the radiation machine has more than one tube head it should be denoted on the tube head and the control panel when in use.
All operators must be licensed through the Department of Health and Mental Hygiene

The dental inspection process involves inspecting the following items:

Radiation Machine
- Minimum patient exposure
- Operator Protection
- Protective Apparel Available
-Timer Accuracy and Reproducibility
- Exposure Reproducibility
- Minimum Filtration (Half Value Layer)
- Field Size

Administrative
- Current Registration
- Personnel Monitoring
- Notice to Employee Posting
- Registration Certificate

Film Processing
- Development Speed
- Film Fog
- Chemistry Log
- Film Processing Quality Assurance

Approximate time taken on each dental radiation machine and film processing:

–~ 30 minutes per Intraoral.
–~ 45 minutes per Panoral.
–~ 45 minutes per Cephalometric.
–~ 45 minutes for film processing

During a dental inspection, the Agency requests that the following documentation be present at the facility:

1. Radiation Machine Registration Form (RX1) – must be available
2. The Registration Certificate – must be posted
3. Personnel Monitoring Records – records must be kept at the facility (monitoring requirements: turn in the badges monthly then monitor for 6 consecutive months or turn in the badges quarterly then monitor for 1consective year)
4. Notice to Employee Posting – must be posted
5. A log of processing solution changes – a log must be maintained which shows when the processor was cleaned, solutions changed, and maintenance

Appendix B: Reasons A Dental Registrant May Notify the Agency

Notification to the Agency is deemed necessary when one of the following situations arises:

Relocation

1. Submit a written letter requesting cancellation of your old registration number.
2. Submit disassembly reports showing the Agency what happened to the radiation machines located at the facility.
3. Submit installation reports showing the Agency how many radiation machines were installed at the new location.

4. All outstanding fees must be paid on the old registration number before the registration number is cancelled.
5. A Radiation Machine Registration Form (RX1) must be completed, payment transmittal form, and annual fees paid before a new registration number is issued.

Ownership Change

1. Submit a bill of sale that shows that ownership has changed.
2. All outstanding fees must be paid on the old registration number before the registration number is cancelled.
3. The new owner must complete a Radiation Machine Registration Form (RX1), payment transmittal form, and fees paid before a new registration number is issued.

Termination of Registration

1. Submit a written letter requesting cancellation of your old registration number.
2. Submit disassembly reports showing the Agency what happened to the radiation machines located at the facility.
3. All outstanding fees must be paid before the registration number is cancelled.

Stolen, Lost, or Missing X-ray machine

1. Notify the Agency immediately by telephone (410-537-3300) that the x-ray machine has been stolen, lost, or missing.
2. Notify the Agency within 24 hours in writing that the x-ray machine has been stolen, lost, or missing.
3. Submit within 30 days a report which details the following: manufacturers name, model, serial number; how the machine was lost or stolen; what happened to the machine, and corrective actions taken.

3-D computed tomography dental imaging system

1. Notify the Agency immediately if your facility acquires this particular type of unit.
2. The facility must submit a plan review performed by a registered service provider or state licensed inspector (http://www.mde.state.md.us/assets/document/air/xray_inspectors.pdf) prior to use of this machine.
3. The facility must continuously use personnel monitoring for anyone who is energizing this unit.

Note: It is the responsibility of the facility, not the service providers, to notify the Agency of any changes.

Mail all correspondence to: Maryland Department of the Environment
Radiological Health Program
1800 Washington Boulevard
Baltimore, MD 21230

Phone number: 410-537-3300 or 1-800-633-6101